PD-ABU-980
113686

RATIONAL PHARMACEUTICAL MANAGEMENT (RPM) PROJECT

September 25, 1992–November 30, 2000

FINAL REPORT

March 2002

Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpm@msh.org

RATIONAL PHARMACEUTICAL MANAGEMENT (RPM) PROJECT

September 25, 1992–November 30, 2000

FINAL REPORT

March 2002

Rational Pharmaceutical Management Project
C.A. No. HRN-A-00-92-00059-13

Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpm@msh.org

2

Table of Contents

Introduction v

Global Reports

Child Survival I-1
HIV/AIDS I-13
Infectious Diseases I-27
Information Dissemination I-71
Reproductive Health I-79
Technical Leadership I-93
Tools Development I-99

Regional Reports

Africa Bureau II-1
Latin America and the Caribbean II-25
Organization of Eastern Caribbean States II-33
Regional Economic Development Support Office II-41

Country Reports

Bangladesh III-1
Central Asian Republics III-17
Ecuador III-61
Honduras III-81
Hungary III-123
Moldova III-155
Mozambique III-183
Nepal III-211
Peru III-239
Poland III-267
Russia III-291
Ukraine III-349
Zambia III-413

3

Introduction

Acronyms

BASICS	Basic Support for Institutionalizing Child Survival (project)
CA	cooperative agreement [USAID]
Danida	Danish International Development Agency
DMP	Drug Management Program [MSH]
EDP	essential drug program
G/PHN	Global Bureau Center for Population, Health and Nutrition [USAID]
IDA	International Dispensary Association
IMCI	Integrated Management of Childhood Illness
INRUD	International Network for Rational Use of Drugs
LAC	Latin American/Caribbean
MDS	*Managing Drug Supply*
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
NIS	Newly Independent States
OR	operational research
PAHO	Pan American Health Organization
QA	quality assurance
RDU	rational drug use
REDSO/ESA	Regional Economic Development Services Office for East and Southern Africa
RPM	Rational Pharmaceutical Management (project)
SO	strategic objective
TA	technical assistance
USAID	U.S. Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

5

The Scope of the Problem

Pharmaceutical commodity management presents some of the most significant issues and chronic problems in health care today. Worldwide, pharmaceuticals account for the largest share of public health expenses, excluding salaries. Nonetheless, approximately one-third of the world's population lacks regular access to safe, essential drugs. The pharmaceutical sector in many developing countries suffers from chronic shortages of supplies, as well as the frequent presence of drugs of questionable worth.

- A World Health Organization (WHO) study conducted in 1998 found that 28 countries in Africa and 5 countries in Latin America reported less than 50 percent of their population has regular access to drugs.

- As much as 50 percent of the therapeutic value of drugs and pharmaceutical supplies is estimated to be lost because of poor management practices throughout the commodity sector.

Although global access to essential drugs has improved, inadequate access remains a serious problem in many regions of the world. In addition, the complex issues associated with unsafe, irrational, and inappropriate drug use, and the potential for the development of antimicrobial resistance that compromises the effectiveness of currently available therapies present significant threats to public health worldwide.

Governments in many developing countries recognize that poor procurement practices and inappropriate use of drugs contribute not only to waste and poor availability of necessary products, but also to inadequate and sometimes dangerously poor quality of care. Various health sector reforms have taken hold throughout the developing world; however, these reforms frequently are designed and implemented without the benefit of a critical analysis of the specific political, economic, and technical implications of various alternatives for the commodity management systems. In most developing countries, a combination of interrelated problems is exacerbated by a lack of adequate consensus and dialogue on priority areas where norms and standards for reform implementation are required.

Brief History

The USAID Response

Although the U.S. Agency for International Development (USAID) began focusing specific attention on the problems and issues in pharmaceutical management less than a decade ago, the agency quickly emerged as a global leader in the development and dissemination of relevant tools and in the provision of technical assistance (TA) in commodity management.

- USAID-sponsored programs have achieved measurable impact in commodity management, including reduced waste and improved efficiency and quality of care through better product selection, forecasting, procurement, and prescribing and dispensing practices.

- The efforts of others to implement interventions such as Integrated Management of Childhood Illness (IMCI), Safe-Motherhood, and infectious disease control approaches such as Directly Observed Treatment, Short-course have been enhanced by USAID leadership in addressing pharmaceutical management issues related to these interventions.

The Implementation of RPM

The primary initial vehicle for serving USAID's goals and objectives in commodity management was the Rational Pharmaceutical Management (RPM) project. The process of establishing leadership in pharmaceutical management issues began when USAID awarded the RPM project cooperative agreements (CAs) to Management Sciences for Health (MSH) and the United States Pharmacopeial Convention (USP) for worldwide work, and CAs to the same two organizations for work to be carried out in the Russian Federation. The worldwide CA was awarded in September 1992 for a five-year period, and the Russia CA was awarded in January 1995. RPM worked in Russia with funds provided through an add-on to the worldwide CA. This funding also provided for work in two other Newly Independent States (NIS): Kazakhstan and Ukraine. The MSH/RPM CA received two extensions and officially ended in November 2000.

The Role of MSH

MSH is a Massachusetts-based nonprofit corporation founded in 1972 with a primary mission to work collaboratively with health care policymakers, managers, providers, and clients to help close the gap between what is known about and what is done to solve public health problems. Since its inception, MSH has managed long-term projects or provided short-term TA in 114 countries. In 2000, the MSH portfolio included work with partner organizations in 52 countries.

Following the RPM worldwide CA award in 1992, the MSH Drug Management Program (DMP) relocated from Boston to Arlington, Virginia, and implemented the RPM worldwide CA. Both the worldwide and Russia CAs operated with significant initial and ongoing sharing of other MSH staff and MSH technical activities. In 2001, the DMP officially changed its name to the Center for Pharmaceutical Management. The ccenter CCCCCxxenter, buildings on the work of the DMP, remainings committed to assisting developing countries with short- and long-term options for the efficient management of pharmaceuticals and medical suppliesproviding high-quality, experienced technical assistance and training in pharmaceutical management worldwide.

7

The Purpose of RPM

The project description prepared by USAID in 1992 provides the following summary of the RPM project's goal, purpose, and intended activities:

- **Goal:** To improve the health status of target populations in developing countries through improvements in allocation and use of financial, human, and information resources within the health sector.

- **Purpose:** To demonstrate that improvements in access to affordable, quality care in developing countries can occur through (1) expanding the financial base from which cost-effective health activities can be organized and implemented; (2) improving the allocation, use, and management of health-sector resources, both public and private; and (3) enhancing access to, dissemination of, and utilization of unbiased drug information.

By project's end, RPM activities were broadly divided into three groups:

- **Central-level programs**, supported by core funds allocated by the USAID Global Bureau, or field-support or operating year budget transfer funds allocated by Washington-based regional bureaus

- **Regional programs,** funded by USAID regional bureaus

- **Country programs**, funded by field-support allocations provided by USAID Missions

RPM's original goal and purpose were to be achieved through work in the following three technical areas:

- Establishing and automating drug registration systems

- Strengthening and rationalizing public-sector pharmaceutical procurement and supply management

- Expanding drug information resources and promoting rational use

Within these technical areas, RPM was to provide long-term assistance at the country level and also to provide information dissemination services. However, the three initial technical areas were revised, following analyses of the results from an indicator-based approach to assessment of pharmaceutical sector operations for targeted countries.

RPM staff began country assessments in June 1993 and carried out assessments in the Eastern Caribbean, Ecuador, El Salvador, Ghana, Mozambique, Nepal, and Ukraine. Criteria for selection included

8

- The need for assistance in RPM's technical priority areas, as demonstrated by the results of the assessments
- A Ministry of Health (MOH) counterpart interest in having an RPM project
- Individual USAID Missions' receptivity to including an RPM project within their health portfolio
- Determination by RPM that reasonable progress was feasible

The country assessment process clearly revealed that the initial priority technical area calling for automation of drug registration was generally not feasible for RPM nor a priority of host governments. All subsequent RPM country-level activities focused on the following three reworked areas of need:

- Improving allocation, management, and use of resources
- Promoting the rational use of drugs
- Improving the level of drug information

Central-Level Programs

RPM built a portfolio of technical programs originating at the central level. Generally speaking, they fell into one of two groups:

- Development of Tools and Dissemination of Information
- Studies and Operational Research (OR)

The activities of each program group also generally fell within the three priority technical areas intended to assist in the development of management tools or approaches to OR that would have worldwide application within RPM countries and beyond.

Regional-Level Programs

USAID regional bureaus provided RPM funding support in

- The Latin American/Caribbean region (LAC) for infectious disease activities
- The Regional Economic Development Services Office/East and Southern Africa (REDSO/ESA) for a regional logistics initiative
- The Africa Bureau for a variety of efforts primarily focusing on drug management issues in IMCI implementation and support of pharmaceutical management activities for malaria programs, including practices and projects related to antibiotic selection, procurement, and use

Country-Level Programs

In March 1994, RPM selected the Eastern Caribbean, Ecuador, Mozambique, and Nepal as the country areas in which to conduct assessments with the intent of implementing long-term assistance programs. In addition to the four initial country areas selected in 1994, RPM/Worldwide ultimately added country programs in Bangladesh, Central Asia, Hungary, Mozambique, Peru, Poland, Ukraine, and Zambia.

Funding

The RPM worldwide CA had an initial estimated cost of $9,830,000, and RPM Russia was awarded the amount of $2,374,264. In 1995, USAID introduced a "field support" funding strategy. Core funding for central-level programs was initially reduced, and core funding was no longer a part of country-level programs. As a result, RPM sought the funding it needed for country work through the field-support allocations that support individual USAID Missions. In retrospect, RPM adjusted well to this new arrangement.

- For country programs, the shift in funding strategies resulted in significant program expansion. When country work had been supported by core funds, RPM worked in four areas: the Eastern Caribbean, Ecuador, Mozambique, and Nepal. With the shift to field support, however, RPM sought funding from any country mission or central bureau in need of the project's services. This change resulted in new programs for Bangladesh, Central Asia, Hungary, the LAC region, Peru, Poland, REDSO/ESA, Ukraine, and Zambia.

- For central-level programs, RPM continued developing management tools, and core funding was increased for 1996 and 1997, allowing RPM to add new activities including

  - OR on drug needs for reproductive health problems

  - Development of an approach to strengthen drug management in support of IMCI

  - Development of new training materials, based on the new edition of *Managing Drug Supply*, and assistance in the areas of HIV/AIDS, polio eradication, and antimicrobial resistance

In June 1997, it was clear that the programs funded by USAID Missions and Bureaus could not be completed in the time remaining or within existing funding. Therefore, MSH requested and received two funding extensions. The first was a two-year extension to September 1999 for an increased cost to $15,265,666. The second extension increased RPM costs to $18,561,811 and extended the CA through November 2000. There were three primary justifications for raising the funding ceiling:

- A significant portion of the original RPM ceiling was used for Russia/NIS obligations.
- Many questions remained concerning the development of optimal approaches for rationalizing pharmaceutical management systems, and there was increased demand for RPM input from Missions and Bureaus.
- Work in the revised program description continued to build on existing activities consistent with the original RPM program description.

Support for Strategic Objectives

> **RPM has contributed significantly to the achievement of the PHN SOs and to the SOs of USAID Missions in the countries where the project operates.**
>
> *—External Review of Rational Pharmaceutical Management Project, 1997*

RPM tailored its interventions to address the following four of the five Strategic Objectives (SOs) of the USAID Global Bureau's Center for Population, Health and Nutrition (G/PHN):

- **SO2:** Increased use of safe pregnancy, women's nutrition, family planning, and other key reproductive health interventions
- **SO3:** Increased use of key child survival and health interventions
- **SO4:** Increased use of proven interventions to reduce transmission of HIV and other sexually transmitted infections
- **SO5:** Reduce the threat of infectious diseases of major health importance

RPM developed and used a three-step process for contributing to the SOs.

1. Use assessments, policy dialogue, training, operations research, information management, communications strategies, and collaboration with other USAID projects and donors to:
2. Implement packages of interventions drawn from the mandated technical priorities to contribute to:
3. Achievement of intermediate results, such as improved policy environment, enhanced capacity of local organizations, improved quality of care, and increased access to service.

Cost Sharing

Cost sharing is defined as the activities funded by nonfederal sources that are "necessary and reasonable for the proper and efficient accomplishment of project objectives" (*Handbook 13, USAID Optional Standard Provisions for U.S. Nongovernmental Grantees*). Cost-sharing activities provided an important channel for dissemination of RPM products.

INRUD

One of RPM's most significant cost-sharing activities came through the Danish International Development Agency (Danida)-funded coordination of the International Network for Rational Use of Drugs (INRUD). Since 1989, DMP has served as the network coordinator for this association of health professionals. The network consists of member groups in Bangladesh, Ghana, Indonesia, Nepal, Nigeria, the Philippines, Tanzania, Thailand, Uganda, and Zimbabwe as well as official collaborating centers in the University of Newcastle, Australia; the Karolinska Institute in Sweden; the Drug Policy Group at Harvard University; and WHO.

Managing Drug Supply (MDS) Second Edition

MSH wrote the landmark textbook *Managing Drug Supply* (MDS) in 1981, and updated it with a revised and expanded edition published in 1997. MDS is the best known and most widely used reference on pharmaceutical management in the world. With funding support from the PEW Charitable Trusts, Danida, and the Swedish International Development Agency, DMP developed the 1997 edition of *Managing Drug Supply.*

Studies and Assessments

During the RPM project, DMP conducted studies and assessments in Cambodia, Guatemala, Mexico, Nicaragua, Nigeria, Papua New Guinea, Senegal, and Sierra Leone. RPM's indicator-based approach to assessments was tested, refined, and disseminated through much of this work. These activities, funded by a wide variety of donors, ranged from targeted pharmaceutical sector assessments, as in Senegal, to specific studies on promoting the use of generics in Nicaragua. One of the largest projects in this category was the World Bank–funded work with the government of Mexico to study financing, procurement, and distribution of pharmaceuticals. DMP also had a project funded by the government of Mexico to study the drug supply system of the Mexican social security program.

Courses

As one of the world leaders in drug management training, DMP undertook a number of important training activities beyond those funded by RPM. Through INRUD, DMP staff assisted

12

in providing rational drug use training in such non-RPM countries as Ghana, Indonesia, Nigeria, the Philippines, Tanzania, Thailand, Uganda, and Zimbabwe. DMP developed a partnership with the International Dispensary Association (IDA) to offer an annual drug management course in Amsterdam. In collaboration with the Basic Support for Institutionalizing Child Survival (BASICS) project and the WHO Child Health Division, the DMP developed a manual and training materials for drug management at first-level health facilities, which was tested and refined in South Africa. This material has directly influenced RPM's work on drug management at local levels in Ecuador, Nepal, and Zambia. In 1994, the DMP completed the WHO-funded *Guide for Improving the Diarrhoea Treatment Practices of Pharmacists and Licensed Drug Sellers*. MSH received a one-year follow-on contract from WHO, through the Diarrhoeal and Acute Respiratory Disease Control Programme, to write two additional chapters for the *Guide*: "Expansion of Training to ARI" and "How to Expand and Sustain the Intervention." Field tests for this work were conducted in Kenya and the Philippines. In 1996, DMP hosted a 12-week course in Drug Information Systems for Indian pharmacists and doctors, funded by the Pan American Health Organization (PAHO). Four homeopaths joined the group for the first four weeks of the course. The main objective of the course was to enable participants to apply acquired knowledge and skills to plan and conduct a drug information research project, and they prepared project proposals to obtain funding and implement improved drug information systems in India. DMP also hosted a four-week course on Drug Regulation Systems for pharmacists from the Philippines, again funded by PAHO. The objective of this course was to evaluate drug information, describe U.S. legislation for quality assurance (QA) and good manufacturing practices, and describe the process for developing QA in pharmaceutical care.

Modes of Implementation

The RPM project used seven modes of implementation to accomplish project goals and objectives:

- Assessments of the Pharmaceutical Sector
- Policy Analysis and Dialogue
- Training
- Improved Information Management
- Studies and OR
- Communication and Social Marketing
- Collaboration with Other USAID Projects and Other Donors

Although some emerged as more prominent than others, all modes of implementation delivered significant accomplishments, including the following representative activities for each mode:

Assessments of the Pharmaceutical Sector

The development of an indicator-based approach to assessment of pharmaceutical-sector operations developed into a major thrust of RPM's work. Working in collaboration with USAID's LAC/Health and Nutrition Sustainability Project, MSH's DMP had begun work on indicator-based assessment methods before RPM's inception. When the work continued under RPM, the project staff

- completed the manual *Rapid Pharmaceutical Assessment: An Indicator-Based Approach*;
- carried out the project's mandated country assessments; and
- developed specialized assessment tools tailored to meet the needs of specific groups of clients.

As RPM evolved and the numbers of country programs and activities increased, the project's approach to assessment had a number of important positive consequences. RPM used assessments as a means of bringing about collaboration in a common effort and creating a sense of "stakeholding" among groups concerned with improving drug management. In addition, RPM used indicator-based assessments that could be applied in different ways to address general need for evaluation. RPM used these assessments in three primary ways:

- For overall country assessment, covering topics of pharmaceutical system operations. This application provided a valuable overview and helped to place specific operations or problems in a familiar context.
- For focused assessments functioning as in-depth analysis of the operations of a specific operation or problem. Such assessments could focus on one institution, such as a poorly functioning central medical store, or on a particular problem, such as drug-cost recovery.
- For specialized applications intended for routine use by local managers. These tools focused on specific system operations using a subset of the overall list of indicators. RPM experienced significant demand for such specialized assessment tools, including self-assessments focusing on drug management at the district level and assessments supporting implementation of specific programs such as IMCI.

DMP also used RPM assessment methods to develop an expanded set of structured survey instruments covering both public and private pharmaceutical sectors, which were tailored to the needs of each new assessment. DMP instruments were adapted for assessments in Nigeria and Vietnam, and these revised survey instruments were in turn revised and adapted for use in additional RPM assessment activities.

Policy Analysis and Dialogue

RPM's goal of contributing to improved allocation and use of financial, human, and information resources within the health sector led the project to call upon host countries and donors to

- support significant changes through reexamination of basic assumptions; and
- propose alternatives to existing ways of doing business.

Although not every activity undertaken had policy implications, RPM did take advantage of opportunities to successfully influence policies that affect or are affected by drug management practices. Technical recommendations advocated by RPM in policy dialogues were established through extensive discussion between both RPM and non-RPM members of DMP staff. During the life of RPM, DMP advised policymakers in Cambodia, Mexico, Nicaragua, Senegal, and South Africa. In addition, the original MDS textbook and the second edition revised in collaboration with WHO continue to have considerable impact on drug policy deliberations.

Training

Training figured prominently in most RPM programs. When appropriate, preexisting training materials were adapted to country situations. Creation of new training materials was based on need for training of trainers for training of line staff as well as on local needs. Lessons learned in RPM training activities were incorporated into the second edition of MDS, and RPM played a primary role in developing a new generation of training materials based on this book. During the course of the RPM project, a mutually reinforcing relationship developed between assessment and training activities. As local managers indicated interest in RPM's approach to indicator-based assessment, demand increased to train local staff to apply these methods. This training in turn led to training in specific topics of drug management as locally based assessment activities called attention to specific problems. This process occurred most significantly in Ecuador, Nepal, and Zambia.

DMP undertook a number of additional important training activities stimulated by those funded by RPM. Through INRUD, DMP staff assisted in providing rational drug use training in such non-RPM countries as Ghana, Indonesia, Nigeria, the Philippines, Tanzania, Thailand, Uganda, and Zimbabwe. DMP developed a partnership with the IDA to offer an annual drug management course in Amsterdam. In collaboration with BASICS and WHO's Child Health Division, DMP developed a manual and training materials for drug management at first-level health facilities, which were tested and refined in South Africa. This material directly influenced RPM's work on drug management at local levels in Ecuador, Nepal, and Zambia.

Improved Information Management

RPM contributed to improved information management within the context of the three mandated technical areas. For procurement/inventory management and drug information/rational use, many activities were carried out that were based on the development of computer software products

15

under the Tools Development and Information Dissemination Program and applying these tools in different country programs. All of the computer software developed by RPM was based on earlier products produced by DMP, and RPM tools have been applied by DMP in non-RPM countries. INVEC-2 has been installed in Cambodia, Mexico, Paraguay, Yemen, and Zimbabwe, and PASS and ESTIMED have been used by INRUD.

Studies and OR

RPM was active in OR at both the country and central program level. Its work with assessments and the stress placed on transferring the rapid assessment technology to counterparts represented a significant effort to create country-based OR capacity. RPM operated in the belief that involving local managers as much as possible in quantitative measurement of the performance of their own pharmaceutical systems was an essential step in institutionalizing improved methods of management. Apart from assessments, RPM carried out a number of important studies summarized in the various RPM country final reports. Much of DMP's work related to RPM involved operations research on various aspects of drug supply systems, often in the form of pharmaceutical sector assessments. RPM and non-RPM research activities built on each other. For example, the DMP research on cost recovery in Vietnam built on RPM studies in Nepal and Ghana (as well as on pre-RPM DMP work in Ecuador). As part of INRUD network coordination, DMP helped core groups in 10 countries design and manage OR aimed at identifying drug use patterns and ascertaining major pharmaceutical sector assessments. Other DMP OR activities included studies of medical supply use in Mexico, generic drug use in Nicaragua, essential drug program (EDP) procurement activities in Nigeria, drug utilization in the Florida Medicaid program, and medical stores operations in Senegal and Sierra Leone.

Communication and Social Marketing

Communication and social marketing played a vital role in much of the training supported by RPM. Training activities in support of rational drug use (RDU) led to a well-rounded package of communication interventions. Communication and social marketing also had an impact on RPM global-, regional-, and country-level initiatives, including the following:

- In collaboration with WHO, DMP produced the *Guide for Improving Diarrhoea Treatment Practices of Pharmacists and Licensed Drug Sellers.* Its major influence on RPM was the inclusion of simulated purchase surveys in the Central Asia, Ecuador, and IMCI programs.

- In Nepal, RPM worked with a local nongovernmental organization (NGO), the Resource Center for Primary Health Care, to support the publication of a drug information bulletin in the newsletter *Bhalakusari.* This publication was aimed at the community level and had a circulation of 7,000.

- The work carried out by USP on establishment of drug information centers in Mozambique and Nepal was an important communication activity. The availability of up-

to-date and unbiased drug information became a prerequisite for institutionalizing communication activities aimed at improving rational drug use.

- In Mozambique, Nepal, and Zambia as well as through IMCI-related activities, RPM intensified its efforts for promoting RDU. In the final analysis, RPM viewed improving drug use as a matter of communicating to promote better prescribing decisions.

- In Ecuador, RPM collaborated with BASICS to launch a school-based activity for communicating about the IMCI health problems, including messages about appropriate drug use. RPM and BASICS worked with schoolteachers to design appropriate teaching curricula and methods for schoolchildren to become the family information agents in RDU.

Cooperation and Collaboration with Other USAID Projects and Other Donors

> **Cooperation and collaboration between and among USAID personnel and the cooperating agencies appears to have been strong, both at the central and country level. Similarly, cooperation and collaboration between MSH and USP appears strong. At the field level, cooperation and collaboration is occasionally so strong that local counterparts show confusion as to whether RPM project personnel are MSH or USP employees. This confusion reflects a real strength on the cooperating agencies' collaboration.**
>
> —*External Review of Rational Pharmaceutical Management Project, 1997*

RPM had an impressive record as a project that actively sought opportunities to collaborate. The project's openness to working with others was undoubtedly a major contributing factor to increases in demand for RPM's services at both the country and central levels. RPM products such as manuals and documents developed around specific tools owe most of their successful adoption to the well-structured plans and close collaboration between RPM and its collaborators. Examples include

- The RPM approach to indicator-based assessment that was originally developed through work funded by the USAID LAC/Health and Nutrition Sustainability Project.

- INVEC-2, which was developed with technical input from the Zimbabwe Essential Drugs Action Programme, funded by Danida.

- Work with the World Bank, UNICEF, PAHO, and Belgium Foreign Aid on the decentralized drug management activity to coordinate TA inputs and share local costs.

- RPM's work in Nepal in collaboration with the WHO Action Programme on Essential Drugs in an evaluation of the EDP.

17

- RPM's extensive collaborations with the USAID (bilateral) Child Survival and Family Planning Services Project and the (centrally funded) Family Planning Logistics Management Project in the planning and implementation of the Logistics System Improvement Plan managed by John Snow International.

- Within reproductive health initiatives, RPM collaborated with the MotherCare II project, applying standard case-management procedures and related reproductive health commodities. RPM applied these data to model the cost of supplying these drugs and medical supplies on a country and/or facility basis.

- RPM worked on a specialized IMCI assessment tool with the USAID BASICS project and collaborated with PAHO for testing it in the LAC region.

Constraints and Challenges

Constraints and challenges to RPM were more in evidence for country programs than core activities, and these varied from country to country. In general, successful completion of country activities was due to the combined enthusiastic support and high degree of cooperation from MOHs, USAID Missions, and donor agencies. Constraints most often occurred when attempting to move beyond training toward systemic change and reform. Characteristic obstacles included

- Changing political environments
- Rigid administrative systems
- Lack of appreciation of the magnitude of the problems
- Poor financial conditions
- Internal cross-purposes/faulty communications within MOHs

RPM as a project looked at constraints with an eye toward turning them into challenges. The general challenges growing out of the most common constraints focused on

- Finding acceptable roles for RPM

- Identifying the types of long-term technical and managerial assistance acceptable to stakeholders

- Supporting country-specific decentralization and/or reform processes

Core activities faced constraints and challenges most specifically with the adoption of tools that were developed. The tools developed under RPM were universally well received by collaborators and other international organizations, and the value of tool-based manuals and documents in particular continues to be widely recognized. However, RPM faced the challenge of training local counterparts to use the tools to full advantage, thus limiting the value of the tools as "hand-off" tools measured by actual use by others.

Overall Achievements

The RPM Legacy: Closing the Gaps in Health Commodities

> **The RPM Project has drawn on MSH's more than 20 years of experience in drug management and USP's historical leadership in the development and dissemination of unbiased drug information. As a result, USAID has been able to overcome the prevailing distrust on its commitment to drug management issues and to establish a leadership role. Moreover, USAID has quickly demonstrated a comparative advantage in on-the-ground technical assistance in drug management and procurement, the development and dissemination of drug information, and the promotion or rational drug use.**
>
> —*External Review of Rational Pharmaceutical Management Project, 1997*

From its inception, RPM called attention to and mobilized activity to change the way in which providers, patients, and the public view and use pharmaceuticals. RPM spearheaded an understanding of the major problems to be solved, and RPM promoted recognition of the need to reorient the role of government at a time when many governments had become less able to directly ensure universal access to drugs and their appropriate use. This strategy led to examination of the challenges posed by working with the public-sector NGOs to achieve public health goals.

RPM also served as a necessary catalyst to an in-depth understanding of the strategies used to strengthen commodity supply system performance, including

- Increasing financial resources that strengthen local capacity to function independently and provide equitable access to essential drugs and commodities
- Improving operation of existing supply systems in order to sustain long-term efficiency, using competition among a number of different service providers and performance-based incentives for staff
- Improving therapeutic decision-making and lowering costs by providing essential drugs through implementing formulary systems; developing standard treatment guidelines for appropriate drug use; and understanding human behavior related to education, management, and regulation

In the eight years of RPM, USAID developed and implemented a variety of technical approaches and tools to reduce waste, improve the allocation and use of resources, promote managerial efficiency, and foster sustainable reforms in developing country pharmaceutical systems. RPM's TA in 14 developing countries supported the creation of the capacity to locally adapt and disseminate up-to-date, evidence-based drug information in order to improve pharmaceutical management decision-making and the appropriate use of drugs. In addition, RPM was able to

document much of the progress made by implementing programs within developing countries that improve the supplies of essential drugs and other health commodities to those most in need. Although the successes are clear, RPM confirmed an ongoing need throughout the developing world to address the enormous gaps that remain both between the demand for essential drugs and health commodities and their availability, and between availability and rational use. For all future efforts in this area, RPM convincingly showed that tools developed to focus on closing gaps that represent the symptoms of ineffective health commodity supply systems can and do work.

Lessons Learned

In its *Request for Applications (RFA) Number M/OP-00-1505 Rational Pharmaceutical Management Plus* document, USAID presented five general key lessons learned from the RPM project:

- Systematic diagnostic information on commodity system performance—even in very weak systems—can lead to improved resource allocation, reduction of waste, and improved availability of drugs and other commodities. This fact is particularly important given the high value of many health commodities and the susceptibility of systems to fraud and abuse.

- Local stakeholder involvement is essential throughout the diagnostic assessment and strategic planning process (design of instruments, collection and analysis of data, policy options analysis, and elaboration of technical interventions and implementation strategy) to ensure the introduction of sustainable reforms in commodity systems.

- Many PHN-sector donors are willing to provide financial support to commodities and commodity system improvements if their inputs can be guided by objective analyses of information generated by resource allocation and quality-of-care indicators, involvement of local stakeholders in the assessment, and a shared consensus on priorities and the specific problems to be addressed.

- Building capacity in commodity management continues to be an important priority; however, it cannot be assumed that provision of training and education to staff will produce sustained improvements in commodity management. If sustained improvement is a goal, such efforts need to be supported by an enabling environment and proper incentives.

- Understanding of the effectiveness of interventions to improve drug use practices by providers has improved dramatically over the past decade, and attention now needs to be given to scaling up of interventions that have proven to be effective. Little is known about patient compliance and drug-seeking behavior, and more research is needed both to better understand the factors that contribute to patient compliance and consumer drug-seeking behavior, and to test interventions to address these areas.

MSH has added eight complementary Lessons Learned during RPM:

1. Countries commonly encounter difficulties implementing health policies and strategies that support drug supply.

2. The private sector can provide valuable support to help improve the availability and proper use of drugs in the public sector.

3. Hospitals present an important opportunity for improving drug management and use in developing countries.

4. Drug product quality in developing countries is a constant, high-profile concern that requires urgent attention.

5. Reliable data are essential for good policy, management, and clinical decision-making, but many countries lack the resources to generate and use information effectively.

6. Although the availability of high quality, unbiased drug information sources can be increased with short-term technical and financial assistance, local adaptation and effective dissemination of drug information remains a challenge.

7. For sustainable improvement, an enabling environment and proper incentives must support capacity-building efforts.

8. Efforts to improve drug management must employ multiple strategies.

Needs at the End of the RPM Project

Five primary areas of concern are key to an understanding of what needs remain to be addressed in rational pharmaceutical management:

- **Financing.** Many developing countries do not have the resources required to finance health care services and essential commodities. The public sector often has limited capacity to raise resources, and resource mobilization efforts are frequently compromised by an inability to access donor funding. The direct and indirect impact of public-sector financing shortfalls on access to drugs is dramatic.

- **Information/Use of Information.** Developing countries often lack the ability to generate and use relevant information for effective commodity planning and management decision-making.

- **Policies and Regulation.** Problems with reduced potency and counterfeit products are common in developing countries, contributing to waste, unsatisfactory treatment

outcomes, and in some cases, even death. These problems are compounded by the nebulous status of drug regulatory authorities.

- **Commodity Management Capacity.** Weaknesses in commodity management are a significant obstacle to ensuring necessary access to essential commodities.

- **Drug Use.** When drugs are available, providers and patients must use them correctly. However, irrational drug dispensing and use are common worldwide, particularly in developing countries.

The RPM project's experience strongly suggests that the complex problems in pharmaceuticals management that developing countries must face in these five primary areas of concern are difficult but not impossible to solve. An integrated approach holds the most promise for success by

- Using extant and newly developed indicators and tools to strengthen system efficiency based on objective information

- Linking commodities management to related health-sector reforms

- Leveraging resources

- Building partnerships and local institutional competence

An integrated approach in turn could be used to confront the emerging challenges of special commodity management problems, such as antimicrobial resistance, and high-priority concerns, such as tuberculosis, malaria, and HIV/AIDS. A major challenge for all projects and programs that follow RPM will be how to achieve sustainability in the face of changing epidemiological patterns, increasing demand for modern health care, growing populations, and shifting political and economic environments.

Final Report Format

This document is divided into three sections. The first section contains the final reports for programs that addressed global issues—overarching health commodity issues that have been organized into strategic areas. The second section contains the final reports for regional initiatives, and the third section contains the final reports for the RPM country programs. Each report includes an executive summary, a program summary, and a section detailing the overall approach to implementing the technical assistance provided by RPM. Each report may also include a list of challenges, specific achievements, outcomes, and likely needs at the end of the project, and offer several lessons learned.

22

GLOBAL PROGRAMS

Child Survival

Executive Summary

From its inception, the Rational Pharmaceutical Management (RPM) project supported USAID's Strategic Objective SO3 (Increased use of key child health and nutrition interventions) by developing activities to ensure that commodities for child survival were available and appropriately used. This area is critically important because deadly diseases and childhood illnesses, as well as HIV/AIDS, contribute substantially to child mortality. Child mortality remains high throughout the developing world, and in some countries the rate continues to increase.

Many of RPM's efforts over the course of the project made significant direct or indirect contributions to SO3, including initiatives on indicator-based assessments, software tools development, procurement and inventory management, improvement of drug logistics, and rational drug use training. RPM most directly addressed SO3 through work associated with the international Integrated Management of Childhood Illness (IMCI) strategy. In recognition of the need to address child mortality and morbidity rates, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) developed the IMCI strategy for the five major causes of childhood illness: acute respiratory infection, diarrhea, measles, malaria, and malnutrition. Implementing a strategy for case management of these five major causes of illness began through the WHO's Division of Child Health and Development (WHO/CHD) in 1996, and since then numerous countries have offered program managers and service providers this unified approach to deal with childhood illness. Virtually all important IMCI child survival interventions require access to drug or vaccine products in order to achieve successful outcomes, and WHO/CHD identified research on improving the supply and management of essential drugs and vaccines as a critical part of improving the health system.

RPM contributed its overall expertise in drug management to support the IMCI strategy and to address the problems associated with attempts to improve child health. Specifically, RPM developed the Drug Management for Childhood Illness (DMCI) tool to assist health managers at the central and district levels to identify problems and constraints related to essential drug use and availability in the implementation of IMCI. After being field-tested and used in Ecuador and Bolivia, the DMCI was adapted and successfully applied in Zambia and Uganda. DMCI success in Latin America and East Africa created interest in using the tool elsewhere in Africa and throughout the developing world. Results from the DMCI produced important information on the status of drug availability in public facilities and private retail outlets, as well as data on various prescribing practices for childhood illness. By way of the ongoing complementary activities of both SO3 and Africa Bureau/Child Survival, RPM continued to use its expertise in assessments through use of the DMCI tool to assist policymakers to identify the best strategies to strengthen their essential drugs and supplies management capacity.

Acknowledgments

RPM gratefully acknowledges the contributions and support from the following people:

All of the Participants in the Ecuador (November 1997) and Tanzania (October 1999) DMCI Regional Workshops

BASICS Project [USAID]
David McCarthy
Rene Salgado
Adama Kone

Pan-American Health Organization
Rosario D'Alessio
Christopher Drasbek
Enrique Fefer

USAID
Al Bartlett
Susan Bacheller

World Health Organization
Moses Chisale
Antoine B. Kabore
Sam Muziki
Stefan Peterson
Remi Sogunro
Hans Troedsson
Severin Von Xylander

Acronyms

ARI	acute respiratory infection
BASICS	Basic Support for Institutionalizing Child Survival (project)
DMCI	Drug Management for Childhood Illness
EDP	essential drug program
HIV/AIDS	human immunodeficiency virus/acquired immune deficiency syndrome
IMCI	Integrated Management of Childhood Illness
LAC	Latin America and Caribbean (region)
PAHO	Pan American Health Organization
RPM	Rational Pharmaceutical Management (project)
SO	Strategic Objective [USAID]
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization
WHO/AFRO	World Health Organization Regional Office for Africa
WHO/CHD	World Health Organization Division of Child Health and Development

Program Overview

In response to the need for support in improving Integrated Management of Childhood Illness (IMCI) drug management, the Rational Pharmaceutical Management (RPM) project held a number of discussions with the Pan American Health Organization (PAHO), USAID, and the Basic Support for Institutionalizing Child Survival (BASICS) project that led to the formation of the Latin America and Caribbean (LAC) Regional IMCI initiative. In support of this initiative, the group collaborated to develop an IMCI drug management assessment manual for integration into the IMCI planning process. This indicator-based manual became the Drug Management for Childhood Illness (DMCI): a key tool to assist the user in assessing those aspects of the drug management system that are critical to ensure the availability and proper use of drugs and supplies essential to IMCI. The complete assessment is built around the drug management cycle and collects and reviews information on selection, procurement, distribution, and use. The tool uses specific indicators to measure the performance of a particular aspect of the drug supply system and its capacity to support IMCI.

Initial field-testing of DMCI was conducted in Ecuador in November 1997 to assess drug prescribing for acute respiratory infections (ARIs) and diarrhea. In addition to the Ecuadorian IMCI and essential drug program (EDP) representatives, the IMCI and PAHO/EDP representatives from Bolivia, Honduras, Nicaragua, and Peru participated in the field test. The country representatives received training in how to use DMCI and participated in testing of the study data collection methodologies.

RPM performed compilation and analysis of the Ecuador field-test data through a subcontract with a local health care consulting nongovernmental organization working in Ecuador. Weaknesses were identified for most components of drug supply: vitamin A, indicated for treatment of anemia, malnutrition, and measles, was not on the essential drug list; the information system was severely hampered by poor record-keeping and inventory management practices; antibiotics were overprescribed for ARIs and nonbacterial diarrheal diseases; and DMCI tracer drugs were available less than 50 percent of the time over a period of one year.

The next phase of testing was conducted in Bolivia in May 1998 and was divided into two parts:

- Testing the revised DMCI tool in relation to ARI and diarrhea, and after data collection and analysis, revising the tool to include the additional three IMCI conditions

- Further revision and testing of DMCI in collaboration with PAHO and BASICS

RPM assisted Bolivia in applying the DMCI methodology and tool. The findings from the assessment were timely because the national health insurance plan, *Seguro Básico de Salud*, was about to include the drugs used to implement the IMCI strategy in the social security program. However, the DMCI assessment identified availability problems for IMCI products, poor stock management of drugs, irrational use of antibiotics, and weak dispensing practices in health

facilities. The study helped inform health policy decision-makers about weaknesses in the system that should be addressed to ensure the success of both the IMCI program and the *Seguro Básico de Salud.*

The DMCI tool and methodology were also packaged and presented in a series of technical workshops for trainers and responsible officials of the LAC region as a follow-up activity to the assessment requested by PAHO and BASICS.

In addition to using the DMCI tool to assist in assessing and monitoring the availability and rational use of drugs and supplies essential to IMCI, RPM's goal was to develop a drug management tool that could be integrated into the IMCI planning process, and a tool that could be revised and adapted for use worldwide. To meet this goal, RPM successfully negotiated with USAID's Global Bureau, Africa Bureau, and WHO's Regional Office for Africa (WHO/AFRO) to implement the DMCI tool in other countries, particularly in Africa.

RPM's IMCI work in general, and the specific DMCI output, enhanced the project's overall work on

- Indicator-based assessments
- Development of software tools for needs estimation
- Procurement and inventory management
- Improvement in drug logistics in order to improve drug availability

Overall Strategy

RPM developed its Child Survival program to address two technical areas: (1) procurement and distribution and (2) drug information and rational use. Initial support for IMCI came through core funds from the USAID/Global Bureau that were used to conduct an operations research activity focused on developing a tool to conduct diagnostic, indicator-based assessments, and to provide the basis for subsequent technical interventions from country-specific assessment findings. The resulting tool was initially known as the *IMCI Drug Management Assessment Manual.* It evolved into the DMCI as RPM built into the strategic development process extensive field-testing, refinements, and revisions. The resultant renamed DMCI tool package includes the *DMCI Manual*, the *DMCI Data Collector's Guide*, and the DMCI Epi Info–based software program for data entry and analysis. This package continues to be a viable, flexible tool for use throughout the developing world. In the LAC region, DMCI's continuing evolution was made possible through ongoing collaboration with BASICS and PAHO. RPM also received child health funding support from USAID/Africa Bureau, and in collaboration with WHO/AFRO, revised and reformulated DMCI for use in Africa. For all applications, RPM's strategy was based on building organizational relationships established during the development and/or field-testing of the tool to facilitate the dissemination efforts. RPM also took advantage of opportunities to make presentations on DMCI at in-country, regional, and international technical meetings and used other communication media to target the IMCI community.

IMCI Achievements

RPM's overall achievements in child health through its support for the global IMCI strategy will have a lasting impact on the study of drug management issues associated with IMCI implementation throughout the developing world. The ongoing refinements of the DMCI tool that RPM developed will continue to provide baseline data on ICMI drug availability, costs, and use in public and private sectors. The tool can also be used to monitor and evaluate the status of IMCI drug management efforts. Representative and specific achievements during the life of the project are listed below.

- Conducted country-specific field-test assessments, sharing the results of the assessment with country programs
- Worked at the country level to develop training workshops in response to assessment findings
- Attended international IMCI operations research meetings coordinated by WHO/CHD and USAID/Global Bureau to share experiences and information
- In collaboration with PAHO and BASICS, developed and field-tested the DMCI tool for use in LAC region
- Provided country-specific training in DMCI methodology and data collection procedures
- With inputs from participating countries, WHO, PAHO, and BASICS, revised and expanded the DMCI tool to include the *DMCI Manual*, a *Data Collector's Guide*, and a DMCI Epi Info software program for data entry and analysis
- Used findings from DMCI assessments to inform ministry of health policy decision-makers about the need for national policy changes in support of IMCI implementation
- Devised a regional training approach to introduce the DMCI tool in Latin America that also promoted dialogue between IMCI coordinators and EDP managers
- Used funding support from USAID/Africa Bureau and collaboration with WHO/AFRO to adapt and then facilitate the use of the DMCI tool in Africa
- Worked with WHO/AFRO to translate the DMCI tool into French and planned the dissemination of the tool in francophone Africa, contributing to wider application of drug management in IMCI programming
- Used the data collection methodologies of the DMCI tool in three Central Asian Republics and in collaboration with BASICS used the DMCI methodology to compare the average cost of treatment by IMCI-trained and untrained health workers
- Produced an informational one-page flyer about the DMCI tool

- Featured the availability of the tool in *INRUD News*
- Conducted a targeted mailing on DMCI to those organizations working in IMCI such as WHO, UNICEF, the Quality Assurance Project, Academy for Educational Development, Johns Hopkins University, Centers for Disease Control and Prevention, BASICS II, CARE, and others
- Made presentations on the *DMCI Manual* at several international conferences.

Outcomes

RPM's most significant outcome was the development of the DMCI tool to assess the availability and use of drugs necessary for successful implementation of IMCI. Related outcomes include

- Provision of data on availability, prescribing practices, and associated costs of IMCI drugs and supplies
- Identification of possible ways to improve IMCI drug management, including availability, treatment, and cost
- Development of the DMCI tool for monitoring changes in systems and the impact of interventions
- Transfer of self-assessment technology by creating country-based operations research capacity
- Improvement in IMCI prescribing practices by identifying specific problem behaviors that should be targeted when designing and planning interventions
- Broader dissemination and increased awareness of the DMCI tool
- Strengthened collaborations and expanded networking between RPM, USAID, and other organizations working on IMCI activities

Lessons Learned

- The specific needs of programs such as IMCI must be taken into consideration within the context of the overall drug supply system. Therefore, the drugs recommended for use in IMCI should be included on a country's essential drug list so that they will not be overlooked in procurement activities. Their availability should be a priority.

- The cost-comparison data generated by the DMCI tool were particularly effective in getting the attention of policymakers. Policymakers are often particularly receptive to financial arguments—for example, if proposed activities are clearly linked to cost savings. If the cost of irrational prescribing by ministry of health staff is made clear—or if the savings that result from changes in treatment guidelines, drug selection criteria, and procurement practices are documented—policymakers may be influenced to institute change.

- A regional approach to introducing the DMCI tool was effective. In Ecuador, RPM conducted a regional DMCI workshop to which representatives from four other countries (Bolivia, Honduras, Nicaragua, and Peru) were invited. This approach also provided a forum for IMCI managers and essential drugs representatives to meet and discuss common drug management issues, something that previously had not been done. These representatives were able to learn about DMCI and use the tool to collect data as part of the workshop. As a result, the Bolivian representative chose to use the tool in Bolivia with limited technical assistance from RPM. In Africa, RPM conducted a regional DMCI introduction workshop in Tanzania that also included IMCI coordinators and essential drugs representatives from Uganda and Zambia.

Needs at End of Project

- The IMCI strategy is being adopted in many developing countries around the world, which means DMCI will continue to be a useful tool. Organizations and/or developing countries interested in applying the tool are likely to need technical assistance to fully implement DMCI.

- Needs to translate the tool for localized use will also likely occur.

- The DMCI tool was designed for use by health managers and service providers at the institutional or facility level, but the tool was not designed to collect information on consumer use at the household level. Information gathered on the community level could be an important factor in the discussion of future interventions.

HIV/AIDS

Acknowledgments

Review of USAID-funded procurement of HIV/AIDS-related pharmaceutical products:

Anthony Boni, USAID Global Bureau Center for Population, Health and Nutrition/HN/HPSR
Douglas Heisler, USAID/DHIV

Review and evaluation of drug management and procurement in Uganda–World Bank mission:

Rogati Kayani, Senior Procurement Specialist, World Bank
Mary Mulusa, Task Team Leader, World Bank
Martin Otebbe, Principal Pharmacist, Ministry of Health, Uganda

Acronyms

AIDS	acquired immunodeficiency syndrome
CA	cooperating agency
CPAR	country procurement assessment review
DHIV	Division of HIV/AIDS [USAID]
FY	fiscal year
HIV	human immunodeficiency virus
IR	intermediate result
MSH	Management Sciences for Health
PERC	Public Expenditure Review Credit
RPM	Rational Pharmaceutical Management (project)
SO	strategic objective
STI	sexually transmitted infection
UNAIDS	United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
USAID/W	USAID Washington, D.C., Office
VCT	voluntary counseling and testing

Program Overview

There is universal agreement that HIV/AIDS is a global health crisis. In 1999, the United Nations Programme on AIDS (UNAIDS) reported that of the 34 million people worldwide living with HIV/AIDS, 95 percent were in developing countries.[1] In sub-Saharan Africa alone, UNAIDS estimated that 3.8 million adults and children became infected with HIV during the year 1999, bringing the total number of people living with HIV/AIDS in the region to 23.3 million.[1] At the end of 1999, Africa was home to 70 percent of the total adults and children living with HIV/AIDS in the world. The key elements of any HIV/AIDS program are the prevention of new infections, treatment and care of those already infected, and mitigation of the effects of the disease on individuals and communities. The availability of pharmaceutical supplies is an essential component of HIV/AIDS health strategies in developing countries. However, the vast majority of people living with HIV/AIDS in developing countries does not have access to the pharmaceutical products that could prolong and improve their lives. Improving access to HIV-related pharmaceutical products presents many challenges including those that are directly related to pharmaceutical commodity management.

In 1998, the Management Sciences for Health (MSH) Rational Pharmaceutical Management (RPM) project held discussions with U.S. Agency for International Development (USAID) Global Bureau and USAID Division of HIV/AIDS (DHIV) and identified a number of HIV/AIDS commodity management issues relating to procurement, commodity management performance assessment, and technical assistance needs involving pharmaceuticals and HIV test kits. In 1999, USAID/DHIV began funding RPM's HIV/AIDS activities and RPM's approach was to help USAID think through some of its drug procurement issues and, where appropriate, provide assistance to address HIV/sexually transmitted infection (STI) drug management issues.

RPM prepared a report that reviewed USAID procurement guidelines and explored options that could facilitate the availability of safe and efficacious drugs and commodities for HIV/AIDS programs. As a follow-on to this activity, RPM was also contracted to develop a document to provide guidance to USAID missions and cooperating agencies (CAs) on USAID procurement guidelines and on preparation of requests for approval to procure USAID-funded pharmaceutical products.

USAID/DHIV funding was also used to support a collaborative relationship with the World Bank and USAID on activities related to commodity management and procurement of pharmaceuticals and medical supplies for STIs and HIV/AIDS programs. RPM representatives participated on a World Bank mission to Uganda and provided technical and programmatic recommendations on drug management to improve the availability of drugs for HIV/STI management and prevention services. In addition, RPM prepared a report to facilitate a dialogue to address some of the critical issues in the supply management of STI drugs in sub-Saharan Africa and to identify areas where a concerted regional approach could be pursued. This activity was principally funded by the Africa Bureau, and USAID/DHIV funds were used to make minor revisions, updates, and analyses of relevant data.

[1] UNAIDS/WHO. *AIDS epidemic update.* Geneva: UNAIDS, 1999.

Objectives

RPM's HIV/AIDS activities contribute to USAID's fourth strategic objective (SO4): Increased use of improved, effective, and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic; and intermediate result (IR) 4.2: Enhanced quality, availability, and demand for STI management and prevention services by identifying constraints to and strengthening commodity management systems to improve the availability of drugs and commodities to support HIV/STI programs. More specifically, RPM's HIV/AIDS objectives were to

- Clarify USAID procurement requirements, identify constraints to obtaining approval to procure pharmaceutical products, and explore options to facilitate the process
- Develop a guidance document to facilitate the process to prepare requests for approval to procure HIV/AIDS-related pharmaceutical products and to reduce the time taken to process and approve the requests by assisting USAID missions/CAs to improve the completeness of the submitted information
- Provide technical and programmatic recommendations on drug management and procurement in Uganda to the World Bank, USAID, and the Ministry of Health to improve the availability of drugs for HIV/STI management and prevention services
- Develop a report to facilitate a dialogue to address some critical issues in the supply management of STI drugs in sub-Saharan Africa and identify areas where a concerted regional approach can be pursued to improve the management and prevention of STIs

Implementation Strategy and Major Activities

RPM's overall approach was to focus on assisting USAID/DHIV to review issues related to the USAID procurement process and to collaborate with the World Bank, as needed, on HIV/STI drug management and procurement activities.

Major activities and implementation strategies follow.

Review of USAID-Funded Procurement of Pharmaceutical Products

As the HIV/AIDS crisis has expanded, so have requests from cooperating agencies (CAs) and USAID missions to purchase pharmaceutical products, which require adherence to USAID regulatory guidelines. However, many USAID missions and CAs have found it difficult and time-consuming to prepare the supporting documentation needed to meet these source/origin and safety, efficacy, and quality criteria. At the same time, the international procurement environment is being changed by efforts of governments in developing countries to increase access to HIV/AIDS drugs. Using a literature review and semi-structured interviews, RPM produced a report that provided an in-depth understanding of the regulatory requirements for

DHIV-funded procurement of pharmaceutical products and identified constraints and explored options to facilitate the process for USAID missions and CAs.

Procurement Guidance Document for USAID Missions/CAs

As a follow-up to *Review of USAID-Funded Procurement of Pharmaceutical Products*, USAID/DHIV also contracted RPM to develop a USAID Pharmaceuticals Procurement Guidance Document specifically designed to assist USAID missions and CAs in the procurement of USAID-funded pharmaceutical products for HIV/AIDS programs. The purpose of the document is to provide guidance to USAID missions and CAs on USAID procurement guidelines and on how to prepare a request for approval. This activity was contracted under RPM and a first draft was developed for review by USAID/DHIV. The document will be field-tested and completed under RPM Plus. RPM reviewed USAID procurement guidelines and interviewed key personnel in USAID Management Bureau/Office of Procurement and conducted a literature search to identify sources of data in order to prepare the first draft.

Review of Drug Management and Procurement in Uganda

USAID/DHIV funding was used to support a collaborative relationship with the World Bank and USAID on activities related to drug management and procurement of pharmaceuticals and medical supplies. In April 2000, RPM representatives participated on a World Bank mission to Uganda to conduct a country procurement assessment review (CPAR) in preparation for a proposed Public Expenditure Review Credit (PERC) for Uganda. RPM's role was to review the situation for procurement and management of drugs, particularly drugs to treat STIs, and provide technical and programmatic recommendations to the World Bank, USAID, and the Ministry of Health in Uganda. A report was prepared using document review, interviews with key informants, and attendance at Health Sector Strategic Planning meetings and work groups in Uganda.

STI Drug Management Considerations in Sub-Saharan Africa

RPM developed a report that reviewed STI standard treatment guidelines and burden of STI disease in six countries in sub-Saharan Africa using document review and data analysis. The purpose of the report was to facilitate a dialogue to address some critical issues in the supply management of STI drugs in sub-Saharan Africa and to identify areas where a concerted regional approach could be pursued to improve the management and prevention of STIs.

Challenges Facing RPM HIV/AIDS Implementation

The review of USAID-funded procurement of pharmaceutical products was delayed by difficulties in obtaining work visas for identified staff. This factor contributed to the delay in completing the procurement guidance document for USAID missions and CAs.

In developing the report, *Sexually Transmitted Infections: Drug Management Considerations for Sub-Saharan Africa*, the authors were unable to determine country-specific costs for STI treatment because of the absence of comprehensive and reliable information on epidemiology, treatment coverage, and drug consumption and procurement. Regional data were therefore used to produce estimates of the costs of treating STIs.

Chronological Activity Timeline

Table 1. Activity Timeline for Review of USAID-Funded Procurement of Pharmaceutical Products

Date	Activity
February 2000	Review of USAID procurement guidelines completed
May 2000	Literature review of domestic and international pharmaceutical trade and procurement policies, including recent revisions to World Bank procurement policies, completed
May 2000	Semi-structured interviews with three USAID/W, two USAID mission, and three CA key informants completed
August 2000	Report completed and submitted to USAID/DHIV

Table 2. Activity Timeline for Procurement Guidance Document for USAID Missions/CAs

Date	Activity
July–September 2000	Interviews with key informants from USAID/W; literature search to identify sources of information for supporting documentation
December 2000	First draft submitted to USAID/DHIV for review

Table 3. Activity Timeline for Review of Drug Management and Procurement in Uganda

Date	Activity
March 2000	Request from World Bank for RPM representative to join PERC/HEALTH mission to Uganda
April 2000	Review of background documents
April 2000	RPM joined PERC mission
August 2000	Report submitted to World Bank for discussion

Table 4. Activity Timeline for STI Drug Management Considerations in Sub-Saharan Africa

Date	Activity
July 2000	Report completed and submitted to USAID/W

Program Accomplishments

RPM received funding for HIV/AIDS activities in 1999, the final year of the RPM project. RPM's work in this field is just beginning and the accomplishments reported are related primarily to three activities completed at the very end of the project. These activities formed the starting point for addressing some of the drug and commodity management issues for HIV/AIDS programs.

Drug and Commodity Procurement

RPM produced a report in August 2000 for USAID/DHIV that reviewed USAID procurement guidelines, identified constraints to obtaining approval to procure pharmaceutical products, and explored options to facilitate the process. As USAID moves forward in immediate and long-term actions for expanding its HIV/AIDS programs, a critical area to address is facilitating the process for USAID missions and CAs to obtain approval to procure drugs and commodities in a timely manner. The report has assisted USAID to think through some options that could be used to support USAID mission and CA procurement of commodities.

A draft of a procurement guidance document was developed for review by USAID/DHIV. The purpose of the document is to provide guidance to USAID missions and CAs on USAID procurement guidelines and to assist them in preparing a request for approval, particularly in obtaining supporting documentation.

Pharmaceutical Sector Assessment

RPM participated on a World Bank mission to Uganda to conduct a country procurement assessment review (CPAR) in preparation for a proposed Public Expenditure Review Credit (PERC). RPM produced a report that reviewed the situation for procurement and management of drugs, particularly drugs to treat STIs, and provided technical and programmatic recommendations to the World Bank, USAID, and the Ministry of Health. These recommendations assist the World Bank and the Ministry of Health to identify options and interventions that can be used to improve the availability and use of drugs in Uganda.

40

Drug and Commodity Management

RPM developed a report that reviewed STI standard treatment guidelines and burden of STI disease in six countries in sub-Saharan Africa. The purpose of the report was to facilitate a dialogue to address some critical issues in the supply management of STI drugs in sub-Saharan Africa and to identify areas where a concerted regional approach could be pursued to improve the management and prevention of STIs. Included in the report was a review of the roles that donors can play in the field of STIs and five clear areas of priority that could easily and usefully be facilitated by donor funds and technical assistance.

Activities Not Completed

The following activities were included in the work plan but were not completed or implemented for reasons described below.

- As mentioned previously, USAID/DHIV also contracted RPM to develop a USAID Pharmaceuticals Procurement Guidance Document specifically designed to assist USAID missions and CAs in the procurement of USAID-funded pharmaceutical products for HIV/AIDS programs, as a follow-up to the *Review of USAID-Funded Procurement of Pharmaceutical Products* report. This activity was contracted under RPM and a first draft was developed for review by USAID/DHIV. The document will be field-tested and completed under RPM Plus.

- It was anticipated that RPM would assist DHIV to respond to requests, as appropriate, for guidance in areas relating to product availability, pricing, quality assurance, supply sources, and the like. RPM was to provide a brief case study–type report summarizing these requests and responses. Although RPM was available to respond to requests from DHIV during fiscal year (FY) 2000 and did provide information in response to specific drug-related requests, the low number of requests received did not merit a case study report.

- RPM was funded by the Africa Bureau to collaborate with the World Bank on activities related to pharmaceutical procurement in Africa, particularly in countries receiving World Bank loans and where the procurement process is stalled. The Bank has developed a paper on "Scaling-up of Multi-Sectoral AIDS Programs," and it has outlined 10 operational guidelines that would be essential to scale-up to national coverage. RPM planned to work with the Bank on drug management issues related to the "Scaling-up" document and to prepare a report providing an overview of the issues and recommended responses. However, because RPM's work with the World Bank under this activity in FY 2000 was specific to the World Bank country programs, a report providing an overview of the issues and recommended responses was not prepared. RPM's work with the World Bank's country programs is described under the MSH/RPM activity Review of Drug Management and Procurement in Uganda.

- RPM planned to seek opportunities to participate in HIV/AIDS technical meetings to increase awareness of drug availability and use issues and to highlight RPM's work with DHIV in this area. However, it was mutually agreed by RPM and DHIV that RPM would not send a representative to HIV/AIDS technical meetings during FY 2000 because RPM's work in HIV/STI drug management was just beginning and RPM was not yet in a position to be able to share and present results from these activities.

Likely Needs at End of Project

As the HIV/AIDS epidemic continues to escalate, USAID has focused on addressing the need to implement expanded and comprehensive HIV/AIDS programs. As DHIV moves into expanding HIV/AIDS programs, there are some critical areas related to the management of drugs and other essential commodities that need to be addressed.

- There is a need to field-test and complete the Pharmaceuticals Procurement Guidance Document to assist USAID missions and CAs in obtaining approval to procure USAID-funded pharmaceutical products for HIV/AIDS programs.

- Voluntary counseling and testing (VCT) provides an entry point for an extended range of support, care, and prevention activities. Rapid HIV test kits are required for same-day HIV testing, allowing patients to obtain their results before leaving the clinic, because studies have shown that a significant number of clients does not return to collect their results. As further interventions for persons living with HIV/AIDS are defined, for example, prevention of mother-to-child transmission and co-trimoxazole prophylaxis, the demand for VCT is likely to rise. As many rapid HIV test kits are not of U.S. source and origin, they must be purchased outside of the United States and there is a need to review international sources and mechanisms that are available to USAID to facilitate the procurement of these kits for USAID missions and CAs. There may also be a need to collect information on prequalification criteria to determine the capacity of individual international suppliers to handle procurement of HIV test kits and other selected products.

- As USAID/DHIV and missions contemplate or are ready to initiate expansion of HIV/AIDS activities, there is a need to assess the country-level capacity to support the scaling-up initiative. There is a need to develop a checklist that could be used by USAID missions and CAs to identify country-specific issues that are critical to health commodity management to support HIV/AIDS programs. In addition, country-specific assessments could provide information necessary for decision making regarding program expansion or for identifying drug management issues related to introducing or expanding access to antiretroviral drugs.

- On the basis of assessment findings, there may be a need to provide training or direct technical assistance to countries in selecting, forecasting, procuring, and distributing HIV/AIDS-related drugs and commodities and also in developing approaches to assess and improve the rational use of these commodities.

Lessons Learned

Although RPM's HIV/AIDS program began very recently in 1999, there are some clear lessons that have emerged from these initial activities.

- USAID missions and CAs have experienced difficulties complying with USAID procurement guidelines when requesting approval to procure pharmaceutical products for their HIV/AIDS activities. As a result, missions and CAs experienced considerable delays and additional expense implementing their programs.

- There are serious deficiencies and complexities in the World Bank international competitive bidding procedures for developing countries like Uganda. As a result, public health facilities have encountered delays and shortages of essential drugs.

- Improved coordination is necessary among World Bank officials, country procurement officials, and other Ministry of Health departments in order to ensure the timely procurement and receipt of essential drugs. Detailed procurement plans, policies, and procedures are also necessary for all procurement programs.

- Drug management programs in Uganda have a low priority in the health care system, which results in poor drug availability and accountability as well as inappropriate drug use.

- The prompt treatment of STIs has been identified as one of the few ways to reduce the spread of HIV/AIDS. However, there is a lack of comprehensive and reliable information on epidemiology, treatment coverage, and drug consumption to inform the planning, design, and implementation of interventions to reduce STI prevalence.

- From a donor perspective, it may be more effective to adopt regional strategies to address STI drug needs, given the epidemiological and demographic similarities in the sub-Saharan Africa. The common regional strategy could focus on harmonizing standard treatment guidelines, using collective procurement and price sharing, cooperating in a regional antimicrobial resistance surveillance center, and improving adherence to standard treatment guidelines.

Annex 1. Documents Produced

Keene, Douglas, and Helena Walkowiak. 2000. *USAID-Funded Procurement of HIV/AIDS-Related Pharmaceutical Products: Constraints and Options for Improvement.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Project. Arlington, VA: Management Sciences for Health.

Gabra, Michael, and Terry Green. 2000. *Review of Drug Management and Procurement in Uganda.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Project. Arlington, VA: Management Sciences for Health.

Rational Pharmaceutical Project. 2000. *Sexually Transmitted Infections: Drug Management Considerations for Sub-Saharan Africa.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Project. Arlington, VA: Management Sciences for Health.

Infectious Diseases

Executive Summary

New and reemerging infectious diseases continue to present a serious worldwide health threat and will increase significantly over the next decade. Malaria and tuberculosis, in particular, are increasing and pose serious health risks to many developing countries. Antimicrobial drug resistance (AMR) is also spreading at an alarming rate, primarily due to inappropriate antimicrobial prescribing and use. Not only do these problems increase morbidity and mortality, but also they divert financial resources that otherwise could have been used for other health care problems. The effect on the health care system is dramatic as more patient visits occur, resulting in higher costs and increased demands on patient care programs. This activity further taxes pharmacy services, particularly drug procurement, inventory management, and distribution and use practices.

In 1997, the Rational Pharmaceutical Management (RPM) project cosponsored the first International Conference on Improving Use of Medicines (ICIUM) in Chiang Mai, Thailand. During this conference, RPM and international partners identified the following activities to address the problem of irrational drug use, especially irrational antimicrobial use, and the global spread of AMR: (1) development and testing of indicators to study antimicrobial use in hospitals; (2) development of a Drug and Therapeutics Committee (DTC) training course; and (3) fostering and coordination of research initiatives on improving prescribing and dispensing practices, improving community use of medicines, and developing effective pharmaceutical policies and regulations. In April 1998, the RPM project received Strategic Objective SO5 funding from USAID for work on infectious diseases and AMR. RPM developed a comprehensive program to address these problems and work continues to this day.

Malaria and tuberculosis (TB) continue to be leading causes of morbidity and mortality in many developing countries. These diseases are also beset by the increasing spread of antimicrobial drug resistance. To make an impact on the treatment of these two infections, RPM began work with other international health care organizations on strategies to increase the availability of medications, define treatment modalities, and prevent the spread of antimicrobial resistance. RPM's methodology to approach these two diseases was to develop rapid assessment tools to analyze and monitor the availability and use of antimalarial and antituberculosis drugs in developing countries. RPM also participated in the World Health Organization (WHO) Joint Review of Tuberculosis in Ukraine in December 1999, providing valuable information for the USAID and the Ministry of Health (MOH) to develop a package of interventions for the Donetsk pilot site. The review report was also used in negotiations between the World Bank and the Ukrainian government regarding a loan to address the TB crisis in the country.

RPM undertook other projects to assess and evaluate methods to address antimicrobial drug use and abuse. RPM researched, developed, and subsequently published a paper describing the effects of provider reimbursement mechanisms and managed care on antimicrobial drug use. A paper was also developed to review interventions and strategies to improve the use of antimicrobials in developing countries.

Accomplishments of the activities in the RPM Infectious Diseases program were significant, especially when one looks at the long-term benefits of the tools and training programs produced. Accomplishments include the following:

- A comprehensive manual was developed that describes indicators for assessing the use of antimicrobials in hospitals. The manual includes indicators and their rationales, definitions and calculation for proposed indicators, model data collection forms, and proposed methods and techniques to collect data needed to derive the indicators. This manual has now been tested in two countries, Ecuador and Nepal.

- A drug and therapeutics training course was researched, developed, and field-tested for its effectiveness. A comprehensive participant's guide and a detailed slide presentation were developed for the training course. Results from the field-test evaluation offer substantial evidence that the training activity has appropriate content and methodology for presentation. Collaboration with WHO is anticipated for future training programs and the development of the WHO manual on DTCs.

Three regional workshops were instituted to train researchers in the development of research proposals. These workshops were invaluable in providing researchers the necessary information to fully develop proposals and implement their projects.

- Malaria and TB rapid assessment manuals have been developed and are now ready to be field-tested. These manuals will be valuable to drug managers in many different countries to improve programs for these serious and widespread diseases.

- Assessment of the TB program in Ukraine had several accomplishments, including the revision of national policies concerning TB and the institution of policies and allocation of funds for centralized tenders. By participating in the review, RPM established working relations in TB issues with the World Bank and WHO. In July 2000, RPM was invited to participate in a follow-up mission to Ukraine sponsored by the World Bank.

- RPM received an invitation to the USAID Asia and Near East/Europe and New Independent States (ANE/ENI) State-of-the-Art (SOTA) meeting to facilitate the session on international TB drug procurement. The focus was on concerns and issues related to host-country drug procurement problems and issues, and measures to address these problems. The presentation was based on RPM's experience in the Newly Independent States (NIS): two surveys in Russia—availability and procurement methods, and diagnosis and treatment in Russian oblasts—and TB drug procurement in Kazakhstan.

- A comprehensive paper was researched and written that describes how incentives and managed care can influence behavior of prescribers and dispensers. Key findings from 37 studies showed that prescribing and dispensing behavior can be modified through the use of financial and managerial mechanisms. The evidence clearly shows that incentives can modify antimicrobial prescribing and dispensing behavior.

49

- RPM attended the WHO global strategy meetings for AMR in February 1999 and September 12–14, 2000. RPM provided input for the global strategy that resulted in a draft document in October 2000. This document describes a comprehensive worldwide strategy that will provide guidance for the future control of AMR.

These tools, training programs, assessments, and research initiatives have significant potential to influence drug management programs in developing countries. They have the potential to improve efficiency in the drug distribution system, promote rational drug therapy and use, especially antimicrobials, and subsequently decrease the incidence of AMR.

USAID's Global Bureau provided funding for these activities that were intended to support SO5: The threat of infectious diseases of major public health importance reduced.

Acknowledgments

USAID
Susan Bacheller (Washington)
Amy Bloom (Washington)
David Losk (Addis Ababa)

CDC
Louis Salinas

WHO
Ian Smith
Kathy Holloway

IUATLD
Hans Rieder

Thailand Network on Rational Use of Drugs
(ThaiNRUD)
Chitr-Sitthi-amorn

Acronyms

AED	Academy for Educational Development
AMR	antimicrobial resistance
ANE	Asia and Near East
ARCH	Applied Research for Child Health (Project)
ARI	acute respiratory infection
CES	Cost-Estimate Strategy
CDC	Centers for Disease Control and Prevention
CMS	Central Medical Stores
CPG	clinical practice guideline
CT	combination therapy
DMCI	Drug Management for Childhood Illness
DMM	Drug Management for Malaria
DMTB	Drug Management for Tuberculosis
DOTS	Directly Observed Treatment, Short-course
DTC	Drug and Therapeutics Committee
EDM	Essential Drugs and Medicines
E&E	Europe and Eurasia
ENI	Europe and New Independent States
ICIUM	International Conference on Improving Use of Medicines
INRUD	International Network for Rational Use of Drugs
IUATLD	International Union Against Tuberculosis and Lung Disease
KAP	knowledge, attitudes, and practices
KNVC	Royal Netherlands Tuberculosis Association
MOH	ministry of health
MIM	Multilateral Initiative on Malaria
MSH	Management Sciences for Health
NIS	Newly Independent States
NMS	national medical stores
NTP	National Tuberculosis Program
PHN	Population, Health and Nutrition
PAHO	Pan American Health Organization
RPM	Rational Pharmaceutical Management (Project)
SEACAT	South East African Combination Anti-malarial Therapy (Evaluation)
SO	strategic objective
SOTA	state of the art
STG	standard treatment guidelines
TB	tuberculosis
TEHIP	Tanzanian Essential Health Implementation Project
USAID	U.S. Agency for International Development
USP	United States Pharmacopeia
UTI	urinary tract infection
WHO	World Health Organization
WHO/DAP	WHO Action Programme on Essential Drugs

Program Overview

In 1997 the Rational Pharmaceutical Management (RPM) project cosponsored the first International Conference on Improving Use of Medicines (ICIUM) in Chiang Mai, Thailand. RPM's international partners included the Applied Research for Child Health (ARCH) Project, the International Network for Rational Use of Drugs (INRUD), the United States Pharmacopeia (USP), and the WHO Action Programme on Essential Drugs (WHO/DAP). During this conference, RPM and partners identified the following areas in which to address the problem of irrational drug use, especially irrational antimicrobial use:

- Indicators to study antimicrobial use in hospitals
- Drug and Therapeutics Committees (DTCs)
- Research initiatives on improving prescribing and dispensing practices, improving community use of medicines, and developing effective pharmaceutical policies and regulations

The conference recommended the development of indicators to study antimicrobial use in hospitals and clinics. Adequate studies addressing effectiveness of rational drug use interventions in developing countries are deficient. RPM developed and tested an indicator-based manual for use in hospitals during this project.

Participants at the conference also recommended that DTC training materials be developed to improve the functions of this drug management committee. Drug and Therapeutics Committees have been in existence for many years, but their effectiveness in improving drug use and their usefulness in most settings is problematic. Committees may exist, but the ability or the will to effect change is absent in many. Training materials to increase capacity and improve outcomes from the DTCs are not available. RPM committed to develop and implement training materials to assist in the development of DTCs in developing countries.

The ICIUM identified key topics for research on improving prescribing and dispensing practices, improving community use of medicines, and developing effective pharmaceutical policies and regulations. A drug use portfolio was being collaboratively developed and cofunded by several organizational sponsors based on research priorities developed at the ICIUM. The history of participation by RPM and its partners in research activities that address drug use problems follows:

- Pre-1990: Descriptive research identifying problems of drug use in developing countries, but very little effort on identifying solutions
- 1990: INRUD formed to stimulate drug use intervention research in developing countries

- 1990s: Collaborative Applied Diarrheal Disease Research project-INRUD-WHO activities on use of medicines, including global advocacy, research training, and seminal intervention studies

- 1997: Partners cosponsor the ICIUM to summarize global experience in developing countries and to define a 5–10 year research agenda

- 1998–Present: Joint Research Initiative to implement the ICIUM research agenda

Following the conference, RPM and partners developed an agenda of research projects under the Joint Drug Use Intervention Research Initiative, based on priorities identified at the ICIUM. The overall goals for the initiative are to increase the capacity for drug use intervention research in developing countries and to stimulate a critical mass of research projects in the identified priority areas. RPM has provided technical assistance for proposal development and evaluated proposals for possible support by RPM and partners.

Research initiatives were proposed in three stages:

Stage I: Research focused on improving the prescribing and dispensing behavior of health providers. Researchers from Africa, Asia, and Latin America have provided proposals for research.

Stage II: For this stage of research, the focus is on improving the use of antimicrobials in communities and households. Proposals for research were developed with technical assistance by RPM and partners for possible future funding. Ten pre-proposals were selected for a proposal-building workshop in Bangkok, Thailand, scheduled to take place in 2001.

Stage III: Studies will be sought to evaluate the impact of specific national, district, and local policies that affect drug use, including strategies for scaling-up of successful interventions. Interested researchers will be identified and then proposals will be developed for possible funding.

In addition to these research-oriented activities, RPM conducted a literature search and subsequently developed a paper on the effects of provider reimbursement mechanisms and managed care on antimicrobial use. This paper provided information concerning managerial and financial mechanisms that may be used to improve prescribing and use of antimicrobials.

RPM also developed a report that evaluated interventions currently being used worldwide and their impact on the use of antimicrobial drugs. A large number of articles were initially reviewed and these were subsequently narrowed to 36 that met inclusion criteria. These studies targeted public and private sector health care providers with interventions that were divided into three main categories including educational, managerial, and regulatory. Although there were many limitations in this review, findings revealed that several interventions were effective in controlling the use of antimicrobials. [*This report was funded under RPM's Technical Leadership Program and, therefore, is covered in that section.*]

AMR/Malaria

In response to the continued place of malaria as a leading cause of morbidity and mortality and its growing resistance to traditional antimalarial drugs, international attention in recent years has been increasingly focused on assessing the effectiveness of alternate treatment regimens. However, program managers and drug policymakers in developing countries do not always have ready access to information on alternate malaria treatments on which to base policy and programmatic decisions. To the extent that current management policies and practices determine the availability and effective use of antimalarial drugs, program managers were perceived to need a mechanism to rapidly gather key information to assess and monitor the functioning of their malaria drug supply system. Information gathered from such an assessment could then be used to improve existing programs and policies, to slow the emergence and spread of resistance, and/or to determine the need to switch to more effective treatment options.

Against that background in March 1999, RPM participated in the Multilateral Initiative on Malaria (MIM) African Malaria Conference in Durban, South Africa. RPM attended at the request of USAID as a first step toward joining international initiatives to improve the malaria situation in Africa.

Subsequent to that meeting, USAID/Africa Bureau and RPM met to define roles and responsibilities of collaborating organizations in the combination therapy (CT) trials for malaria in Tanzania and South Africa. In support of the CT trials, it was agreed to make AMR funding available to develop a malaria-specific drug management assessment tool to assist with the pre-implementation assessment phase of the Tanzania CT trial that was to be led by investigators from the Centers for Disease Control and Prevention (CDC).

The work conducted under AMR/Malaria was complemented by other malaria work conducted on behalf of the USAID Africa Bureau (Infectious Diseases).

AMR/Tuberculosis

Tuberculosis (TB) is a major infectious disease worldwide and, according to the World Health Organization (WHO), it poses an increasing problem, especially in low-income countries, causing more than 25 percent of avoidable adult deaths.[1] In 1993, WHO declared that TB was a global emergency and introduced the Directly Observed Treatment, Short-course (DOTS) strategy as the most efficient approach to fighting TB. The DOTS strategy has become a cornerstone of national tuberculosis programs (NTPs) in more than 100 countries. The elements of the DOTS strategy include the political will to fight tuberculosis, diagnosis through microscopy, direct observation of patients taking each medication, compliance with a full course of treatment, rigorous reporting mechanisms, and an uninterrupted supply of quality TB drugs. Despite this and other efforts to improve the treatment and prevention of TB, several factors may adversely affect their effective implementation. These factors include lack of adequate training and supervision of both providers and recipients as well as unreliable or poorly managed TB

[1] Antonio Pio and Pierre Chaulet, *Tuberculosis Handbook* (Geneva: WHO, 1998).

drug supply that results in incomplete treatment and the emergence of multidrug resistant TB strains.

To address issues pertaining to TB drug management, RPM received funds to develop a Drug Management for Tuberculosis (DMTB) tool aimed at helping TB program managers to quickly assess their TB drug supply, identify weaknesses in the system and, once appropriate interventions are designed and implemented, monitor their impact. The program was to build on RPM work in TB drug management issues in Russia and Central Asia.

[This report summarizes activities of the RPM AMR project over the past two and one-half years. For more detailed information on the activities accomplished for this project, see individual reports prepared for each activity. A list of reports, documents, and tools are provided in Annex 1.]

Objectives of the RPM Infectious Disease Program

The RPM activities supported USAID's SO5: The threat of infectious diseases of major public health importance reduced. The basic RPM AMR objectives were to

- Develop a manual to describe, compare, monitor, and assess antimicrobial drug use in hospitals
- Research, develop, and implement a training program to capacitate DTC members to provide basic functions of the committee for hospitals and primary care clinics
- Support research initiatives to improve prescribing and dispensing behavior of health care providers
- Support research initiatives aimed at improving antimicrobial use at the household and community level
- Review, assess, and develop a paper on the impact of provider incentives and managed care on the prescribing of antimicrobials in developing countries
- Research, design, and develop rapid assessment manuals for health care managers to assess tuberculosis and malaria drug management programs
- Participate in the WHO survey of the national TB program in Ukraine
- Serve as a source of TB drug management expertise for USAID and other donors
- Participate in and provide input for the WHO AMR global strategy meetings

Implementation Strategy and Major Activities

RPM's overall approach is to identify mechanisms to improve rational drug use through the support of studies and programs that may influence policy development. The main areas of focus included the development and implementation of key drug management tools and training programs, regional development workshops for research initiatives, and assessments of TB programs. These strategies are all intended to improve the use of antimicrobials and decrease the spread of AMR.

These activities involved literature reviews, targeted surveys, workshops, and technical and financial support for intervention studies. USAID SO5 funding was also used to support RPM's attendance at several state-of-the-art (SOTA) meetings and attendance at the WHO strategy conference for AMR. Collaborators in these projects included Academy for Educational Development (AED), ARCH, CDC, INRUD, International Union Against Tuberculosis and Lung Disease (IUALTD), Royal Netherlands Tuberculosis Association (KNCV), World Bank (WB), and WHO/Essential Drugs and Medicines (EDM). Implementation strategies and major activities associated with RPM's infectious disease program were as follows.

Indicator-Based Methodology to Assess Antimicrobial Use in Hospitals

A rapid assessment indicator-based manual was developed to assess antimicrobial use in hospitals. This manual was developed after a focused literature review and survey of key researchers and INRUD members. The draft manual has been produced and includes the rationale, definition, and calculation for proposed indicators; model data collection forms; and proposed methods and techniques to collect data needed to derive the indicators. The draft document has been successfully field-tested at six hospitals in Nepal and Ghana.

The manual is intended as a rapid assessment tool that can be used by hospital administrators, DTCs, researchers, and program managers in developing countries to identify problems with antimicrobial use in their facilities. The manual will help detect problems, guide health care personnel to identify their underlying causes, and promote interventions to correct the problems. Indicators in the manual are categorized into groups that include hospital, prescribing, patient care, and supplemental indicators.

Drug and Therapeutics Committee

A draft discussion paper on the role of Drug and Therapeutics Committees in improving antimicrobial use was developed. A literature search of WHO, INRUD, MEDLINE, and other publication sites was performed prior to development of the paper. Information gathered in the review was used in the development of the DTC training materials.

Training modules for DTCs were designed, developed, and field-tested. These modules provide technical information for members of a DTC on what is the role of a DTC, how to effectively

manage a DTC, and how to improve its efficiency. A well-established committee using the framework from this training program will have the necessary information and skills to provide appropriate drug selection, identify drug use problems, promote rational drug use, and improve the use and control of antimicrobials. A field test of the training materials was carried out in June 2000 in Bangkok, Thailand. Information obtained from this field test has been used to modify some sessions in the DTC training materials.

The training materials include a comprehensive slide presentation and a participant's guide that is divided into separate sessions or modules that cover important facets of a comprehensive DTC. The modules in the training course are

- Drug and Therapeutics Committee Overview
- Formulary Management
- Assessing Drug Efficacy
- Assessing Drug Safety
- Assessing Drug Cost
- Assessing Drug Quality
- Identifying Drug Use Problems
- Identifying Why Drug Use Problems Occur–Qualitative Methods
- Interventions to Improve Drug Use–Overview
- Standard Treatment Guidelines
- Drug Use Evaluation
- Managing the DTC

Technical Assistance to Researchers Involved in Proposal Development Workshops

Phase I Studies: Proposal Development Workshops

Support of antimicrobial drug use intervention research was accomplished by providing three proposal development workshops. RPM cosponsored (with ARCH, INRUD, and WHO/EDM) a proposal development workshops in Yogyakarta, Indonesia, in April 1998; Kampala, Uganda, in September 1998; and Mexico City, Mexico, in April 2000. This workshop series addressed important research concepts that are necessary in the development of proposals for research that were identified at the ICIUM. The focus of Phase I studies was on improving the prescribing and dispensing behavior of health providers. Steps in achieving goals of the research initiative include

- Articulate defined set of research topics in Request for Proposals

- Evaluate quality of Letters of Intent/pre-proposals submitted in response to Request for Proposals

- Work actively with highest-ranking teams to develop proposals, receive funding, implement research, and analyze and interpret data

Of the 21 studies initially approved for the portfolio, currently 15 are in progress. One study received funding from RPM and the others are funded by ARCH, INRUD, USAID, and WHO. As of October 2000, two research projects have been completed.

Phase II Studies: Proposals That Evaluate Behavioral and Policy Interventions to Improve Antimicrobial Use at the Household and Community Levels

The ICIUM identified a critical need for focused research to develop promising tools, methods, and strategies for effective patient and community interventions to improve care-seeking behavior and use of medicines. Community intervention projects developed during Phase II of the Joint Initiative will focus on improving antimicrobial use (antibiotics and antimalarials) to address the growing problem of resistance and widespread consumer misuse of this class of drugs. In addition to households and community members, the interventions to be tested will encompass all relevant suppliers of medicines at the community level including mobile drug vendors, drug retail shop owners, community health workers, health center personnel, and private practitioners. RPM and partners reviewed proposals in April 2000 and in Sumatra in October 2000.

On the basis of letters of intent in response to a framework articulated by the partners in the Joint Initiative (AED, ARCH, INRUD, RPM, WHO), 10 research teams will be invited to attend a proposal development workshop at which the research ideas for community interventions will be clarified and developed into full proposals. This workshop will be held November 29–December 8, 2000, in Bangkok, Thailand. Depending on available funding, four to five teams are expected to begin studies during early 2001.

Technical support will be provided during study implementation, with at least one visit per year by technical experts to each study team. During the third year, research teams will be invited to participate in a joint data analysis workshop. In addition to analyzing their data, the research teams will prepare policy briefs for disseminating results of their studies at local and national levels.

Review of Effects of Provider Reimbursement Mechanisms and Managed Care on Antimicrobial Drug Use

RPM conducted an extensive literature search and developed a comprehensive paper on the effects of provider reimbursement mechanisms and managed care programs on antimicrobial drug use. The hypothesis for the research was that prescribing and dispensing of antimicrobials in developing countries can be modified through the use of managerial and financial tools that influence behavior and that these tools often exist in a managed-care setting. The research involved a systematic review of published and unpublished studies on the impact of reforms and

interventions on the behavior of providers and consumers. Only scientifically rigorous studies were included in this paper.

A comprehensive search of MEDLINE 1966–2000 was undertaken using both MeSH and non-MeSH terms related to managed care, provider reimbursement mechanisms, developing countries, and antimicrobial drug use. In order to capture relevant social science literature, the same search strategy was carried out using HealthSTAR's 1992–present database. This search was followed by a comprehensive review of the INRUD database using key dictionary terms related to managed care, drug utilization, prescribing, and payment mechanisms. Finally, a systematic review of the Database of Reviews of Effectiveness (DARE) and the Cochrane Library (Version 1999, Issue 1) was carried out using relevant MeSH terms.

In order to broaden the search, in particular to capture nonpublished material, a request for information was sent to E-mail discussion groups. Finally, the authors attended the fourth Annual Summit on International Managed Care Trends, held in Miami, Florida, December 5–8, 1999. Prior to the summit, several participants were contacted to arrange interviews during the summit meeting days. Participants interviewed were specifically asked how managed care tools and provider payment mechanisms were being used in their country-specific contexts to influence provider prescribing and dispensing behavior.

The paper, entitled *The Effects of Managed Care and Provider Reimbursement Mechanisms on Antimicrobial Drug Use: Evidence from Industrialized Countries to Inform Policy in Developing Countries*, was published and a poster session of the results presented at the Global Health Council conference in Arlington, Virginia, in June 2000.

Participation in WHO Strategy Development Meetings

RPM attended and participated in these meetings that were designed to develop a global strategy to address AMR. The first meeting was held in Geneva, Switzerland, in February 1999, with follow-up meetings in February and September 2000. The most recent meeting was designed to prioritize identified interventions to address the problem of AMR. Possible interventions were categorized into educational, managerial, regulatory, and financial groups. A draft document has been produced by WHO that describes interventions, strategies, policies, and procedures that are necessary worldwide to help control the emergence and spread of resistant organisms.

The strategy provides a framework of interventions to slow the emergence of and to decrease the spread of resistant organisms. According to the WHO document, antimicrobial use is the most important component in the development of resistance, principally from the overuse and misuse of these drugs. The strategy addresses important drug management programs to decrease the incidence of AMR, including improving access to appropriate antimicrobials, reducing the disease burden and spread of infection, and strengthening health care systems. The strategy also addressed the concern for more research into the causes of AMR and interventions to address AMR.

The strategies and interventions proposed by WHO argue strongly for drug management programs like RPM, because they specifically deal with identified problem areas in which RPM has considerable experience and proven success.

AMR/Malaria

USAID Global and Africa Bureaus and RPM have worked together in defining roles and responsibilities of collaborating organizations in the combination therapy (CT) trials for malaria in Africa. To assist with the planned Tanzanian trial, RPM agreed to develop and test a rapid assessment tool to assess and monitor the availability and use of antimalarial drugs in developing countries. This tool follows the same developmental approach taken by the RPM-produced Drug Management for Childhood Illness (DMCI) tool, which includes a *Manual* and *Data Collector's Guide*. The DMCI approach for assessing drugs for Integrated Management of Childhood Illness (IMCI) was therefore adapted to create a new tool for assessing the availability and use of antimalarial drugs. The assessment methodology includes a structured questionnaire to be applied in both the public and private sectors to obtain data for conducting a cost-comparison analysis, lead-time analysis, availability of key drugs analysis, and a review of prescribing practices.

The original intention was for the Drug Management for Malaria (DMM) tool to be distributed for external peer review, with a structured feedback mechanism. After revisions from the feedback had been completed, the DMM would be field-tested in Tanzania. On the basis of the field-test concepts, language and presentation of the material would be clarified and data collection methods would be refined. The field test was planned to involve collaboration with local and international counterparts in the design, planning, implementation, and follow-up review and analysis of the assessment results. Field-testing of the DMM is pending the identification of a suitable country to provide testing and evaluation of the manual.

AMR/Tuberculosis

The AMR/Tuberculosis activity used a variety of implementation strategies, which included the following:

- Build upon existing RPM assessment tools in developing the DMTB tool
- Explore the opportunities for use of RPM assessment methodology in the WHO survey of NTPs
- Establish collaborative relations with international organizations dealing with tuberculosis
- Develop a presentation and facilitate roundtable discussion at USAID regional meetings and SOTA trainings

The draft DMTB tool was built around two existing and well-tested RPM tools. One, the *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach,* was developed in 1995 to provide donors and health managers with a comprehensive analysis of a country's pharmaceutical sector. The second tool used, the *Drug Management for Childhood Illness Manual,* was designed to assess the specific drug management concerns of countries considering and implementing IMCI programs.

The DMTB tool discusses key drug management issues for the treatment of TB; indicators for assessing the status of TB drug management, their calculation, and interpretation; and suggestions for follow-up actions.

The WHO developed its own tool for reviewing a national TB program with the focus on diagnosis, treatment, and record-keeping of TB cases. RPM had the chance to conduct a joint survey of an NTP in Ukraine in collaboration with the WHO and CDC. The joint survey documented that the RPM assessment methodology complemented and contributed to the WHO tool by addressing specific TB drug management issues, an important component of DOTS.

Through joint review of the NTP in Ukraine and discussion of the DMTB tool, RPM established collaborative relations with the CDC, IUATLD, KNCV, WHO, and World Bank, thus becoming a leader in drug management expertise in the international arena.

Challenges Facing RPM Infectious Diseases Implementation

Staff turnover had a significant effect on the development of the concept paper describing the DTC role and functions and subsequent development of the DTC training modules. Staffing for the project was also delayed because of difficulties in obtaining work visas for identified staff.

Research proposal development workshops encountered some difficulties because of the relatively low level of experience and training of proposed researchers. The instructors at the workshops were hard pressed to present all of the information necessary because very basic training had to be addressed before proceeding with more advanced concepts of the research-proposal development process.

The development of the research paper on the effects of managed care and provider reimbursement mechanisms on antimicrobial drug use was hindered by the lack of research in developing countries that adequately addresses the subject. As a result, RPM developed a framework to describe how managed-care tools can affect prescribing and dispensing of antimicrobials. This framework was used to identify relevant literature in developed countries to help inform policy on how managed-care tools can affect prescribing and dispensing of antimicrobials in developing countries.

The major challenge facing implementation of the DMM was the weak interest on the part of CDC in using the DMM as part of its work in Tanzania. At least in part, this attitude arose from

the perception of the CT investigators at CDC that they had not been fully involved in the discussions leading to the decision to develop the DMM and field-test it as part of their CT work in Tanzania.

The RPM project faced some significant challenges while implementing the AMR/TB program. These included

- Currently, no effective mechanisms exist to coordinate development of TB tools by different agencies and organizations.
- Joint review of tuberculosis in Ukraine had a very limited time frame that did not allow all indicators selected for DMTB to be field-tested.
- The unstable political situation in Ethiopia, which was selected by USAID as a test site, did not allow RPM to conduct the field test.

Chronological Activity Timelines of Individual Projects

Table 1. Indicator Manual to Study Antimicrobial Use in Hospitals

Date	Activity
July 1998	Literature review and research for manual
July 1999–June 2000	Draft of indicator-based manual developed
October 2000	Field-test indicator manual in Nepal and Ghana

Table 2. Drug and Therapeutics Committee

Date	Activity
July 1998	Literature review and research for DTC
August 1999	Draft discussion paper describing the role of the DTC in improving antimicrobial use in hospitals
February–June 2000	Develop training modules
June 2000	Field-test training modules in Thailand

Table 3. Research Proposal Development

Date	Activity
January 1998	Pre-proposals received and selections made for first workshop
April 1998	Asia Regional Workshop on Drug Use Intervention Research Proposal Development
September 1998	Africa Regional Workshop on Drug Use Intervention Research Proposal Development
April 2000	Latin American Regional Workshop on Proposal Development for Drug Use Intervention Studies
April 2000	Review proposals that evaluate behavioral and policy interventions to improve antimicrobial use at the household and community levels
October 2000	Review proposals that evaluate behavioral and policy interventions to improve antimicrobial use at the household and community levels
November 2000	Workshop on Interventions Research Proposal Development

Table 4. Other Antimicrobial Resistance Activities

Date	Activity
February 1999	WHO AMR Global Strategy Meeting
December 5–8, 1999	Attend fourth Annual Summit on International Managed Care Trends
May 2000	Review paper on interventions and strategies to improve the use of antimicrobials in developing countries
February 2000	WHO AMR Global Strategy Meeting
February–June 2000	Review effects of provider reimbursement mechanisms and managed care on antimicrobial drug use
September 2000	WHO AMR Global Strategy Meeting

Table 5. AMR/Malaria

Date	Activity
October 1999–June 2000	Draft *DMM Manual* and *Data Collector's Guide* developed *[See Africa Bureau report for additional malaria work.]*

Table 6. AMR/TB

Date	Activity
October 1999–May 2000	Develop draft *DMTB Manual* and *Data Collector's Guide*
October 1999	Participate in USAID ANE and Europe & Eurasia (E&E) Population, Health and Nutrition (PHN) Regional Meeting and SOTA Training
December 1999	Joint review of NTP in Ukraine by USAID/CDC/WHO
June 2000	Draft *DMTB Manual* and *Data Collector's Guide* developed

Program Accomplishments

All technical areas that RPM worked in experienced significant accomplishments. These accomplishments should have long-term positive results because several tools, a training course, and research proposals have been developed.

Indicator-Based Methodology to Assess Antimicrobial Use in Hospitals

The manual *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators* was completed and tested. This manual was produced to complement the WHO/INRUD publication that provides indicators and methodology to investigate drug use in outpatient health facilities. The RPM manual provides indicators and procedures to assess the use of antimicrobials in a hospital setting. This manual will therefore provide valuable information for hospital-based drug management programs to evaluate antimicrobials in an area where there is a lack of indicator-based methodology. Field-testing of this document was planned in Ghana and Nepal, with an expected completion date of mid-November 2000.

The manual will provide local hospitals and countries with a method to measure antimicrobial use in their facilities. This measurement is accomplished by one or more of the following methods:

- Describing antimicrobial prescribing practices
- Comparing performance between hospitals or prescribers
- Monitoring performance and supervision
- Assessing changes resulting from interventions

Field-testing of this manual was accomplished in three hospitals in Nepal and in three additional hospitals in Ghana. The field tests were structured so that actual use of the manual in developing-country hospitals could be evaluated. Results of the field tests provide the following information:

- Data on the indicators described in the manual can be collected over a five-day period by a team of two individuals working full time.

- The majority of the indicators could be used and accurate results were obtained.

- Definitions of some indicators should be evaluated and redefined to more accurately describe the indicator.

- Variables in some of the indicators need to be defined more clearly before start of data collection, for example, determination of key antimicrobials.

- Additional field tests are recommended to finalize this manual.

The field tests also identified the need to assess the data record system for suitability before including the hospital in an indicator study. Alternatively, other methods of data collection should be identified for hospitals with less structured records systems.

The benefits of this manual are difficult to assess at this time, but there is every reason to believe it will have a significant impact on antimicrobial use in hospitals. Improved control on the use of antimicrobials and ultimately improved patient care and a decrease in antimicrobial resistance will result.

Drug and Therapeutics Committee Training Materials

A discussion paper was developed on the effects of DTCs on antimicrobial and drug use in hospitals. This draft document presented extensive research that found few studies in the literature address the effectiveness or impact that a DTC has in improving the quality of medical care. Most studies described the structure and functions of the DTC and the policies they have used to control antimicrobial use. Some studies have documented that DTC activities resulted in cost savings, more appropriate therapeutic antimicrobial use, decreased inappropriate surgical prophylaxis, decreased use of nonformulary drugs, and decreased incidence of resistant bacteria in hospitals. Further study is necessary to determine what factors promote the effectiveness of the DTC and to determine the most appropriate indicators to measure the impact of DTC policies and procedures and their effect on patient outcomes.

A comprehensive training course was developed for DTCs during February–June 2000. This draft training program included a detailed participant's manual and slide presentation for all sessions discussed at the training course.

The training program was subsequently field-tested in Bangkok, Thailand, with more than 30 individuals from 12 different countries attending. Participants were provided with the participant's guide and the course was presented in a lecture/discussion and group activity format. A field study was developed during the course, based on participant's level of knowledge, background, and interest, to utilize and test skills learned during the course. Results of the field test showed a high level of interest from participants in the content because sessions brought out extensive discussion and comments. Table 7 summarizes the overall session evaluation.

Table 7. DTC Training Program Evaluation

Session	Median	Average	Range
Overview	7	6.7	3–8
Formulary Management	7	7.2	3–9
Assessing Drug Efficacy	8	7.4	5–9
Assessing and Managing Safety	7	6.7	4–8
Assessing Cost	8	7.5	6–9
Identifying Drug Use Problems	7	7.4	4–9
Identifying Drug Use Problems, Qualitative	7	7.2	5–9
Strategies to Improve Drug Use, Overview	7	7.0	4–9
Strategies to Improve Drug Use, Drug Utilization Evaluation	7	7.2	5–9
Strategies to Improve Drug Use, Standard Treatment Guidelines	7	7.2	5–9
Quality Assurance	8	7.5	4–9
Managing the DTC	8	7.7	4–9

Scale: Outstanding 7–9
Satisfactory 4–6
Poor 1–3

This training program was well received at the field test and, indeed, several participants expressed an interest in providing a similar course in their home country, including Nepal, the Philippines, and Thailand.

There was also a significant amount of interest by WHO. A WHO representative was in attendance and this person expressed an interest in adapting WHO's materials to RPM's to provide a common theme between the two documents. The WHO publication has since been changed significantly to correspond to the materials developed by RPM. This important WHO document will list RPM as a collaborator.

The DTC training material has already been shown to provide developing countries the necessary material to increase capacity within their committee and provide a framework for that committee to be functional and effective. The results will be improved selection of drugs, improved efficiency in the health care system, and improved quality of care to the patient and consequently a decrease in the incidence of AMR.

Research Development Workshops

Three proposal development workshops have been presented as of October 2000. A total of 15 research studies have been developed and implemented in 10 countries in Africa and Asia, and 10 more are in development in Latin America. The technical assistance provided in the development workshops for these research proposals was invaluable and necessary in order to get these projects started. Specific advice and consultation was provided in the following areas of proposal development:

- Stating the research problem
- Reviewing literature for previous experience
- Defining specific objectives or hypothesis

- Developing appropriate
  - Study design
  - Data collection methods and instruments
  - Study measures
- Describing data analysis plan
- Identifying resources and time required
- Preparing for ethical review and institutional clearance
- Creating abstract or summary

Researchers were capacitated during the proposal development workshops and this activity was instrumental in the development of research methodologies and the ultimate completion of the proposals. As a result of the workshops, projects were funded by ARCH, RPM, and WHO. The portfolio of Phase I projects included

- Twenty-one studies initially in the portfolio, of which 15 studies currently are in progress
- Eleven studies that received funding from ARCH
- One project funded by RPM
- Four studies that received INRUD funding
- Three studies that received WHO support; WHO will potentially fund three more studies, although two teams are likely to drop out
- One study from Nigeria, potentially to be funded through the Africa Bureau

See Annex 2 for a list of Phase I researchers, proposals, and funding status.

Phase II proposal development continues and 10 research projects are expected to be developed and implemented that will look at methods to improve antimicrobial use at the household and community level. These research projects are anticipated to provide valuable information for the development of tools, methods, and strategies for effective interventions to improve care seeking and use of medicines. See Annex 3 for a list of researchers that have been selected for the research development workshop in Bangkok, Thailand.

Paper on Effects of Provider Reimbursement Mechanisms and Managed Care on Antimicrobial Drug Use

The effects of provider reimbursement mechanisms and managed care on antimicrobial use were researched and analyzed, and a paper describing the results was published. This research provided verifiable information concerning provider reimbursement schemes and managed care and their impact on prescriber behavior. Key findings from 37 studies that met inclusion criteria revealed the following:

- There was a deficit of studies that addressed the issue of incentives and managed care on antimicrobial prescribing, dispensing, and use. Most studies in this area looked at decreasing cost and not at appropriate use of antimicrobials.

- Findings showed that evidence exists that incentives, both financial and managerial, can modify antimicrobial prescribing and dispensing behavior. There was evidence that these incentives decreased prescribing levels, increased prescribing and dispensing of generics, and increased therapeutic substitution with less costly equivalents.

- Although no conclusive evidence was found that documented the impact of managed care or provider payment mechanisms on appropriate antimicrobial prescribing and dispensing, evidence from related literature and ideas from the theoretical framework presented indicate that the potential for improved use does exist. Providers and dispensers respond to both financial and nonfinancial incentives, such as guidelines, drug utilization review, formularies, disease management, and performance-based reimbursement. Many of these tools can also exist in non–managed care environments.

- On the basis of this evidence, it is likely that increased *appropriate* prescribing and dispensing could result from appropriately designed managerial and incentive structures.

The review concluded that current health care reform in many developing countries provides an opportunity to promote appropriate antimicrobial prescribing and dispensing policies. It also concluded that incentive structures need to be developed that promote more-appropriate behavior in health care providers. In the context of ongoing health care reform in many developing countries, there is significant opportunity to promote and institute appropriate antimicrobial prescribing and dispensing policies.

AMR/Malaria

A comprehensive draft Drug Management for Malaria *Manual* and *Data Collector's Guide* were developed. They were made available to partners involved in the CT study in Tanzania and to the WHO/Training in Tropical Diseases Task Force on Drug Resistance and Policy. The DMM manual focuses on the assessment of important aspects of malaria drug management based on indicators. The DMM tool has been designed so that it can be integrated into host countries' procedures or used to conduct stand-alone studies.

AMR/TB

Development of Draft DMTB Manual *and* Data Collector's Guide

In 1998, WHO published its *Guidelines for Conducting a Review of a National Tuberculosis Programme.*[2] The *Guidelines* summarized five years of experience by WHO and national governments in conducting the NTP reviews and provided tools that could be used to evaluate the success of an NTP. The tools consist of data collection forms and questionnaires that cover all aspects of diagnosing and treating tuberculosis. The tools allow reviewers to produce a comprehensive report on the TB situation in a country, including epidemiology, demographics, reporting, treatment methods, and outcomes.

The *Drug Management for Tuberculosis Assessment Manual* focuses on the assessment of important aspects of TB drug management based on indicators. The DMTB tool has been designed so that it can be integrated into the WHO review of the NTP process in host countries or used to conduct stand-alone studies. In December 1999, Management Sciences for Health (MSH), through its USAID-funded RPM project, participated in the WHO/USAID/CDC NTP survey in Ukraine, where some of the indicators discussed in the *DMTB Manual* were successfully used.

It is important to mention that the challenge of ensuring an efficient and cost-effective drug supply system is constantly evolving. Changes in country policies, budgets, and economic priorities can have an impact on pharmaceutical systems. USAID, WHO, and others interested in drug supply systems will continue to work toward updating and improving the tools and strategies presented in this manual.

Objectives of the DMTB Manual

The purpose of the *DMTB Manual* is to assist the user in assessing those aspects of the drug management system that are critical to ensure the availability and proper use of TB drugs essential to NTPs. This manual is not intended for users who need or wish to conduct a complete assessment of the entire pharmaceutical system. Such an assessment is beyond the scope of the manual. RPM has developed the *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* manual to serve as a guide for conducting a complete assessment. The *DMTB Manual*, while based on the rapid assessment model, is tailored to the needs of an NTP and complements the more general manual. A comprehensive *DMTB Data Collector's Guide* has been developed to accompany the *Manual.*

[2] Jacob Kumaresan, Fabio Luelmo, and Ian Smith, *Guidelines for Conducting a Review of a National Tuberculosis Programme* (Geneva: WHO, 1998), WHO/TB/98.240.

Assessment Methodology

The *DMTB Manual* is designed to take users step by step through the NTP drug management process, beginning with introducing the concept of indicator-based assessments, then conducting studies that identify specific strengths and weaknesses of the drug supply system for NTP, and ending with recommendations for ongoing performance monitoring and possible strategies for improvement. The assessment is built around two complementary studies: a drug availability study and a drug use study. The two studies assess various aspects of drug management in the public and private sectors.

Outcomes

The draft Drug Management for Tuberculosis tool and *Data Collector's Guide* have been developed, and are ready for field-testing by RPM or country TB programs. Several copies were sent to India, Indonesia, and Nigeria on the request of NTPs. The list of recipients of the draft tool is provided in Annex 3.

Joint Review of Tuberculosis in Ukraine

Since 1990, the number of TB cases in Ukraine has dramatically increased. By 1998, the number of cases had grown by 73 percent, reaching emergency proportions and growing steadily from 32 cases per 100,000 persons in 1990 to 55.2 in 1998. During 1997 alone, the growth rate was 12.4 percent. In 1998, 28,000 new cases were registered, and 7,850 people died of TB. According to the Ukrainian Ministry of Health (MOH), tuberculosis is currently the most widespread infectious disease in the country and is the number one cause of death.

To address the growing TB problem, in August 1999 the Ukrainian government adopted its National Tuberculosis Program (NTP) and requested assistance in implementing it from the USAID, WHO, the World Bank, and other international organizations and donors. As a first step, during December 6–15, 1999, a team of USAID and WHO experts conducted a review of the TB situation in Ukraine. The review included field visits to the MOH-identified TB facilities and health administrations in Donetsk and Chernigov oblasts and Kiev city, and interviews with senior officials in national government departments and international agencies in Kiev.

The survey team used the WHO's standardized data collection tool[3] to assess the structure, process, and outcome of TB control services in the institutions visited. Because failures in TB control may be attributed to a combination of factors, including the inability of the health system to ensure an uninterrupted supply of antituberculosis drugs, it was decided that a separate tool would be used to assess the gaps and needs of the Ukrainian TB drug management system. Subsequently, RPM developed and used a set of indicators and a structured questionnaire for the TB drug management assessment. RPM produced a report that summarized findings of the TB drug management assessment in Ukraine.

[3] *Ibid.*

Outcomes and accomplishments of the joint review are as follows:

- RPM contributed a section and recommendations on TB drug management to the WHO Joint Review of Tuberculosis in Ukraine and developed a stand-alone comprehensive report. On the basis of the information presented in the WHO and RPM reports, USAID/Kiev developed a package of interventions for the Donetsk pilot site. The documents were also used in negotiations between the World Bank and the Ukrainian government regarding a loan to address the TB crisis in the country.

- By participating in the review, RPM established working relations in TB issues with the WHO and the World Bank. In July 2000, RPM was invited to participate in a follow-up mission to Ukraine sponsored by the World Bank.

- Following recommendations of the RPM assessment, Ukraine developed a draft national policy on TB drug management to support the NTP; that policy included TB drug registration, selection, quantification, and usage restrictions. Ukraine has also drafted policies that provide for strict control of TB drug distribution and restrictions on TB drug sales in municipal pharmacies. These draft documents were produced in July 2000.

Recommendations from RPM included the development of a national financial mechanism that would ensure cost-effective centralized NTP procurement and accounting. Recently, central funds were allocated for a tender for the year 2000. RPM also recommended that a centralized TB drug procurement system with the capacity to conduct competitive tenders be established. This mechanism has now been established for first-line drugs.

USAID Regional Meeting and SOTA Training

The ANE and E&E PHN Regional Meeting and SOTA Training Population, Health and Nutrition Partnerships into the Next Millennium was held on October 10–15, 1999.

RPM received an invitation to the ANE/ENI SOTA to facilitate the session on international TB drug procurement. The session focused on concerns and issues related to host-country drug procurement problems and issues, and measures to address these problems. The presentation was based on RPM's experience in NIS: two surveys in Russia—availability and procurement methods, and diagnosis and treatment in Russian oblasts—and TB drug procurement in Kazakhstan.

In disease control and management programs such as DOTS, a reliable, high-quality drug supply is absolutely essential. Procurement practices by host governments affect the availability and quality of the required drugs, and securing these drugs at a competitive price can dramatically affect the ability to provide care and treatment. It is thus crucial that USAID and other international donors are aware of the situation in host countries in order to plan their TB strategy.

Outcomes of the regional meetings and training resulted in RPM's participation in discussion on TB drug supply in NIS, which ultimately helped missions in Russia and Ukraine. As a result of this meeting, Kazakhstan developed its country TB strategy.

Activities Not Completed

Technical Review of ARCH Paper on the Determinants of Interventions to Improve Antimicrobial Use by Health Providers and Community Members

RPM developed a work plan to provide technical review of a research paper developed by ARCH. This paper was to review determinants of and interventions to improve antimicrobial use by health providers and community members. The paper is being developed by ARCH and is not completed.

AMR/Malaria

Following discussions with researchers involved in the Tanzanian CT trial at a CT planning meeting in Tanzania in January 2000, it was agreed that conducting a field test as part of this trial would not be possible. The possibility of field-testing DMM as part of the work of either the Tanzanian Essential Health Implementation Project (TEHIP) or the South East African Combination Antimicrobial Therapy (SEACAT) project was then explored. TEHIP was unable to find the time and resources needed to participate in a field test, and the postponement of SEACAT's program of work until late 2001 meant that it could not follow up its interest.

An evaluation of the usefulness of adapting the Cost-Estimate Strategy (CES) tool for inclusion in the DMM led to the conclusion that it would add little real value to the DMM. Because the CES was designed for evaluating drug and medical supply costs of relatively complex health activities, such as those found in reproductive health, the investment of time and money that would be involved in remodeling the CES for a single disease using a small number of drugs, such as malaria, was difficult to justify.

Furthermore, the CES was of only limited value for the CT trials since the economic evaluations planned were qualitatively more comprehensive than the CES could do. The CT economic studies were designed to cover a much broader range of costs than simply those of drugs and supplies.

For these reasons, and following discussions with CDC, it was decided not to include a remodeled CES in the DMM.

AMR/TB

The DMTB tool and *Data Collector's Guide* were not field-tested. USAID/Washington recommended Ethiopia as a field-test site. The mission in Addis Ababa supported the selection, and MOH expressed interest in testing the tool. It was planned to conduct the field test in collaboration with the KNCV and the All Africa Leprosy/Tuberculosis and Rehabilitation Training Centre. However, because of political instability, the Mission recommended postponing the field test. It is expected that the test will be conducted within the RPM Plus Program cooperative agreement. As with the DMM manual, the CES tool was discontinued because of the poor prospects that this tool could be implemented successfully in developing countries.

Likely Needs at End of Project

AMR is a worldwide problem threatening the lives of millions of people and the effectiveness of health care systems. The inappropriate use of antimicrobials in humans and in agriculture and farm animals continues to provide a medium for the rapid development of AMR. AMR will continue to be a significant problem even with the best policies, procedures, and AMR management programs. It is very important for RPM to continue its leadership role in addressing these problems by collaborating with international health care organizations to develop strategies to address these problems.

Many of the activities described in this report will need to continue for the foreseeable future. The full development of the indicator manual for antimicrobial drug use in hospitals will need refinement and further testing to validate its effectiveness. After being fully tested and implemented, the manual should be rolled out to regional and local experts who will apply its indicators.

It is likely that the DTC training materials will need expansion and revisions, including the development of a comprehensive trainer's manual. These training materials will then be useful for presentation at regional and local workshops to train physicians and pharmacists in the technical functions of an *effective* DTC. Ideally, this training course would be provided to a regional or local professional group, which could then train other committees at the local level. DTCs that have been properly implemented and trained will have the capacity to select appropriate drugs, improve procurement and drug distribution, promote rational drug use, and control the use and abuse of antimicrobials. The following has been proposed to strengthen the DTC training materials for future roll out in developing countries:

- Expand session on quality assurance of procured drugs
- Add session on DTC management
- Expand section on drug information
- Add session on planning, monitoring, and evaluation of the DTC
- Expand graphics, tables, and illustrations in session materials and slides
- Expand field study to include more analysis and discussion of results during the course

- Develop a comprehensive trainer's guide

Because the WHO has expressed an interest in the DTC training materials, a collaboration with the WHO needs to be established to maintain a common theme between RPM training materials and WHO's DTC manual.

MSH needs to continue to provide technical assistance in collaboration with ARCH, WHO, WHO/EDM, and others in developing operational intervention research to address the many problems associated with AMR. Phase II community antimicrobial intervention research has only just begun. Because of the nature of drug use research, it will be necessary to continue these projects for several years. Phase I results can be expected next year, and Phase II results will start to become available in two years. Results of these research programs should provide strategies and interventions that can be applied to health care settings in many developing countries.

Findings of the research proposals need to be disseminated on a wide scale in order to obtain the most impact from them. There are tentative plans with the partners to continue technical assistance in research development and to sponsor at least two data analysis workshops during fiscal year 2001–2002 to prepare policy briefs and scientific articles to report the researchers' findings. Phase I research projects are nearing completion, and Phase II will be starting in the near future. During Phase III, it is anticipated that RPM would support studies to evaluate the impacts of specific national, district, and local policies that affect drug use, including strategies for scaling up of successful interventions. The impact of the proposal development workshops has been dramatic and this form of training course needs to be continued.

Field-testing of the DMM assessment manual did not take place during the RPM project. On the basis of an eventual field test, minor revisions can be anticipated. In addition, ongoing technical assistance may be required in the country conducting the field test to address identified weaknesses in the malaria drug supply system.

DMTB also needs to be field-tested in various settings and revised on the basis of the field-test experience. Poor availability and improper use of TB drugs remains one of the main obstacles for successful implementation of antituberculosis programs. The DMTB assessment tool will be instrumental in identifying gaps in TB drug management for NTPs, developing interventions, and tracking results. The DMTB tool may be used in conjunction with available WHO tools for assessing a country's eligibility for TB drug procurement through the Green Light Committee of the Global Drug Facility.

Lessons Learned

Successful training materials for DTC have been developed and it is anticipated that these materials will be useful and valuable in many developing countries. Field-test reports are encouraging and support the need to continue development and distribution of this important

tool. Participants at the field test of this activity were very receptive to the content and presentation format and were very interested in seeing future productions of the course.

Research proposal development workshops were found to be a valuable component for the development of a comprehensive research proposal. As a result of these workshops, the following lessons were learned:

- There is a definite need for this type of training in the future. Many worthwhile researchers would not be able to conduct meaningful research without the training provided in the workshops.

- To present information and fully develop proposals, workshops need to be allotted more time because researchers need more time to be trained in basic research fundamentals. The development workshop would probably be more effective when given over a 10-day period.

- Regular follow-up technical assistance would be advisable to augment the training provided in the workshops.

- Researchers need to prepare in advance for workshops, taking into consideration their pre-proposal comments and incorporating them into their current proposal.

Managed care and incentives can make a difference in the delivery of health care. RPM's paper on this subject showed that incentives and managed care can change providers' behavior in prescribing drugs and consequently suitable incentives can motivate more appropriate prescribing. Another important lesson learned is that significant opportunity exists to promote the appropriate antimicrobial prescribing and dispensing policies as health care reform is currently being instituted in many countries. Evidence from this review substantiates the hypothesis that managed care and provider reimbursement mechanisms can modify provider prescribing and dispenser dispensing behavior. Developing-country health sector reform initiatives should include financial and managerial mechanisms to target inappropriate prescribing and dispensing of antimicrobials. This strategy could bring about greater returns to society, both in terms of improved health and a potentially decreased AMR growth rate. Future research needs to focus on what incentives work best to generate appropriate antimicrobial prescribing, dispensing, and use.

In conjunction with the malaria work conducted as part of Africa Bureau activities, the need to make drug management a central concern of malaria researchers and program managers has been underlined. The ability to guarantee that safe and effective antimalarial drugs are available and affordable is largely a function of how well drugs are managed in the broadest sense. In order to plan for the successful introduction of new therapies, the full range of drug management issues must be fully incorporated in all research and planning activities.

Lessons learned from the AMR/TB project included the following:

- Joint country-level review of tuberculosis (WHO/USAID/CDC/RPM) proved to be very effective and comprehensive as each of the organizations' expertise complemented each other.

- A TB drug management country assessment report is necessary for USAID and World Bank to make correct decisions in addressing TB issues through technical assistance or World Bank loan to the government of the host country.

- Comprehensive data on quality of TB drugs, especially of those manufactured in the surveyed country, is very important. This factor may require development of additional indicators and data collection methodology.

- It is important to select a politically stable country to field-test the DMTB tool. It may be preferable to conduct field tests in two or three countries based on a convenience sample rather than in one country using a larger sample size.

- Cooperation with international organizations involved in tuberculosis is crucial.

The final lesson learned from the activities of the RPM AMR project is the importance of a coordinated, persistent, and comprehensive approach to deal with the complexities of infectious diseases and the serious problem of AMR. No single tool or activity will have a significant effect. A combination of strategies coordinated with other health care organizations and governments will provide the foundation for managing these diseases and decreasing the spread of AMR.

Annex 1. List of Documents, Tools, and Trip Reports for RPM AMR Project

Adams, I., and A. Zagorski. *Joint Review of Tuberculosis in Ukraine, TB Drug Management.* Management Sciences for Health, December 5–16, 1999.

Callender, D. The Role of Drug and Therapeutics Committee in Improving Antimicrobial Use in Hospitals. Management Sciences for Health, August 1999.

Clark, Malcolm. *Drug Management for Malaria Assessment Manual.* Management Sciences for Health, June 2000.

Clark, Malcolm. *Drug Management for Malaria: Data Collector's Guide.* Management Sciences for Health, June 2000.

Eichler, R., and A. Regalia. *The Effects of Managed Care and Provider Reimbursement Mechanisms on Antimicrobial Drug Use: Evidence from Industrialized Countries to Inform Policy in Developing Countries.* Management Sciences for Health, June 2000

Green, T. *Drug and Therapeutics Committee Training Course: Participant's Guide.* Management Sciences for Health, June 2000

Green, T. *Drug and Therapeutics Training Course: Field Test Report.* Management Sciences for Health, July 2000.

Kafle, Edmud. *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators* (Nepal Field Test). November 2000.

Lee, L., and M. Miralles. *RPM AMR Mexico Trip Report.* Management Sciences for Health, April 23–May 5, 2000.

Miralles, M., and D. Lee. *RPM AMR Indonesia Trip Report.* Management Sciences for Health, April 18–25 1998.

Miralles, M., and D. Lee. *RPM AMR Uganda Trip Report.* Management Sciences for Health, September 12–25, 1998.

Nelson, D. *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators.* Management Sciences for Health, June 2000.

Ofori-Adjei, David. *How to Investigate Antimicrobials Use in Hospitals: Selected Indicators* (Ghana Field Test). November 2000.

Zagorski, A. *Drug Management for Tuberculosis (DMTB) Assessment Manual.* Management Sciences for Health, June 2000.

Zagorski, A. *Drug Management for Tuberculosis: Data Collector's Guide.* Management Sciences for Health, June 2000.

Annex 2. Joint Initiative on Improving Use of Medicines in Developing Countries

Portfolio of Phase I Projects

The portfolio on drug intervention research is being developed and cofunded by the cosponsors of the ICIUM initiative (ARCH, INRUD, RPM, WHO). Phase I of the Joint Research Initiative has focused on interventions targeting the practices of physicians, paramedics, and other health providers working in primary care, hospital, or retail pharmacy settings. A 1997 call for proposals on these topics by the sponsoring organizations resulted in 88 submissions that were reviewed and prioritized. The top-ranked 21 of the pre-proposals were invited to advance to the next stage of full proposal development, either independently or during one of two proposal development workshops that were held in 1998 in Yogyakarta, Indonesia, and Kampala, Uganda. Since then these research teams have worked with technical staff from the partner organizations to revise and finalize their research protocols.

- Twenty-one studies initially were in the portfolio, and currently 15 studies are in progress.
- Eleven studies have received funding from ARCH.
- One project has been funded by RPM.
- Four studies have received funding from INRUD.
- Three studies have received WHO support; WHO will potentially fund three more studies, although two teams are likely to drop out.
- One study from Nigeria will be funded through in-country Mission funds.
- One study in Tanzania will potentially be funded through Africa Bureau.

We summarize below the topics and status of these proposals by topic area.

A. Improving Pharmaceutical Use in Primary Care Settings

Goal: Improve the use of antibiotics in treating children with diarrhea and acute respiratory infections (ARIs) in public-sector health facilities to include primary health care workers and drug sellers, other types of infections, and private-sector health practitioners.

Significance: Innovative approaches to behavior change include group interactions with drug sellers involving community members and use of local hospital specialists as influential opinion leaders in educational efforts to facilitate change among primary health care physicians.

Results:

1. ***Small group discussion (SGD) among paramedics at health-center level to improve compliance to acute respiratory infection standard treatment guidelines***
   Sri Hidayati, Gadja Mada University, Yogyakarta, Indonesia

   Preliminary results showed a change in the prescribing pattern among health-center paramedics who participated in SGD and self-assessment (SA) intervention groups. Percentage of oral antibiotics prescribed decreased from 63 percent at baseline to 30 percent after SGD and 25 percent after first SA. Percentage of oral antihistamines prescribed decreased from 79 percent at baseline to 33 percent after SGD and 27 percent after first SA. Percentage of oral corticosteroids prescribed decreased from 21 percent at baseline to 7 percent after SGD and 4 percent after first SA. Percentage of oral phenobarbital prescribed decreased from 3 percent at baseline to 0.5 percent after SGD and 0 percent after first SA. Average number of drugs per prescription decreased from 3.95 at baseline to 3.43 after SGD, and 3.4 after first SA. A prescribing survey for 12 health centers in the control group is in progress.

2. ***Test of strategies for implementing standard treatment guidelines (STGs) in improving use of drugs***
   Kumud Kafle, INRUD-Nepal

   Collection of baseline data and development of training materials has been completed and the intervention phase is in progress.

3. ***Improving private physicians' prescribing practices in the diagnosis and treatment of uncomplicated urinary tract infection (UTI) through clinical practice guidelines (CPGs)***
   Mediadora Saniel, Philippines Society for Microbiology and Infectious Diseases

   Findings from this study indicate that full adherence to the recommended antibiotic regimens was low among private physicians, but that compliance markedly improved after both large- and small-group interactive education and group feedback for dissemination of new UTI guidelines. Education led to an increase in adherence to the guidelines as measured by appropriate antibiotic (including dosage regimen and duration) and laboratory prescriptions for acute uncomplicated UTI in ambulatory nonpregnant and pregnant women. Equally interesting were the revealing comments of physicians during focus group discussions regarding factors that influence their prescribing practice and barriers to adherence to the CPGs. Group feedback and interactive sessions were both effective approaches in disseminating the guidelines. Therapeutic Committees and HMOs should adopt such strategies in health facilities.

4. ***Improving rational drug use by the private physicians in Uganda: An educational intervention study***
   Jasper Ogwal-Okeng, Makerere University, Uganda

Collection and analysis of baseline prescription data (for ARIs, nondysenteric diarrhea, and malaria) and interviews of 25 randomly selected physicians using structured questionnaires have been completed. Training workshops were conducted in October and November 1999. Prescription data collection for the follow-up analysis is expected to start in December 2000/January 2001.

B. Improving Antimicrobial Use in Hospitals

Goal: Improving and expanding the role of Drug and Therapeutics Committees (DTCs) across health care facilities from teaching hospitals to district hospitals, public to private to mission institutions, neonatal intensive care units to pediatric outpatient departments, and specialists to general medical officers.

Significance: Improved antimicrobial practices at all levels of the health delivery system with decreased morbidity, costs, and pressure for the development of antimicrobial resistance.

Results:

1. ***Improving community drug use through peer review and implementation of clinical guidelines***
   Dr. Pham Huy Dung, Health Strategy and Policy Institute, Hanoi, Vietnam

   Baseline survey in18 selected districts of knowledge, attitudes, and practices (KAP) of prescribing physicians and collection of medical prescription encounters; evaluation study before intervention, an analysis of physician KAP and their prescription encounters of the intervention and control groups; three workshops in three provinces for peer development of guidelines and evaluation indicators; and nine dissemination seminars in nine intervention district hospitals have been conducted. Results of the KAP survey show that there is not always correlation between awareness of treatment guidelines and willingness to apply them. From the encounter analysis, indicators vary greatly from one district to the other. Therefore, there is a need to match pairs for purposes of comparison. Peer review meetings of the intervention district hospitals and supervision are currently being implemented. The study also included an additional activity of collecting data on encounters in intervention district hospitals during the intervention period.

2. ***Reducing the use of expensive antibiotics for ARI in children using small group, face-to-face intervention (Indonesia)***
   Rustamaji, Gadjah Mada University, Yogyakarta, Indonesia

   Implementation delayed, but fieldwork due to begin in October 2000.

3. ***Improving clinical and economic rationality of prescribing in a teaching hospital***
   Wimon Anansakunwatt, Mahidol University, Bangkok, Thailand

   Baseline data have been collected and intervention is under way.

4. ***The effect on treatment of ARI cases after introducing clinical guidelines and drug and therapeutics committees in mission health facilities in Kenya***
   Lillian Gitau, Mission for Essential Drugs Supply, Nairobi, Kenya

   This study was delayed because of transfer of the principal investigator to another institution. The study team is now in the baseline data collection phase.

5. ***Improving doctors' prescribing habits at a teaching hospital***
   David Ofori-Adjei, University of Ghana Medical School, Accra, Ghana

   Fieldwork began in July 2000.

C. Improving Practices of Retail Drug Sellers

Goal: Intervention research to identify cost-effective ways to improve adherence to prescribing guidelines in the private sector with appropriate advice regarding the use of antimicrobials. This work will investigate how to influence private-sector, over-the-counter purchases of medicines.

Significance: Improved antimicrobial and antimalarial drug prescribing practices within community and households should decrease morbidity, costs, and pressure for the development of antimicrobial resistance.

Results:

1. ***Improving dispensing of drugs for treatment of ARIs in children under five years of age by private pharmacists and dispensers in Kampala district, Uganda, by small group, face-to-face intervention***
   Winifred Tumwikirize, Makerere University, Kampala, Uganda

   Baseline data collection has been completed and intervention is under way.

2. ***Improving appropriate dispensing practices of antimalarials and antimicrobial agents in treating malaria and diarrhea in Dar-es-Salaam, Tanzania***
   Stephen Nsimba, Muhimbili Medical Centre, Dar es Salaam, Tanzania

   Baseline data collection is in progress.

3. ***The effect of an intervention to promote correct use of antimalarial drugs at the household level in Nakonde district, Northern Province, Zambia***
   Frederick Kaona, Tropical Diseases Research Centre, Ndola, Zambia

   Instruments for data collection were prepared, pretested, and printed in readiness for the actual fieldwork for the baseline survey. Baseline data collection was completed in July 2000.

4. ***Effect of an educational activity on the dispensing practices of drugstore clerks***
   Rainier Galang, College of Medicine, University of the Philippines, Manila

   Funding of the study was delayed because of administrative problems. Baseline data collection has just begun (October 2000).

D. Interventions concerning Decentralization Policies

Goal: Investigate the effects of decentralization on district-level pharmaceutical decision-making and assess whether the policy of decentralization has improved access to health services and prescribing and availability of drugs.

Significance: Decentralization has given greater responsibility and authority to local leaders for decision-making and resource allocation. These studies will lead to a proper appraisal of the policy and recommendations to streamline health delivery at local-district levels.

Results:

1. ***The impact of decentralization on access to health services and use and availability of drugs in two district hospitals in Uganda***
   Willy Anokbonggo, Department of Pharmacology and Therapeutics, Makerere University

   The findings in the two districts of Apac and Lira seem to indicate that decentralization policy may vary from district to district depending on varied factors, most importantly political tolerance and appreciation of the role of all stakeholders in the implementation process by local politicians, availability and efficient utilization of resources, presence of reasonable infrastructures prior to decentralization, appropriate sensitization of the implementers, and the goodwill and active involvement of the local community. Workshops and seminars have been conducted to sensitize personnel on their "new roles" and implementation requirements in Lira. However, there is no indication that Apac has conducted any such workshops. One major area of difference between the two districts is that in Lira drugs are paid for in advance on a quarterly basis at the national medical stores (NMS), whereas Apac owes the NMS large sums and, therefore, cannot get drugs from the NMS on credit. The most serious situation in both districts is lack of job security. Funds have not been decentralized fully to cover the decentralized responsibilities. This problem was felt very strongly in both districts. A detailed report on the qualitative survey is on file. The quantitative data collection is near completion. A workshop for the two district leaders and their teams is planned for early December 2000.

2. ***The effect of an educational activity on the drug use purchasing practices of village heads***
Isidro Sia, College of Medicine, University of the Philippines, Manila

Baseline data collection and a formative qualitative study have been completed, along with assignment of municipalities to intervention and control groups. Intervention workshops were completed in August 2000.

Annex 3. List of Principal Researchers Anticipated for Phase II Research Development Workshop, Bangkok, Thailand

Dr. T.A. Okeke
Senior Lecturer
Department of Community Medicine
College of Medicine, University of Nigeria
Enugu Campus, Enugu, Nigeria

Prof. David Ofori-Adjei
Noguchi Memorial Institute of Medical Research
University of Ghana
Accra, Ghana

Dr. Sangeeta Sharma
Assistant Professor
Department of Neuropsychopharmacology
Institute of Human Behavior and Allied Sciences
Delhi, India

Natalia Cebotarenco
Chairperson, Association DRUGS
90 Moscow Avenue, 13/3
Chisinau, 2068 Moldova

Shiba Karkee
Drug Schemes Coordinator
The Britain Nepal Trust
Biratnager, Nepal

Christina Torres
Associate Dean of Academic Affairs
College of Arts and Sciences
University of the Philippines

Liz Dartnall
Senior Program Development Manager
African Medical and Research Foundation
Pretoria, South Africa

Prof. Chitr Sitthi-amorn
Thai Network on Rational Drug Use
Thailand

Dr. Xavier Nsabagasani
Makerere Institute of Social Research
P.O. Box 16022
Kampala, Uganda

Prof. Pham Huy Dung
Center for Social Sciences in Health
Hanoi Medical Faculty
138 Giang Vo Street
Hanoi, Vietnam

Information Dissemination

Executive Summary

One of the Rational Pharmaceutical Management (RPM) project's mandates was to disseminate information gained from the project's work in the field of drug management. From the beginning of the project, RPM documented its experience in reports, presentations, and the RPM Project Update in the *INRUD News.* Over time, RPM developed flyers to provide targeted, in-depth information on selected subjects. With the emergence of the Web as a major technology, RPM also posted information on the Internet for worldwide access and dissemination. Documentation on the project's accomplishments has been disseminated through mail, E-mail, courses, and handouts. During the project, RPM continuously disseminated project information to interested parties by responding to requests for information and producing materials to distribute at various forums.

Acronyms

BASICS	Basic Support for Institutionalizing Child Survival (project)
CES	Cost-Estimate Strategy
DMP	Drug Management Program
MDS	Managing Drug Supply
MSH	Management Sciences for Health
MTP	monitoring-training-planning
RPM	Rational Pharmaceutical Management
USAID	U.S. Agency for International Development
WHO	World Health Organization

88

Program Overview

RPM produced a wide variety of pertinent manuals and publications, many of which were tied to specific dissemination activities. In addition, RPM staff consistently made presentations at major conferences each year the project was active. RPM staff also played key roles in the development, publication, and distribution of the fully revised second edition of the *Managing Drug Supply* (MDS) textbook written by the Drug Management Program (DMP) in collaboration with the World Health Organization (WHO). RPM provided its projects with training materials using the MDS three-volume series, as well as responding to requests from other organizations such as WHO. Other activities indicative of RPM's efforts in information dissemination include

- *The Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*, a manual detailing the process of conducting indicator-based assessments of the pharmaceutical sector. The indicators in this manual were harmonized with those developed under the Latin America/Caribbean Health and Nutrition Sustainability Project. The manual was translated into Spanish.

- The development of a manual to teach pharmacists and physicians how to establish a formulary in their institution. The manual was also translated into Spanish for future use in Latin America. RPM also developed and produced a drug utilization review manual, *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.*

- The establishment of checklists and procedures for writing, formatting, and producing reports as effective quality-control measures. These procedures were finalized and documented in the *DMP/RPM Standard Operating Procedures* manual.

- The placement of RPM materials in the offices of the Centers for Disease Control and Prevention in Atlanta, Georgia; University Research Corporation in Bethesda, Maryland; the BASICS project in Arlington, Virginia; the Ministry of Health in Quito, Ecuador; and the Euro Health Group in Denmark, increasing the scope and reach of the project.

- The launching and support of new information activities in RPM countries such as

  - Supporting the publication of drug information bulletins that became a source of unbiased drug information and thus a viable communications activity and a future resource in Nepal and Mozambique

  - Collaborating with BASICS to disseminate information about integrated management of childhood illness health problems in Ecuador

Overall Strategy

The focus of the RPM Information Dissemination program was the documentation of the project's work through reports, flyers, updates, and articulated lessons learned. This information was disseminated through several media, including print, E-mail, and the Web. RPM's goal was to reach the greatest number of people with the lowest dissemination cost, making effective and increased use of the Internet essential.

Information Dissemination Achievements

The active involvement of RPM in information activities led to the use of multiple dissemination mediums. Key achievements included:

- Production of a series of one-page flyers on RPM project activities and accomplishments

  Flyers were produced to provide in-depth information on selected activities, such as treatment schedules conducted in Nepal, the monitoring-training-planning (MTP) methodology, and decentralization in drug management. RPM also produced flyers about the drug management cycle in specific concentrations such as the selection, procurement, distribution, use, management support, and policy framework processes. Subsequently, flyers were distributed by specific topic interest areas. These served as useful educational pieces for USAID missions and other activities in the field of drug management.

- The updating and expansion of the RPM content on the Management Sciences for Health (MSH) Web site

  With the objective of reaching a large group of people at the lowest cost, RPM updated and expanded its content on the MSH Web site. The content posted on the site included both information about the project's accomplishments and copies of selected tools for downloading and use. This work was done in collaboration with the MSH Webmaster and continued for the duration of the project. The RPM section of the MSH Web Page was regularly updated and informational sections on several tools for the ERC (Employee Relations Committee) Web Site were produced.

- The writing of required Quarterly Reports

  In fulfillment of RPM's cooperative agreements requirements, project staff wrote and submitted Quarterly Reports used by USAID to remain abreast of project activities.

- Production of RPM Updates for dissemination in the *INRUD News* newsletter

RPM Updates were produced for dissemination in the *INRUD News* newsletter. The newsletter was sent to more than 3,000 people worldwide and was used to provide information on a wider scale about the RPM project. The Updates included the most recent writing developments produced by RPM such as the MTP methodology, and the Cost-Estimate Strategy (CES). Copies were distributed to the World Bank, the World Health Organization, and the Essential Drugs Program.

Cost Sharing

The following publications and information-sharing activities were produced within the DMP/Cost Sharing:

- E-mail access through the Internet in 1994 and a presence on the World Wide Web in 1995 offered an excellent medium to respond to information requests.

- Three editions (1992–93, 1993–94, and 1995) of the *International Drug Price Indicator Guide* were produced. This manual offered pharmaceutical prices from more than 10 international suppliers for comparison and study. The *Guide* is routinely sent to almost 300 individuals and organizations worldwide, including institutions such as the World Bank, the World Health Organization, and the Essential Drugs Program.

- The *Manual for the Development and Maintenance of Drug Formularies*, which had been designed for Russia, was expanded for worldwide application. The manual was again made available in both French and Spanish.

- Staff members made presentations at the American Public Health Association; the Drug Information Association; the National Council on International Health; the National Medicinal Drugs Conference in Australia; the Man and Drugs Congress in Moscow, Russia; and at the World Health Organization.

- With the DMP, created a special 1997 edition of the *International Drug Price Indicator Guide* for WHO-AFRO, including prices from 16 African countries.

Outcomes

RPM was able to distribute project and drug management information to a wide audience using multiple media. The materials produced contributed to an ongoing global understanding of the complex field of drug management among counterparts, collaborators, USAID, donors, and others.

At the close of the project, RPM took steps to disseminate information on successfully completed activities. Project materials were archived for easy future access and made accessible on the Web to expand the availability of information beyond the life of the project. Increased funds and time were used to develop project and educational materials and to expand dissemination efforts. Documents and software programs produced under RPM were circulated, and INVEC-2 installations were supported beyond the scope of project.

Needs at End of Project

Project staff recognized the need at the end of the RPM project to still be able to disseminate information on the project's work. As noted above, materials have been archived properly for easy future access. Including more project information and products on the Web will help ensure that dissemination can continue at little to no cost. There remains a need for an integrated suite of drug management software programs to be used together or separately for all aspects of drug management. RPM developed stand-alone programs that could lay the foundation for this work. Following are the projected specific needs at the end of project:

1. Complete and disseminate RPM Lessons Learned document to USAID
2. Write and produce a series of eight one-page flyers on RPM project activities and accomplishments
3. Update and expand the RPM content on the MSH Web site
4. Produce RPM Updates to be disseminated with the *INRUD News* newsletter
5. Disseminate project information
6. Write final report

Reproductive Health

Acknowledgments

Ms. Susan Bacheller, Pharmaceutical Management Advisor, USAID/G/PHN/HN/HPSR
Ms. Jeanne McDermott, MotherCare Project, John Snow Inc.
Ms. Tomoko Fujisaki, Rational Pharmaceutical Management (RPM) Project
Ms. Nancy Blum, United States Pharmacoepia
Ms. Francoise Saverot, United States Pharmacoepia
Ms. Maria Pia Sanchez, Management Sciences for Health (MSH)
Dr. Dennis Ross-Degnan, Harvard Medical School
Mr. Randy Wilson, MSH
Ms. Valerie DePass, RPM Project
Dr. Achola Ominde, Division of Primary Health Care (DPHC), Ministry of Health (MOH), Kenya
Mrs. Margaret Mbugua, DPHC, MOH, Kenya
Mrs. Anne Njeru, DPHC, MOH, Kenya
Dr. Michael Thuo, University of Nairobi, Kenya

Dr. Getambu, Chief Administrator, Coast Provincial General Hospital (CPGH), Kenya
Dr. Aruna, CPGH, Kenya
Dr. J Othigo, CPGH, Kenya
Mr. Ian Sliney, COP, APHIA Financing and Sustainability Project, Kenya
Ms. Shirley Ko, MSH

Ms. Jane-Meya Nyirenda, Central Board of Health, Zambia
Ms. Peggy Fulilwa, Central Board of Health, Zambia
Mr. Oliver Hazemba, Consultant to RPM, Zambia

Acronyms

APHA	American Public Health Association
APHIA	AIDS, Population and Health Integrated Assistance
CES	Cost-Estimate Strategy
CPGH	Coast Provincial General Hospital
DPHC	Division of Primary Health Care
JSI	John Snow Inc.
MBCT	Mother Baby Package Costing Tool
MNH	Maternal and Neonatal Health (Project)
MOH	Ministry of Health
MSH	Management Sciences for Health
REDSO	Regional Economic Development Support Office
RH	reproductive health
RPM	Rational Pharmaceutical Management (Project)
UNFPA	United Nations Population Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

Program Overview

Donor agencies and governments implementing reproductive heath (RH) programs often lack the information necessary for assessing the cost and quantity needed of RH drugs and supplies. Without this information it can be difficult to adequately plan and maintain RH programs; for without realistic needs and costs estimations, a program's ability to improve supply systems, budgeting, and policy making are hindered.

To fill this gap, the Rational Pharmaceutical Management (RPM) project developed the Cost-Estimate Strategy (CES), a set of planning, budgeting, and management tools for estimating the cost of supplying RH commodities. The CES package guides decision making for improving the availability and management of CES commodities and includes

- CES Model: Spreadsheet-based costing tool
- CES Survey: Standard survey forms for collecting and organizing data
- CES User's Guide: Manual for designing and implementing the CES

In 1998 and 1999 RPM field-tested the CES Model and Survey tools in six districts in Kenya. Findings from the field test were presented at a CES dissemination workshop in Nairobi in February 1999. The findings helped RPM develop the practical and comprehensive CES User's Guide.

In addition to the Kenya field test, the CES has been applied in two additional health care settings. In one application, a major provincial hospital in Kenya used the CES to plan for the expansion of reproductive health services at an upgraded maternity ward. RPM provided technical assistance to the hospital, funded by the USAID-Kenya AIDS, Population and Health Integrated Assistance (APHIA) Financing and Sustainability Project. In Zambia, RPM applied the CES to assess RH commodity needs of 11 USAID-supported districts implementing the national integrated reproductive health plan.

Following the development of the CES, the program aimed to disseminate the tool as widely as possible using multiple channels, such as forums, presentations, information flyers, electronic posting, and so forth.

Objectives

Objectives included the development of an approach for costing reproductive health commodities used in reducing maternal mortality in order to quantify the pharmaceutical cost implications of RH services in those countries that intend to implement the recommendations of the International Conference on Population and Development that was held in Cairo in 1994.

More specifically, this objective entails developing a methodology to estimate the cost of supplying the commodities (drugs, medical supplies, and medical equipment) required to meet the needs for a range of RH services and conditions.

95A

This work directly supports USAID's second strategic objective in Population and Health, which is "increased use of safe pregnancy, women's nutrition, family planning, and other reproductive health interventions," by identifying ways to improve the availability and access to safe, effective, and affordable reproductive health drugs, medical supplies, and basic equipment.

Implementation Strategy and Major Activities

The RPM strategy was to collaborate with USAID and MotherCare Project to identify the key issues to be addressed in determining RH commodity costs, to elaborate the functionality of a methodology to estimate needs and costs, and to develop a set of suitable tools to facilitate accurate and reliable cost estimation and assessment of existing RH service performance in terms of use and availability of RH commodities.

RPM would then disseminate the Cost-Estimate Strategy methodology and its usefulness to donors and cooperating agencies in a targeted manner, focusing on those organizations whose mandate clearly emphasizes reproductive health. In addition to a training/orientation workshop for key groups, RPM will promote CES through contemporary media, such as the Web and other electronic means of communication. Because CES is available to East and Southern Africa through the Regional Economic Development Support Office (REDSO) project, RPM will provide direct technical assistance in the CES to a country in another region. This work is intended to respond to USAID's Strategic Objective SO2: Increased use of safe pregnancy, women's nutrition, family planning, and other key reproductive health interventions.

The major activities of the program were

1. Development of a practical, computerized tool to assist reproductive health managers and policy makers better determine the costs of RH commodities and use this information in decision making.

2. Rigorous field-testing of the tool.

3. Preparation of a comprehensive guide to the CES methodology to enable potential users to be able to use the tool easily.

4. Development and dissemination of an information package on the Cost-Estimate Strategy.

5. Dissemination of the CES to organizations active in the area of reproductive health.

Chronological Activity Timeline

Table 1. Activity Timeline

Date	Activity
1995–96	Contribute to examination of issues related to pharmaceutical management for reproductive health with MotherCare Project and USAID. Development of prototype costing spreadsheet for reproductive health commodities.
1996	Development and refinement of the normative cost estimate model
September 1997	Field-test CES in Kenya
September 1998	Finalize analysis and report on CES field test in Kenya
November 1998	CES presented at American Public Health Association
February 1999	CES Policy Workshop held in Nairobi, Kenya
May 1999	Presentation on CES to USAID
March 2000	Information pack on Cost-Estimate Strategy finalized
March 2000	Present CES to United Nations Population Fund technical staff in New York
March 2000	CES spreadsheet application finalized
March 2000	CES User's Guide finalized and published
April 2000	CES Forum, Washington, D.C.
June 2000	CES featured at a Global Health Council panel presentation on computerized tools

Program Accomplishments

Development of the Tool

A methodology was developed for costing reproductive health commodities to facilitate including the cost implications of RH commodities into decision and policy making by those involved in RH programs.

The basis for the methodology was determined in collaboration with USAID and staff from the MotherCare Project of John Snow Inc. (JSI), through the identification and review of reproductive health conditions and services, consensus-building on standard treatment

97

guidelines, and the development of computer applications to facilitate the costing processes and analysis of data.

Initially developed in QuattroPro, the reproductive health commodity costing tool was refined and finalized in the more widely used Excel spreadsheet software. The program consists of a template condition/service-costing sheet; integral cross-referenced sheets for drugs, medical supplies, and medical equipment, including a database of more than 450 commonly used generic drugs; and summary sheets that display the results of the costing exercise.

The cost of an individual episode of a reproductive health condition or service is generated in the first instance and, by introducing epidemiological or caseload data for a target population, the costs for meeting the reproductive health requirements of the population can be determined. By changing one or more parameters in the treatment algorithm, the CES can rapidly facilitate generation of the costs of alternative program decisions.

The prime costing component of the spreadsheet tool has been developed in a flexible, general way, which enables the tool to be used for health issues other than reproductive health.

The second major component of the CES is the survey. Survey instruments have been prepared—that can be modified to local circumstances—to enable the collection of data that will assist the user to assess the quality of care, compliance by health providers with official standard treatment guidelines, and the availability and use of drugs and medical supplies in the health delivery system.

Field-Testing of CES

It is usual in the development of a tool or methodology to test its procedures, suitability, and ease of use by applying it in a real-life situation. Consequently, with the agreement and collaboration of the Department of Primary Health Care of the Ministry of Health in Kenya, the Cost-Estimate Strategy methodology was field-tested in four stratified randomly sampled districts, plus Nairobi.

Improvements to the CES approach were introduced during the field test, including the development of a more specific data collection framework and refinements to the costing spreadsheets to enhance the tool's ability to be applied to different groupings and its flexibility to be used for other health issues.
It was concluded, at the end of the field test, that the CES (1) was useful in quantifying commodity needs, (2) identified where treatment guidelines failed, (3) enabled validation and cross-checking of findings through the use of multiple data-collection methods, and (4) needed further development to make it more readily usable to different health care settings.

Dissemination of Cost-Estimate Strategy

Information on the CES was shared with interested parties and at appropriate forums both during its development phase and immediately following the finalization of the spreadsheet and survey tools and the User's Guide.

The developing CES was presented at the annual conferences of the National Council for International Health (now the Global Health Council) in June 1998 and the American Public Health Association in November of the same year.

In May 1999, progress on the approach was shared with key staff at USAID Washington. In the following July, interested parties at George Washington University were introduced to the CES.

Reproductive health and the implications of the costs of drugs and medical supplies and equipment needed to provide quality RH services to all those who need them are of keen interest to the United Nations Population Fund (UNFPA), whose decal conference on population and development in 1994 had been a prime motivation for the development of the CES. In March 2000, the CES approach and its tools were described in detail to 15 technical and program staff based at the UNFPA headquarters office in New York.

The Cost-Estimate Strategy was more formally launched at a forum held in Washington, D.C., in April 2000, to which representatives from donor, bilateral, USAID-cooperating agencies and nongovernmental organizations with a direct interest in reproductive health were invited. More than 40 participants were briefed on the history and development of the CES, learned about what the CES can and cannot do, were informed of the findings of the applications of CES in Kenya and Zambia, and were provided with the opportunity for hands-on experience of the costing spreadsheet program. The forum program was opened by Dr. Labbok and Mr. Emrey of USAID, who set the context for the development of a tool such as CES, and wrapped up by Ms. Bacheller of USAID. See Annex 1 for a list of participating individuals and organizations.

RPM had planned to apply the CES in another country jointly with the Maternal and Neonatal Health (MNH) project. And since MNH is the follow-on project to MotherCare, RPM worked closely with staff from MNH to share information about the development of CES and how to implement the CES approach. An article titled "Optimizing Health Funds—Planning for Reproductive Health Services in Kenya and Zambia" was prepared for the quarterly newsletter of the MotherCare Project and published in Volume 9, No. 1, July 2000.

The Cost-Estimate Strategy was presented at the Global Health Council 27th Annual Conference, June 13–16, 2000, Arlington, Virginia, during a session titled Hooked on Technology: Using IT Applications Wisely. The objectives of the CES presentation included outlining the concept and purpose of the methodology for improving the use and availability of reproductive health commodities, illustrating the utility of the spreadsheet application to provide cost information for the management of reproductive health services, and emphasizing the importance of assumptions and the collection of key data inputs to ensure that the costing model produces valid and reliable cost estimates.

The report on the Forum on the Cost-Estimate Strategy held on April 20, 2000, at the Academy for Educational Development Conference Center, Washington, D.C., was published in September 2000 and distributed to participants.

Since September 2000 the CES has been featured on the Electronic Resource Managers Toolkit on the MSH Web site, where it is linked to the RPM page. Visitors to the site can learn about the tool and its application in health settings and are referred to sources for additional information on how to obtain a copy of the tool.

Activities Not Completed

The planned joint application of CES with the MNH project could not take place before the close of the RPM project in June 2000 because of the difficulty of identifying and scheduling technical assistance to an appropriate country that was compatible with both projects' objectives.

Dissemination of Cost-Estimate Strategy to Department for International Development (DFID) technical and program staff and collaborating agencies in the United Kingdom could not be completed because of scheduling conflicts.

An electronic conference on reproductive health issues was not held as planned.

Likely Needs at End of Project

Further capacitate MNH (or alternative project/organization) to be able to use/apply Cost-Estimate Strategy in developing country situation. Jointly implement Cost-Estimate Strategy in a suitable developing country situation.

Build on interest in Cost-Estimate Strategy within UNFPA by development of training course in the methodology for UNFPA technical and program staff.

Ensure Cost-Estimate Strategy is a key methodology to be used by the Informal Working Group on Reproductive Health Commodity Security.

Refine Cost-Estimate Strategy spreadsheet tool to more effectively quantify and cost contraceptive commodity requirements for family planning services. Incorporate minor amendments and suggestions from participants at various dissemination forums to spreadsheet application to improve user-friendliness.

Consider upgrading the CES costing spreadsheet tool to a database format, which would increase its flexibility and applicability to health areas other than RH.

The World Health Organization (WHO) has also developed a spreadsheet tool for costing reproductive program costs, which includes capital as well as recurrent expenses (personnel and utilities in addition to commodities), called the Mother Baby Package Costing Tool (MBCT). The opportunity exists for, and there is interest on the part of WHO in, future collaboration on further developments to the CES and MBCT.

Lessons Learned

The Cost-Estimate Strategy aims to assist users to accomplish several things, each requiring different expertise, information gathering effort, and technical assistance to make use of the findings from costing exercises and survey analysis. At its simplest level, the CES can generate estimates of the costs of commodities to provide selected RH treatments and services to a target population using the normative model that requires minimal information. Greater country relevance of cost estimates is achieved through the country-specific model, which requires a larger effort at data collection. Information to assess the availability and use of RH commodities is obtained through the CES survey, which involves considerable manpower and expertise to be useful. By not sufficiently segregating the costing and the survey components, or by presenting them as independent, though useful, complementary activities, we may have reduced the availability of the tool to potential users.

The emphasis of the reports on the field test of CES in Kenya and its application in Zambia appears unduly weighted toward the presentation of the results of the analysis of data on the availability and use of RH commodities. The more important issues are to determine what the analysis says and how to use this information to improve decision making, resource allocation, and services.

Annex 1. List of Individuals and Organizations Who Received the CES User's Guide

Those at the CES Forum in Washington, D.C., April 2000, and at the Regional CES Workshop in Mombasa, Kenya, May 2000, plus:

Jeanne McDermott, Program Officer, Division of International Research and Training, Fogarty International Center, National Institutes of Health

Margaret Rowen, Independent Consultant working on reproductive health financing issues in Egypt

Rowena Edgeworth, MSH APHIA Project, Kenya

Mandy Rose, Measure Evaluation Project, Macro International Inc.

Vicki Denman, Freedom from Hunger

Technical Leadership

Acronyms

MDS	Managing Drug·Supply
MSH	Management Sciences for Health
PAHO	Pan American Health Organization
RPM	Rational Pharmaceutical Management (project)
USAID	U.S. Agency for International Development
WHO	World Health Organization
WHO/EDM	WHO's Department of Essential Drugs and Medicines Policy

Program Overview

The Rational Pharmaceutical Management (RPM) project focused USAID's work on pharmaceutical management and provided leadership in this field. As part of its role in technical leadership, RPM raised awareness among international development organizations and throughout the developing world about the importance of drug management in public health and pushing the boundaries of traditional approaches to solving drug management problems. RPM's technical leadership activities were made possible through global funding and allowed broader drug management issues to be addressed that spanned specific country programs.

Technical Leadership Achievements

As a primary global leadership activity, RPM contributed to the revision and expansion of the Management Sciences for Health (MSH) internationally acclaimed hallmark text *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals*. Published in 1997 by Kumarian Press, the text was written by international pharmaceutical management experts and edited by Management Sciences for Health in collaboration with the World Health Organization (WHO). It presents the latest knowledge and experience in the field. RPM, with USAID global funding, also developed a set of training materials based on *Managing Drug Supply* (MDS). The training materials include one introductory and 20 technical modules covering main components of drug supply management. Two hundred sets were produced and are being distributed to pharmacy schools and public health institutions worldwide. Four MDS Training Series modules were placed on MSH's Web site to aid in the dissemination of the documents. Both the text and the training materials may be ordered from MSH's bookstore.

A related leadership activity was the Spanish translation of *Managing Drug Supply* (Second Edition). For this project, RPM worked with the Universidad Carlos III de Madrid, Spain. The Pan American Health and Education Foundation's program for textbooks received funding from USAID through RPM and WHO's Department of Essential Drugs and Medicines Policy (EDM) for this activity. Publishing and distribution will occur in 2002.

To further RPM's mission of educating health managers, providers, consumers, and the public, RPM coordinated two technical seminars focusing on drug management, which were cosponsored by MSH, the Global Health Council, the Pan American Health Organization (PAHO), and the World Bank. In November 1999, RPM coordinated a seminar titled The Strategic Role of Drug Management for Improved Public Health Outcomes. Presenters at this well-attended seminar included Tony Savelli (RPM), Keith Johnson (United States Pharmacopeia), and Dennis Ross-Degnan (Harvard University). Rosario D'Alessio (PAHO) and Al Bartlett (USAID) were respondents, and Tony Boni was moderator. The second technical seminar was titled Improving Drug Use in an Era of the Resurgence of Infectious Diseases. Speakers were Amy Bloom (USAID), Mary Ettling (USAID), Renato Gusmao (PAHO), David Lee (International Network for Rational Use of Drugs/RPM), Dennis Kyle (Walter Reed), and

105

Andrei Zagorski (RPM). Proceedings were prepared from both seminars. Other seminars that RPM sponsored covered broader public health topics, but with a drug management component. These included the value of indicator-based assessments, management issues in the decentralization of health care systems, and managing the integration of vertical programs.

RPM technical staff also made presentations to academic programs for public health and pharmacy. A presentation was made at a joint graduate seminar on pharmacy health care administration for the University of Florida and Florida A&M University Schools of Pharmacy in December 1999. Another seminar was presented at Johns Hopkins University School of Public Health in spring 2000. These presentations helped to inform pharmacy and public health students and faculty about the field of international pharmacy and the role of good drug management for improving public health outcomes. Both presentations generated interest on the part of graduate students in completing an internship or rotation at MSH as part of their academic training.

In collaboration with MSH's Health Reform and Finance program, RPM drafted a discussion paper on the role of incentives for improving the performance of drug management systems. The paper was distributed for comment and used during discussions on designing future drug management projects. Using examples from RPM country programs to highlight the relevance of incentives to drug management issues, the paper raised difficult questions such as: Why should employees of a public health program strive to keep expenditures to a minimum? How can loss because of staff waste and theft be minimized? Who has the incentive to ensure procurement of drugs and medical supplies at the lowest possible price and their appropriate use? How can corruption be discouraged?

Outcomes

As a result of RPM's technical leadership, a broader public was made aware of issues and developments in drug management around the world. RPM expanded the scope of drug management skills and activities by exploring areas beyond immediate interventions in order to address issues of sustainability. RPM's participation in national and international meetings resulted in the dissemination of information and tools on RPM activities and accomplishments to a large audience.

Needs at End of Project

By pursuing technical leadership, RPM exposed many of the existing gaps in understanding about drug management. There is a need to critically assess RPM's attempted interventions from a leadership perspective in order to determine relevant successes. RPM worked at the cutting edge of drug management and technical leadership. Future efforts need to be equally innovative to seek more effective and sustainable interventions.

Tools Development

Executive Summary

Governments and donor agencies have become aware of the need to place a greater emphasis on supplying commodities necessary for improving public health care. However, they often lack the information and practical tools necessary for accurately assessing the quantities and costs of required commodities—information that significantly aids the budgeting, planning, and management of health programs. Rational Pharmaceutical Management (RPM) maintained a strong commitment to the development of state-of-the-art tools in health commodities and essential pharmaceuticals, including techniques, methodologies, software, information resources, and training materials. These tools were tested in project countries and made available to other USAID projects, agencies, and organizations active in providing pharmaceutical management technical assistance. The tools program facilitated drug management functions by developing products to simplify or automate specific tasks, addressing different portions of the drug management cycle. From its inception, RPM built on the experience of Management Sciences for Health's (MSH's) Drug Management Program (DMP) with computer software programs for specific aspects of drug management, such as inventory management and drug needs quantification.

As RPM evolved and the numbers of country programs and activities increased, the need for tools also grew. The project's approach to assessment had a number of important tools-related consequences. Among counterparts, the notion of capacitating local staff to collect and analyze data on performance of the systems they manage resulted in a nearly universal response indicating that certain chronic problems were known to exist, but until RPM's approach to assessment was utilized, there were few opportunities to describe or quantify them. This tangible result also served as an excellent means of bringing about collaboration and creating a sense of "stake holding" among various groups concerned with improving drug management. Specialized RPM tool applications, intended for routine use by local managers, focusing on specific system operations resulted in significant demand—including self-assessments focusing on drug management at the district level and assessments supporting implementation of specific program needs such as those for integrated management of childhood illness, tuberculosis, and malaria.

Acronyms

CES	Cost-Estimate Strategy
CPS	capacity-building, planning, and supervision
DMP	Drug Management Program
ECDS	Eastern Caribbean Drug Service
LAC	Latin American and Caribbean (region)
MIS	management information systems
MSH	Management Sciences for Health
MTP	monitoring-training-planning
PASS	Prescription Analysis Software System
RH	reproductive health
RPM	Rational Pharmaceutical Management
USAID	U.S. Agency for International Development

Program Overview

One of the RPM project mandates was to develop state-of-the-art tools, techniques, methodologies, software, information resources, and training materials. RPM implemented a procedural system of testing tools in project countries and making them available to other USAID projects, agencies, and organizations active in providing pharmaceutical management technical assistance. The tools development program encompassed publications and software, and included a wide variety of activities. The development of tools for pharmaceutical management took place concurrently with the assessment and country program initiatives. This resulted in the production of such products as the *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* manual, the *International Drug Price Indicator Guide*, and computer software products such as the INVEC-2 inventory control program, PASS for analysis of drug prescribing practices, ESTIMED for quantifying drug needs, and ECPRO-2 for managing competitive procurements.

In many instances, RPM established a leading role in innovating tool development, especially when utilizing computer technology. Early in the project, RPM could not find usable computer programs for drug needs quantification, tender management, or analyzing prescribing patterns. In addition, software that included all required operations for inventory management for pharmaceuticals in a stable, tested system was not available. RPM identified a need to coordinate the varied efforts necessary to develop rapid indicator-based assessment methods, field-test the methods, and describe results in such a way that others could use them to conduct assessments of their own systems. The indicator-based approach to assessment of pharmaceutical sectors developed into a major tools-related thrust of RPM's work. Working in collaboration with USAID's Latin American and Caribbean Health and Nutrition Sustainability Project, the DMP had begun work on indicator-based assessment methods prior to RPM's inception. Subsequently under RPM, project staff developed specialized assessment tools tailored to meet the needs of specific groups of clients. This approach involved collecting and processing both quantitative and qualitative data sufficient for deriving indicators of performance in key areas of pharmaceutical management operations that in turn could have a range of applications, including

- Verification of operational strengths and weaknesses
- Design of interventions for improvement
- Definition of pharmaceutical system resource requirements
- Identification of alternative approaches to management
- Comparison of the performances of different systems, programs, or countries

In Russia, RPM was the first project to introduce the concept of using tools to restrict drug formularies. This led to the need for a manual to teach pharmacists and physicians how to initiate formularies in their institutions. The same concept was applied to drug utilization review, resulting in a manual. Both manuals were designed for use in Russia and other countries, and the formulary manual was translated into Spanish.

Overall Strategy

The RPM Tools Development program focused on facilitating drug management functions by developing products to simplify or automate specific tasks. The tools themselves could address any portion of the drug management cycle, from selection to management information systems (MIS). Most of the RPM tools were designed to assist with selection, quantification, MIS, and training in any area. Tools were developed with the expectation that other projects and collaborators would use them and the related methodologies would be developed and refined by RPM.

Program Accomplishments

Project activities leading to the development and implementation of the Cost-Estimate Strategy (CES) tool are indicative of the success of RPM tools development efforts. In 1995, representatives of USAID, RPM, and the MotherCare Project formed the Reproductive Health (RH) Working Group to develop a tool that would assist RH program managers, governments, and the donor community to better estimate the costs of RH commodities. The resulting CES tool guides decision making for improving the availability and management of RH commodities by providing a framework for incorporating cost information into policy and program decisions.

- Following field-testing in Kenya and implementation of the CES in Zambia and at a health facility in Kenya, a *User's Guide*, spreadsheet files, and sample survey instruments were finalized and published.

- The Cost-Estimate Strategy was officially launched at a forum for more than 40 participants from bilateral and multilateral donors, nongovernmental organizations, and private voluntary organizations working in the RH field. The forum was held in Washington, D.C., on April 20, 2000.

- The rationale for the development of the CES—from both maternal and neonatal health, and drug management perspectives—was placed in context by speakers from USAID and RPM. Members of the development team then informed the forum about the structure of the methodology and described the costing tool and survey components in detail. These presentations highlighted the applications of the tool and its potential users.

CES contains several complementary though discrete activities that can trigger ancillary tool development. For example, decentralization efforts in the pharmaceutical sector have been hampered by poor dissemination of policy changes and the lack of capacity at the local level to assume new roles and responsibilities. In response, RPM developed and implemented a new training tool for capacity-building, planning, and supervision (CPS). The CPS tool consists of five interactive modules that help professionals analyze their own drug management problems, implement solutions, and monitor their work.

Additional tool development accomplishments include

- Production of a set of training materials based on the second edition of *Managing Drug Supply.* These materials are now available as a universal tool for use in training sessions.

- Development of RPM's family of standard-setting computer software programs, including

  - INVEC-2 inventory control and management software installed in St. Vincent and the Grenadines, St. Lucia, Grenada, Dominica, Antigua, Cambodia, Zimbabwe, Paraguay, and Mexico, complete with manuals in English, Spanish, and Russian.

  - The prescription analysis software system (PASS) that analyzes prescribing patterns based on user-defined study criteria.

  - ESTIMED drug needs quantification software, field-tested in Yemen. This software program uses both consumption and morbidity data to estimate drug needs.

  - ECPRO-2 tendering and procurement software, used by the Eastern Caribbean Drug Service (ECDS) to manage their pooled procurement system

  - A Windows-based software program used to facilitate ABC/VEN analysis.

Completion and dissemination of a "how-to" manual on monitoring-training-planning (MTP) methodology offers assistance for building capacity in key functions of the drug management cycle through documenting the principles of the MTP strategy, describing how to customize this to specific settings, and giving examples of modules for specific purposes.

Annex 1 shows an inventory of RPM tools used in country-specific settings.

Cost Sharing

Software programs developed or finalized under the RPM project have been used in cost-sharing activities involving multiple sources. For example, under contracts with WHO, the Zimbabwe Essential Drugs Action Programme, the World Bank, the government of Mexico, and the Federal Government of Nigeria, the DMP installed INVEC or INVEC-2 in more than 10 countries during the RPM project. These software programs were usually installed in one or more central or regional medical stores and are designed to assist in improving inventory management practices.

Outcomes

The CES development and implementation represent RPM's commitment to collaborative efforts working on practical issues with tangible working results in tool development and use. RPM's work on indicator-based assessments and development of software tools for needs estimation, procurement, and inventory management, and its work to improve drug use all contributed to improved drug availability. The development of RPM's prescription analysis software (PASS) has proven an important contributor to promoting rational use. In addition, the development of monitoring-training-planning (MTP) methodology helped to build capacity of local counterparts in key functions of the drug management system.

Needs at End of Project

Dissemination of the documents and software programs produced under RPM should continue with adaptation and updates as necessary. There is a need for an integrated suite of drug management software programs that can be used together or separately for all aspects of drug management. Dissemination and support of training materials in support of RPM tools should continue, especially within the context of a future edition of *Managing Drug Supply.* The Web needs to be used as an ongoing vehicle for posting tools-based material, including manuals and software programs.

Annex 1. RPM Inventory of Tools: Country Specific, Core Funded, and Funded by Other Donors

Country-Specific Tools				
Tool	**Where Used**	**Language**	**Degree of Customization in Original**	**Distribution**
1. *Manual for the Development and Maintenance of Hospital Drug Formularies*, Russia version (manual for establishing hospital drug formulary programs)	Russia	English, Russian	Minor for Russia	Free
2. *Manual for the Development and Maintenance of Hospital Drug Formularies*, Generic version (manual for establishing hospital drug formulary programs)	Ecuador, Hungary	English, Spanish, Hungarian	None	Free
3. *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals*, Russia version (manual for establishing and conducting hospital-based drug utilization review programs)	Russia	English, Russian	Minor for Russia	Free
4. *Guidelines for Implementing Drug Utilization Review Programs in Hospitals*, Generic version (manual for establishing and conducting hospital-based drug utilization review programs)	Hungary, Mozambique	English, Hungarian, Portuguese	None	Free
5. *DILSAT: District Integrated Logistics Self-Assessment Tool* (designed to be used for logistics self-assessment at the district level in Zambia)	Zambia	English	High for Zambia, but easily adapted	Limited to Zambia
6. *Quantification of Medical Supplies* (manual for training Zambian district-level staff in quantification of drug needs)	Zambia	English	High for Zambia	Limited to Zambia
7. *Trainers' Manual on Stores Procedures for Health Centers and Trainers' Manual on Stores Procedures for Districts* (trainers' manuals for training Zambian staff in proper stores management techniques)	Zambia	English	Moderate for Zambia	Limited to Zambia
8. *Manual on Stores Procedures for Health Centers and Manual on Stores Procedures for Districts* (users' manuals for training Zambian staff in proper stores management techniques)	Zambia	English	Moderate for Zambia	Limited to Zambia
9. *Manual on Stores Procedures for Nonmedical Supplies* (users' manual for training Zambia staff in management of nonmedical supplies)	Zambia	English	Moderate for Zambia	Limited to Zambia

114

Tool	Where Used	Language	Degree of Customization in Original	Distribution
10. *Monitoring-Training-Planning Modules (MTP)* Training sessions for staff at hospitals, district-level facilities, and health center-level in basic concepts of the following subjects: • Stores management • Setting up a Pharmacology Committee • Management of health facility pharmacy • Drug financing • Prescribing practices • Evaluation and health district accreditation • Managing revolving drug funds • Improving rational drug use • Managing a district medical store	Bangladesh Ecuador Peru	English Spanish		
11. *Capacitação-Planificação-Supervisão (CPS)* Mozambican basic training materials for training Ministry of Health staff in: • Inventory control • Procurement planning • How to order supplies • How to receive drugs and supplies • Information systems and reporting • Rational use of drugs	Mozambique	Portuguese	High for Mozambique	Free
12. *Uso Racional de Medicamentos en Escuelas Saludables (URMES)* (school-based rational drug use education project consisting of a workbook for students and a guide for the teacher, which are designed for grades 1 and 2, 3 and 4, and 5 and 6; one introductory video and three training videos)	Ecuador	Spanish	Minor for Ecuador	Free
13. *RDU Training Manual–Bangladesh* (three-day training of trainers manual for fundamentals of rational drug use)	Bangladesh	English	Minor for Bangladesh	None yet

115

Tool	Where Used	Language	Degree of Customization in Original	Distribution
14. *Gestao do Aprovisionamento e Uso Racional de Medicamentos, Guia de Armazenagem de Medicamentos e Material* (Mozambique-specific training materials based on *Managing Drug Supply*)	Mozambique	Portuguese	Moderate to high for Mozambique	Free
15. *Community Pharmacy Management Manual* (manual developed to assist Russian community pharmacists in managing transition to a competitive, commercial setting)	Parts used in Russia	English	Moderate for Russia	None

116

Core-Funded Tools				
Tool	**Where Used**	**Languages**	**Degree of Customization in Original**	**Distribution**
1. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* (manual for conducting indicator-based assessments of pharmaceutical systems)	12+ countries	English, Spanish, Russian	None	Free
2. *Managing Drug Supply Training Materials* (trainers' and participants guides' and visual aids based on the *Managing Drug Supply* text)	MSH/IDA course 1997, 1998 Adapted for ECDS and Kazakhstan	English	None; selected sessions adapted for special short courses and seminars as needs arise	Limited
3. *Drug Management for Childhood Illness (DMCI) Manual* (manual for assessing drug management needs and identifying improvement strategies for implementing Integrated Management of Childhood Illness [IMCI] programs)	Ecuador, Bolivia	English, Spanish	Minor for Latin America	Limited
4. *Data Collector's Guide for the Drug Management for Childhood Illness Manual* (manual to use in training staff who are collecting data for drug management for integrated management of childhood illness assessment)	Bolivia	English, Spanish	Moderate for Bolivia	None
5. *Cost-Estimate Strategy* (CES) (spreadsheet model and manual for estimating the cost of reproductive health commodities and treatment)	Kenya	English	None	Limited
6. *ABC/VEN* Analysis Software (Windows 95–based software for conducting ABC and VEN analyses of drugs and medical supplies)		English	None	None yet
7. *INVEC-2* Software and Manual (DOS-based inventory control and drug management software)	12 countries	English	Minor	None, pending new Windows suite
8. *ESTIMED* Software and Manual (DOS-based drug needs estimation and quantification software)	Yemen, Kenya	English	None	None, pending new Windows suite

117

Tool	Where Used	Language	Degree of Customization in Original	Distribution
9. *PASS* Software and Manual (DOS-based prescription analysis software)	Russia, Central Asia, Ukraine, Ecuador	English	None	None, pending new Windows suite
10. *ECPRO-2* Software (No Manual) (DOS-based pooled procurement and tender management software)	ECDS	English	Moderate	None, pending new Windows suite

Funded by Other Donors				
Tool	**Where Used**	**Languages**	**Degree of Customization in Original**	**Distribution**
1. *INRUD News* (newsletter with rational use articles and research references, produced twice a year)	Worldwide	English	None	Free
2. *International Drug Price Indicator Guide* (listing of comparative international prices for essential drugs, includes WHO therapeutic classification and median and average prices)	Worldwide	English, French, Spanish	None	Free
3. *Managing Drug Supply* (textbook covering nearly all aspects of drug supply)	Worldwide	English	None	Order from Kumarian Press
4. *Structured Survey Instruments* (questionnaires designed to collect necessary information for assessment of pharmaceutical systems)	Vietnam, Ghana, Kenya, Ecuador, South Africa	English, Spanish	High	Free

Regional Programs

Africa Bureau

Executive Summary

In fiscal years 1998 and 1999 the Rational Pharmaceutical Management (RPM) project received $600,000 ($400,000 and $200,000, respectively) from USAID's Africa Bureau (AB) to support a range of pharmaceutical activities through to the end of project (EOP) in June 2000. During this period, RPM was working in four broad areas:

- USAID health and pharmaceutical sector assessments
- World Bank health and pharmaceutical sector assessments
- Adaptation and application of the Drug Management for Childhood Illness (DMCI) tool to Africa
- Drug management activities in support of infectious disease programs, particularly malaria

The work completed in each of these four areas can be summarized as follows:

USAID health and pharmaceutical sector assessments

RPM contributed to the pharmaceutical-sector portion of a USAID Health Sector Assessment in Liberia in 1998. Recommendations covered measures to improve availability and rational use of essential drugs, the development of a national drug policy, and re-establishing a national laboratory for quality control of drugs.

World Bank health and pharmaceutical sector assessments

RPM was able to strengthen its ties to the World Bank by supporting activities related to pharmaceutical procurement and use in Africa. Specifically, RPM collaborated in reviews of the Medical Stores Department (MSD) in Tanzania and the pharmaceutical sector in Lesotho. In Tanzania, RPM recommendations were instrumental in assisting the Ministry of Health (MOH) to reach an agreement with donors supporting the health sector on the continuation of external management and advisory support to the MSD. In Lesotho, RPM assisted the government and the World Bank to define priorities for the development of the pharmaceutical sector, especially in relation to establishing a national drug regulatory authority, reviewing the national formulary, and reforming the National Drug Supply Organisation. In April/May 1999, RPM provided assistance to the Zambian MOH to prepare and evaluate a World Bank tender for pharmaceuticals.

Participation in these missions fostered stronger links among RPM, the World Bank, and USAID on problems related to drug management and promoted better coordination of interventions related to pharmaceuticals.

Application of the DMCI tool to Africa

Following a comprehensive review of Integrated Management of Childhood Illness (IMCI) activities in Africa, RPM identified three countries (Tanzania, Uganda, and Zambia) in a position to benefit from implementing a rapid assessment of IMCI drug management. A regional workshop was organized in Tanzania to introduce the DMCI into Africa, after which assessments were carried out in Zambia and Uganda.

As a result of these activities RPM has been able to

- Develop and test a DMCI tool suited to African conditions
- Train a cadre of IMCI health care workers in three countries to carry out rapid assessments
- Promote the inclusion of IMCI referral drugs at primary health care level in national drug policies
- Foster the incorporation of drug management into IMCI training courses
- Develop a regional network of drug management expertise in IMCI programs in three countries

RPM is currently translating the DMCI into French. When the translation is complete it is proposed to implement an assessment in a francophone African country. Tentative plans have also been made to carry out an assessment in Tanzania. However, these activities will not be completed as part of RPM I activities.

Africa Bureau Infectious Diseases

In fiscal years 1998 and 1999, RPM received $200,000 to support pharmaceutical activities related to infectious diseases with a focus on malaria. Following participation in the Multilateral Initiative on Malaria African Malaria Conference in March 1999 and a World Health Organization, Regional Office for Africa (WHO/AFRO) malaria meeting in Harare, Zimbabwe, in May 1999, RPM and USAID's Africa Bureau Infectious Diseases defined the role of RPM in coordinating activities of USAID-funded partners in the Tanzanian combination therapy (CT) trial. In addition it was agreed to adapt the DMCI tool to create a Drug Management for Malaria (DMM) tool. The latter is reported on as part of antimicrobial resistance (AMR) activities. RPM was also to provide technical assistance to USAID Missions requiring expertise in drug management aspects of malaria program management.

Following discussions with USAID and the Centers for Disease Control and Prevention (CDC), RPM developed a role in defining, planning, and coordinating activities related to ensuring the timely availability of suitably packaged and affordable drugs for the CT trials. Through this work RPM has made an important contribution to ensuring the timely availability of CT drugs and to reducing the immediate-development and long-term costs of these drugs for WHO/Tropical Disease Research (TDR) and national malaria programs.

Acknowledgments

RPM gratefully acknowledges the important contributions and support from the following people:

Mary Ettling, ScD, Infectious Disease/Malaria Advisor, USAID Africa Bureau
Dennis Carroll, USAID Global Bureau

Peter Bloland, D.V.M., M.P.V.M., Medical Epidemiologist, Malaria Epidemiology Section, Division of Parasitic Diseases, CDC

Dr. Piero Olliaro, Manager, WHO/TDR Task Force on Drug Resistance and Policies
Dr. Jean Rigal, Manager, WHO/TDR Task Force on Drug Resistance and Policies
Dr. Bob Taylor, Manager, WHO/TDR Task Force on Drug Resistance and Policies

Margriet den Boer, Médecins sans Frontières Campaign for Access to Essential Medicines

Dr. Paul Ickx, Basic Support for Institutionalizing Child Survival (BASICS)
Dr. Rene Salgado, BASICS
Dr. Yousef Tawfik, BASICS

Dr. Al Bartlett, USAID

Dr. Yousef Gamatie, WHO consultant
Dr. Severini Von Xylander, WHO
Dr. Remi Sogunro, WHO/AFRO

Mr. Oliver Hazemba, RPM consultant
Dr. Anne Kissalu, RPM consultant

Dr. Colleta Kibassa, MOH Tanzania
Prof. Massele, International Network for Rational Use of Drugs (INRUD) Tanzania

Dr. Jessica Nsungwa, MOH Uganda
Dr. Peter Stephenson, WHO Uganda

Dr. R. Clay, USAID Zambia
Dr. P. Chibuye, USAID Zambia

Acronyms

AB	Africa Bureau [USAID]
AB/ID	Africa Bureau Infectious Diseases [USAID]
AMR	antimicrobial resistance
BASICS	Basic Support for Institutionalizing Child Survival (project)
CBOH	Central Board of Health [Zambia]
CDC	Centers for Disease Control and Prevention
CHAL	Christian Health Association of Liberia
CT	combination therapy
DMCI	Drug Management for Childhood Illness
DMM	Drug Management for Malaria
DRA	drug regulatory authority
EOP	end of project
GOL	government of Liberia
IDA	International Dispensary Association
IMCI	Integrated Management of Childhood Illness
INRUD	International Network for Rational Use of Drugs
MOH	Ministry of Health
MOH&SW	Ministry of Health and Social Welfare [Liberia]
MSD	Medical Stores Department [Tanzania]
NDS	National Drug Service [Liberia]
NDSO	National Drug Supply Organisation [Lesotho]
NGO	nongovernmental organization
PAHO	Pan American Health Organization
RAP	Task Force on Drug Resistance and Policy [WHO]
RPM	Rational Pharmaceutical Management (project)
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases [UNDP-World Bank-WHO]
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization
WHO/AFRO	World Health Organization Regional Office for Africa
WHO/TDR	World Health Organization Tropical Disease Research

Program Overview

Objectives, Implementation Strategy, and Major Activities

The Rational Pharmaceutical Management (RPM) project's work with the USAID Africa Bureau (AB) was initiated in1998 with the receipt of $400,000 from the AB in support of a number of pharmaceutical activities through to September 1999. On the basis of an extension of the RPM end of project (EOP) to June 2000, a revised work plan was agreed to in April 1999 based upon planned activities through to EOP. The principal focus of this extended work plan was drug management activities in support of the Integrated Management of Childhood Illness (IMCI) strategy, for which additional funding of $200,000 was received.

RPM's broad strategy for implementing AB activities was to work in four main areas. They were

- Participation in USAID health and pharmaceutical sector assessments
- Participation in World Bank missions to provide technical expertise in the area of drug management, particularly procurement issues
- Adaptation and application of the Drug Management for Childhood Illness (DMCI) tool to Africa
- Drug management activities in support of infectious disease programs, particularly malaria

USAID Health and Pharmaceutical Assessments

RPM was provided funding to respond to requests for technical assistance and involvement in health and pharmaceutical sector assessments from USAID/AB and USAID Missions in Africa on an as-needed basis. In 1998, in response to a request from USAID, RPM provided a drug management expert (as one of a six-member team) to participate in a mission to assess the state of the health sector in Liberia in order to provide recommendations to USAID/Liberia for strategic and programmatic options for short- and medium-term activities in health-sector programming following the civil war. This mission represented RPM's first experience of assessments in a postconflict situation.

Field visits and interviews of health care providers at every level were conducted in five counties in urban and rural areas of the country. Representatives of major donors and nongovernmental organization (NGOs) were also interviewed regarding their experiences and lessons learned. Five critical issues were identified as immediate challenges to reforming the health sector: reversing sector bias; enhancing financial support in conjunction with the government of Liberia (GOL), fee-for-service and revolving drug fund mechanisms, and insurance health plans; retraining and redeploying health workers; strengthening supervision at lower levels; and ensuring the availability of drugs and essential supplies.

For the pharmaceutical sector, priorities identified included ensuring the availability and rational use of essential drugs and medical supplies, establishing and implementing key policies, and reestablishing a national drug-testing laboratory. Following are a few key assessment findings:

- In 1998, Liberia had no official national drug policy, but a draft policy was prepared in August 1992. The draft policy advocated an autonomous, not-for-profit drug supply service that would be a public-private venture with adequate GOL support to ensure its perpetual existence.

- The existing drug laws had not been updated since 1976. The drug regulatory authority, the Pharmacy Board, was responsible for drug registration, quality control, and licensure of pharmacists and pharmacy businesses. However, these activities were difficult to implement because of the loss of records, personnel, and logistics support after the war. At the time of the report, there was no registration of pharmaceutical products, and no records existed on the number of pharmaceutical products previously registered.

- All public health facilities dispensed drugs free of charge. The Ministry of Health and Social Welfare (MOH&SW) did not make budgetary allocations for drugs, did not operate a revolving drug fund, and did not budget for or import drugs. NGOs supplied most of the drugs for the country. Drug acquisition for the public sector was primarily through the National Drug Service (NDS) and the Christian Health Association of Liberia (CHAL). The funding for drugs and medical supplies to NDS was from the European Union and UNICEF.

- The MOH&SW was not involved in the distribution of drugs and supplies. All 12 selected tracer drugs were available at the NDS and CHAL warehouses and most facilities had approximately 79 percent of the tracer drugs on the shelf in the dispensary. Drugs for the treatment of tuberculosis (TB) were not available at most of the facilities with TB programs. Major constraints to distribution included the poor state of the roads and the absence of trained pharmacists and dispensers in the country. There were about 29 pharmacists in the country. Only one of the 29 was in the public sector, serving in the role of chief pharmacist. The other pharmacists were mainly in the private sector.

- A national Essential Drug List was released in March 1998 by the MOH&SW but had not been widely circulated. Treatment guidelines developed for mid-level professionals, circa 1986, had not been revised and were only available in approximately 30 percent of the facilities visited.

- There were 52 pharmaceutical wholesalers and 160 private pharmacies and medicine stores in Liberia, most in Monrovia. Drug prices were not regulated in the private sector and all of the 10 shops visited sold the prescription drugs ampicillin and metronidazole without a prescription.

Pharmaceutical sector recommendations included

- Provide support to NDS and CHAL to improve their planning, stores management, training, and monitoring and supervisory capacity. Support should also be provided to NDS to assist in developing a plan to be self-sustaining.

- Assist the NDS to open subdepots at county level to facilitate distribution of drugs and supplies to rural areas, especially during the rainy season.

- Assist the GOL to establish a plan to implement a cost-recovery mechanism, such as a revolving drug fund.

- USAID should seek partners in the international health community, such as the World Health Organization (WHO) and the World Bank, to assist the GOL to complete the process for establishing its national drug policy, which could provide the necessary framework for the development of the pharmaceutical sector. The national drug policy could also form the basis for revising the existing pharmacy laws.

- USAID should explore the possibility of providing short-term technical assistance to the GOL to assist in designing appropriate mechanisms for ensuring the quality of drugs imported and circulating in the country.

A report detailing the complete assessment findings and recommendations, entitled "Rebuilding Liberia's Health Sector: Analysis, Strategies, and Recommendations," was produced in June 1998.

Participation in World Bank Missions

RPM's strategy was to seek opportunities to collaborate with the World Bank on activities related to pharmaceutical procurement and use in Africa. In particular, RPM was to

- Consult with World Bank country program managers and officials to identify USAID countries needing assistance, including those that were receiving World Bank investments and loans and where the drug procurement process had stalled

- Identify the type of RPM technical assistance that would be required for those countries

- Develop scopes of work for providing technical assistance for priority pharmaceutical activities that RPM could implement using available Africa Bureau funds

In 1998, RPM participated in a joint World Bank-Danida-Government of Tanzania Mission in Tanzania to review the performance of the Medical Stores Department (MSD) and make recommendations on the need for continued donor support to facilitate the development of the MSD. The outcomes of the mission were documented in a comprehensive report that was presented to the Ministry of Health (MOH) of Tanzania and the donor community in early 1999.

RPM also made two visits to Lesotho in 1999 as part of World Bank-Government of Lesotho missions to define policy and institutional reform requirements following the breakdown of apartheid in South Africa. During the first mission, the RPM consultant focused attention on the operations of the medical stores and the government drug-manufacturing unit. Recommendations included separating the business operations of the two institutions and adapting regulations and capacity development through focused study tours and training in drug management, particularly procurement. RPM recommendations were integrated into a Lesotho World Bank technical review report. A second mission was made to Lesotho in December 1999. The RPM scope of work was to advise the World Bank Pharmaceutical Working Group on the pharmaceutical component of the World Bank/Lesotho health project appraisal.

DMCI

In 1997, through the use of core funds from USAID/Global Bureau, RPM, in collaboration with the Pan American Health Organization (PAHO) and Basic Support for Institutionalizing Child Survival (BASICS), developed the *Drug Management for Childhood Illness Manual.* The *Manual* is an indicator-based tool to assess drug management issues related to implementing IMCI. On the basis of successful field tests of the manual in Latin America and Central Asia, the Africa Bureau decided to provide support to adapt and apply the tool in Africa.

As part of the initial strategy for applying the DMCI tool in Africa, RPM conducted a desktop study of drug management issues associated with IMCI implementation in Africa. The objective of this study was to identify African countries that could

1. Host and participate in a regional workshop to introduce the DMCI tool and review its potential for adaptation to the African context, and appraise the DMCI materials in terms of appropriate terminology, readability, length, clarity, and redundancy

2. Field-test the adapted DMCI in African conditions

The desktop study found that Tanzania, Uganda, and Zambia had mature and expanding IMCI programs and would benefit most from having IMCI drug availability and use issues identified, along with recommendations for improvement. The recommendations of the study, together with subsequent discussions, led to a decision to hold a subregional workshop in Tanzania. Tanzania was also selected for field-testing the DMCI following the regional workshop. Participants at the workshop were invited from the ministries of health in Tanzania, Uganda, and Zambia. In addition, representatives from USAID, WHO/Regional Office for Africa (WHO/AFRO), WHO/Geneva, and local organizations were also invited to attend. As part of RPM's commitment to disseminate the tool and strengthen local capacity in drug management, RPM organized the workshop in collaboration with International Network for Rational Use of Drugs (INRUD)/Tanzania. INRUD/Tanzania, a local research group focusing on drug use practices, helped identify and train local data collectors in the DMCI methodology.

Prior to the workshop, a first revision of the original DMCI *Manual* and *Data Collector's Guide* was completed to ensure that all lessons learned from the previous field tests and applications were incorporated before beginning the process of adapting DMCI to fit African conditions.

Following the initial field test in Tanzania, the strategy was to further revise the DMCI *Manual* and *Data Collector's Guide* in the light of that experience and then to implement a DMCI assessment in Zambia and Uganda. The results from all three studies would subsequently form the basis of a cross-country evaluation of drug management issues needing to be addressed in relation to IMCI programs in eastern and southern Africa.

In order to be able to make an assessment in francophone Africa, it was also planned to translate the DMCI into French.

Unfortunately, the lack of IMCI staff in Tanzania forced the MOH to postpone the application of the DMCI tool. Instead, the DMCI tool was applied in Zambia (December 1999–January 2000) and Uganda (March–April 2000). Following is a summary of findings and recommendations from each of the assessments.

Zambia Findings

- In 1998–1999, the most recent period for which complete figures were available, the Ministry of Health paid on average 129 percent of the average median international price for a set of IMCI tracer drugs. Of the 36 tracer drugs and supplies listed, 14 (38%) were purchased for more than the median international procurement price.

- On average, 65 percent of the drugs in the tracer list were available in government facilities at the time of the study. The availability of the drugs was more of a problem for the health centers (60–67%) than for the hospitals (72–83%). Chloramphenicol, co-trimoxazole, erythromycin, ferrous sulfate, nalidixic acid, oral rehydration salts, and paracetamol were the drugs most commonly out of stock.

- In only 56 percent of records did the IMCI tracer list of products correspond with physical counts.

- Inappropriate prescribing of antibiotics was found. Of no-pneumonia (a common cold) encounters 65 percent received an antibiotic, while only 13 percent of pneumonia cases were prescribed an appropriate antibiotic.

- The current cost of treatment of the five IMCI conditions was almost 6 times higher than if IMCI norms for treatment had been followed. The average drug treatment cost per treatment of acute respiratory infection encounter was 4 times more than the drug treatment cost recommended by IMCI guidelines, 20 times more for diarrhea, 15 times more for malaria, and 3 times more for pneumonia. On average, the cost of treatment was 24 times more expensive in simulated purchases in drug retail outlets than if IMCI treatment norms had been followed.

Recommendations

- Incorporate management training and rational use of drugs in the IMCI training component.
- Train district staff on quantification methods, sustainable financing mechanisms, drug management, and budgeting.
- The Central Board of Health (CBOH) should work to support and incorporate all training components for rational drug use, including clinical diagnosis and use of drugs by prescribers, dispensers, and consumers.
- Introduce district-based tools to improve drug management and inventory systems.

Uganda Findings

- The incidence of individual drug stock-outs during the previous 12 months was on average 32 percent. Amoxycillin 250mg tablets were out of stock 70 percent of the time, co-trimoxazole 120mg tablets 42 percent of the time, and folic acid 5mg tablets 71 percent of the time.
- The inventory records of 66 percent of the surveyed health facilities did not correspond with physical counts.
- Only 50 percent of the surveyed health facilities had any reference materials on treatment guidelines.
- Of the no-pneumonia patient records that were surveyed, 91 percent of cases were prescribed an antibiotic. Only 58 percent of the pneumonia cases received the appropriate antibiotic.
- Of malaria encounters diagnosed in health facilities, 75 percent were prescribed an appropriate antimalarial according to IMCI treatment guidelines, compared with 63 percent in private drug outlets.
- The average cost of drug treatment for no-pneumonia encounters were three times higher when compared with IMCI standard treatment norms, and five times higher for diarrhea. The cost of treating diarrhea in the private sector was 161 times more expensive, while malaria was eight times higher.

Recommendations

- Disseminate the national standard treatment guidelines and IMCI treatment protocols and harmonize the treatment interventions in both documents.
- Introduce easy-to-read drug management and rational use flowcharts and posters in the health centers and drug retail outlets.

- Design and equip managers with a simple tool (e.g., forms) to monitor inventory of critical IMCI supplies by introducing small-scale supply information and control systems, and devise communication systems between the district centers and the health centers.

- Reduce the inappropriate use of antibiotics and injections through community-based information, education, and communication campaigns.

Africa Bureau Infectious Diseases (Malaria)

In 1998, the RPM project received $100,000 from the USAID/Africa Bureau Infectious Diseases (AB/ID) to support pharmaceutical management activities in relation to AB/ID work. In March 1999, RPM participated in the Mulitlateral Initiative on Malaria African Malaria Conference in Durban, South Africa. RPM attended at the request of USAID as a first step toward joining international initiatives to improve the malaria situation in Africa. In May 1999, RPM participated in a meeting on malaria organized by WHO/AFRO in Harare, Zimbabwe, at which RPM assisted WHO and the USAID/Africa Bureau to develop a framework for malaria drug policies for Africa.

USAID/Africa Bureau and RPM subsequently met to discuss, define, and assign the roles and tasks of participants in the combination therapy (CT) trials planned for malaria in Tanzania and South Africa. At the time, the Centers for Disease Control and Prevention (CDC) and WHO were preparing for those trials. RPM was requested to assist with the drug management aspects of the pre-implementation assessment phase of the Tanzanian CT trial, as well as serve as the coordinator for the USAID-funded organizations participating in the assessment. Following this activity, RPM participated in a preparatory meeting for the WHO/Tropical Disease Research (TDR) Task Force on Drug Resistance and Policy (RAP) in Cape Town, South Africa, in August 1999 to discuss the preparation for the CT trial in South Africa, which was conducted by the WHO/TDR unit.

RPM was also requested to adapt the DMCI tool for use in malaria programs. This work was conducted as part of the USAID Strategic Objective SO5 AMR/Malaria work plan.

For fiscal year 1999 RPM received an additional $100,000 from AB/ID to support activities focusing on two areas:

- Providing technical assistance on an as-needed basis to USAID Missions requiring expertise in drug management aspects of malaria programs

- Coordinating USAID-funded partners in the pre-implementation phase of the CT trial led by CDC in Tanzania

Challenges Facing RPM Africa Bureau Implementation

DMCI

- Country IMCI programs have insufficient resources for the demands placed upon them. In Tanzania, for example, a single person without access to secretarial support or telephone manages IMCI. In addition to DMCI, Tanzania was also participating in a number of other IMCI and child health–related studies.

- Because of the staffing problem, officials from the Tanzanian Ministry of Health requested that another country be selected for the field test, as they did not have sufficient time to make all the necessary arrangements and make key staff available. Following this request, RPM's strategy was revised and concentrated instead on field-testing and implementation of the tool in Zambia and Uganda.

  Following consultation with the CBOH and the USAID Mission, Zambia was selected to host the first implementation of the DMCI in Africa, which was conducted in November–December 1999. The second assessment, in Uganda, took place in March 2000.

- In both Zambia and Uganda, IMCI programs were not implemented as widely as at first thought. For example, IMCI managers could claim that IMCI was in place in a certain district while in practice only a single person trained in IMCI was working in the office of the District Medical Officer. Assessing DMCI at a health-facility level, where staff had not received IMCI training, was therefore problematic because of the potential problems of mixing findings among facilities with trained and untrained staff, particularly with respect to following IMCI treatment protocols.

- Conducting the data entry, analysis, and report writing was also challenging because of the difficulty in finding available staff locally that could commit time to the effort. One of the RPM goals, to provide local managers with the experience of data collection and analysis as a way of building their local capacity was, at times, in conflict with the goal of conducting those aspects of the assessments as timely and efficiently as possible.

- Because of the time and labor required for the DMCI assessments, some health ministries and IMCI programs expressed concern about being able to use the tool independently.

- The most effective and efficient method of presenting the results of DMCI assessments to all stakeholders must be found. It is clear that dissemination of a final report is not enough in and of itself to achieve the greatest impact and influence on decision-makers.

Malaria

The coordinating responsibilities of RPM in the Tanzanian CT trial were not initially clear to all partners involved. In the early stages of the work, therefore, considerable effort was put into clarifying and defining RPM's role to the satisfaction of all concerned. Following discussions with CDC and USAID AB/ID, it became clear that a key problem facing the trial was the timely availability of drugs to be used in the CT trials. RPM has since played a leading role in defining, planning, and coordinating activities within the RAP Task Force that would ensure drug availability for CT trials not only in Tanzania, but also in South Africa and other countries.

No requests for technical assistance were forthcoming from USAID Missions in relation to AB/ ID malaria activities.

Chronological Activity Timeline

Table 1. DMCI Timeline

Date	Activity
June 1999	Desktop study on IMCI implementation in Africa
July–September 1999	Initial adaptation of DMCI *Manual* for use in Africa
October 1999	Regional DMCI workshop in Tanzania
December 1999–January 2000	Implementation of DMCI assessment in Zambia
March–April 2000	Implementation of DMCI assessment in Uganda

Table 2. Liberia Timeline

Date	Activity
April–May 1998	USAID Mission to assess health sector in Liberia

Table 3. Tanzania Timeline

Date	Activity
September–October 1997	Review of Medical Stores Department

Table 4. Lesotho Timeline

Date	Activity
May 1999	First World Bank Mission
November 1999	Second World Bank Mission

Table 5. Zambia Timeline

Date	Activity
April–May 1999	Preparation and evaluation of World Bank tender for pharmaceuticals

Table 6. Malaria Activities Timeline

Date	Activity
January 2000	CT meeting, Bagamoyo, Tanzania
March 2000	RAP Task Force meeting, Chiang Mai, Thailand
May 2000	Procurement group meeting, Geneva, Switzerland
	Protocol development workshop, Bamako, Mali
September 2000	RAP Task Force meeting, Oxford, UK

Program Accomplishments

DMCI

The major accomplishments of the program have been

- Developing and testing a management tool able to comprehensively assess drug management issues necessary to support IMCI programs in Africa
- Training a cadre of health workers in three African countries (Tanzania, Uganda, and Zambia) to be able to carry out the assessment
- Implementing the DMCI assessment in two countries (Uganda and Zambia)
- Promoting and incorporating elements in National Drug Policies to cover the use of IMCI referral drugs at primary health care level
- Fostering the incorporation of drug management in IMCI training courses
- Promoting discussions to define the role of households and communities in the use of vital IMCI drugs.
- Raising awareness of MOH officials on the irrational use of antibiotics in IMCI programs
- Identifying savings that could be made per unit cost of treatment when IMCI treatment guidelines are followed
- Developing a regional network of drug management expertise in IMCI programs in three countries

USAID Assessments

In April and May 1998, RPM participated in the USAID Health Sector Assessment in Liberia. RPM contributed to the pharmaceutical sector portion of the study and provided an assessment of the performance and functioning of the pharmaceutical sector. RPM made recommendations in three broad areas:

- Availability and rational use of essential drugs and medical supplies
- Development of a National Drug Policy
- Support for reestablishing a national drug-testing laboratory

The report identified several steps, both short-term and long-term, that could be implemented to help rebuild and strengthen the pharmaceutical sector.

World Bank Assessments

USAID, through RPM, has strengthened its ties with the World Bank by supporting activities related to pharmaceutical procurement and use in Africa. Specifically, RPM collaborated with the World Bank to conduct reviews of the Medical Stores Department in Tanzania and the pharmaceutical sector in Lesotho. In addition, AB funds were used to provide technical support to the Zambian MOH in their preparation and evaluation of a World Bank pharmaceutical tender.

Tanzania

In September and October 1998, RPM participated in a Danida-led, multidonor mission to review the performance of the MSD and make recommendations for future donor assistance following the end of Danida's first five-year management support program in June 1999. RPM's contribution was primarily related to the management and operational functions within MSD. On the basis of RPM's recommendations, the Ministry of Health agreed to accept external technical assistance from Danida for an additional two years in order to continue to consolidate the development of staff, infrastructure, and systems within the distribution, storage, and sales directorate of MSD.

Lesotho

In May and November 1999, RPM participated in health sector assessments in Lesotho. The findings from the assessment and the recommendations made to address the identified weaknesses in the system formed part of the government of Lesotho's efforts to develop its health-reform strategy and to ensure that the World Bank would be able to endorse the strategy.

Recommendations from the first visit covered the following:

- The need for a comprehensive structured assessment of the pharmaceutical system, for which terms of reference were developed
- The need to develop a Drug Regulatory Authority commensurate with the needs and resources of the country
- The need to improve communications within the pharmaceutical department of the MOH in order to provide access to drug regulators in the region
- The future of the Lesotho Pharmaceutical Company and its relationship with the National Drug Supply Organisation (NDSO)
- Recognition of the legal status of the NDSO as an autonomous medical supplies organization
- Revision of standard treatment guidelines and the promotion of rational drug use
- Training of NDSO personnel in procurement and primary health care drug management
- Training of Pharmacy Department staff in primary health care drug management
- The need for public drug awareness campaigns to promote rational drug use
- The need to increase the number of qualified pharmacy personnel working in the public sector

Following this mission, in November 1999 RPM participated in a second World Bank appraisal mission to Lesotho. Noting the geographic position of the country, RPM recommendations highlighted the need for Lesotho to seek effective cooperation with neighbouring countries in the following areas:

- Drug policy and legislation
- Drug regulation
- Training of regulatory inspectors
- Drug procurement

The World Bank's project in support of the government of Lesotho's reform strategy was approved by the World Bank Board in June 2000 and was expected to become effective in November 2000. The project is planned to be in three phases, each lasting three years. Phase I will focus on institutional development, phase II on pilot-testing reform initiatives, and phase III will be concerned with scaling up.

During phase I the pharmaceutical work will focus on the following:

- Defining the role and responsibilities of a Drug Regulatory Authority (DRA)

- Defining the requirements for establishing a DRA
- Reviewing the national formulary
- Reforming the NDSO

RPM assisted the government and the World Bank to define the terms of reference for these studies, to define the need for a DRA, and to help define the potential role of the DRA. RPM also assisted the government and the World Bank to define and establish priorities and a detailed work plan for the pharmaceutical sector.

Overall, RPM collaboration and participation in these missions contributed to

- The fostering of collaborative links and dialogue among RPM, the World Bank, and other donors on problems related to drug management

- The promotion of coordinated interventions related to drug management

- The strengthening of USAID and RPM understanding of World Bank procedures

- Establishing USAID and RPM as a technical leader on drug management issues within the World Bank

- Raising the profile of drug management issues in the context of broader discussions about health sector reform

Malaria

RPM attended a planning meeting for the Tanzanian CT trial in Bagamoyo, Tanzania, in January 2000. Drug management issues relevant to the CT trial were raised and discussed. The need to have high-level political commitment from the MOH for the trial was accepted by the researchers, and actions were to be planned to win this support. The meeting also discussed the usefulness of the Drug Management for Malaria (DMM) assessment tool (see Infectious Diseases final report for fuller details on the DMM) in the pre-implementation stage of the research. After a full discussion, it was agreed that, because much of the ground covered by the DMM was already incorporated in the CT protocol, it would not be necessary or practical to use the DMM at this stage.

The possibility of conducting a field test in Tanzania with the Tanzanian Essential Health Interventions Project and the Ifakara Research Centre was discussed with both parties. However, neither was able to commit the time and resources necessary for conducting the work. In addition, investigators from the South African CT trial (South East African Combination Anti-malarial Therapy [SEACAT] evaluation) expressed an interest in using the DMM as part of their pre-implementation studies. However, delays in beginning the trial meant that SEACAT was not in a position to follow through on its interest.

RPM attended the RAP Task Force meeting in March 2000 in Chiang Mai, Thailand. At this meeting, RPM was instrumental in persuading the task force to adopt the following guiding principles for its work in making affordable CT drugs available for the CT trials:

- The motivation behind making CT drugs available is to satisfy public health objectives.
- There should be no compromise in quality standards.
- The planning and arrangements made for supplying drugs for the CT implementation trials need to be consistent with long-term plans for making CT drugs available and affordable on a large scale.
- WHO needs to retain the ownership of the new product data that has been developed by WHO and its scientific partners and associates.
- Roll Back Malaria and/or other partners will need to identify and ensure adequate sources of financing for drug development and deployment costs.

In line with this strategy, the task force decided to introduce competition into the search for a pharmaceutical manufacturer to develop the drugs required for the CT trials. The intention behind this decision was to reduce the eventual cost of CT drugs.

Following the Chiang Mai meeting, RPM participated in meetings in Geneva, Switzerland, to discuss how to put this strategy into operation. As a result of these meetings the RAP Task Force formed a Core Procurement Group. RPM was made a member of the group. This group was responsible for coordinating activities related to the procurement of new artesunate tablet formulations required for the CT trials. The task force, meeting in Oxford, U.K., in September 2000, agreed to award a contract to the International Dispensary Association (IDA) in Amsterdam, the Netherlands, for the development of two formulations of artesunate (100mg and 25mg) suitably packaged in blister packs with sulfadoxine pyrimethamine. The development cost for these products is 50 percent below the costs quoted by the company that the task force had been in discussions with before inviting IDA to quote. In addition, the final product prices were significantly lower than would otherwise have been the case. The final cost of a full adult dose was projected to be around $1.25. This cost is almost $1.00 lower than current international prices for the same combination. Furthermore, in contrast to prices quoted by IDA's principal competitor, the product prices made available to WHO/TDR by IDA will also be made available to public health sectors in all developing countries. IDA prices may fall further depending on eventual market size.

In addition to these drug sourcing–related activities, RPM also attended a RAP Protocol Development Workshop in Bamako, Mali, in May 2000. Attendance at this meeting was to assist researchers to develop the drug management assessment components of the research proposals being prepared for submission for funding to the RAP Task Force. A presentation on drug management assessments was made and assistance was offered to help incorporate drug management assessments into the proposals.

Activities Not Completed

- The French translation of the DMCI is awaiting technical review and final editing.
- The DMCI assessment was not implemented in Tanzania.

Likely Needs at End of Project

- Completion of French translation of DMCI *Manual* and *Data Collector's Guide*
- Implementation of French DMCI assessment in a francophone African country
- Implementation of DMCI assessment in Tanzania
- Continued involvement in coordination of drug management work with CDC and RAP in relation to CT studies

Lessons Learned

DMCI

- DMCI is a generic tool that requires customization for specific country settings.
- A range of clinical and pharmacy expertise is required in data collection teams in order to provide a balanced approach to the work and to avoid bias.
- The training period for data collectors should be increased to include more time for simulated data collection exercises.
- The data entry team members should be proficient users of Epi Info and should be included in the training. Data entry should form part of the simulated exercises.
- Local study organizers and managers require strong project management skills to efficiently and effectively plan and organize DMCI assessments.
- Data analysis needs to be well coordinated between host country and RPM to avoid duplication of effort.

- Interventions planned on the basis of DMCI findings should be consistent with national pharmaceutical sector strategies and plans. Therefore, interventions need to be discussed fully with key officials responsible for drug policy and operations prior to being finalized in the assessment report.

- Investing more time explaining DMCI and raising awareness of its value with these officials before the assessment is done would provide a solid basis for subsequent discussions on DMCI findings and recommendations.

- A follow-up visit after the assessment should always be planned and budgeted. A follow-up visit to present the assessment findings and discuss options for improvement is a critical part of completing the assessment process.

Malaria

There is a continuous need for drug management advocacy and technical expertise in global malaria initiatives. Too often, particularly in the planning phase, details of drug procurement, distribution, and use issues are not adequately addressed.

Annex 1. Publications and Reports

Clark, Malcolm. *Drug Management for Malaria Manual.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, Va.: Management Sciences for Health, 2000.

Clark, Malcolm. Geneva and Bamako Trip Report; Africa Bureau Infectious Diseases Malaria Activities. May 2000.

Clark, Malcolm. Oxford Task Force Trip Report; Africa Bureau Infectious Diseases Malaria Activities. September 2000.

Clark, Malcolm. Tanzania Trip Report; Africa Bureau Infectious Diseases Malaria Activities. February 2000.

Gabra, Michael, Oliver Hazemba, and Anne Kissalu. DMCI Country Assessment Reports for Zambia and Uganda (Drafts). October 2000.

Hughes, Barbara, C. Kirk Lazell, Alan Malina, Mary Mertens, Dr. Paul E. Mertens, and Dr. David Ofori-Adjei. *Rebuilding Liberia's Health Sector: Analysis, Strategies and Recommendations.* June 1998.

Ickx, Paul. Joint Health Sector Reform Program Appraisal Mission, Lesotho, Debriefing Note. December 1999.

Ickx, Paul. Technical Report on Pharmaceuticals (Report from May 1999 Mission to Lesotho).

Joint Government of Lesotho, World Bank, African Development Bank, Ireland Aid and WHO Health Sector Reform Program Appraisal Mission. Draft Aide Memoire. December 1999.

Keene, Douglas, Paul Ickx, and Julie McFadyen. *Drug Management for Childhood Illness Manual.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, Va.: Management Sciences for Health, 2000.

Keene, Douglas, and Thomas Moore. *Drug Management for Childhood Illness: Data Collector's Guide.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, Va.: Management Sciences for Health, 2000.

Regalia, Alexandra, Michael Gabra, and Paul Ickx. RPM Tanzania Drug Management for Childhood Illness (DMCI) Workshop, Workshop Proceedings and Trip Report. November 1999.

Utshudi, Armand. Desktop Study of Drug Management Issues Associated with IMCI Implementation in Africa. June 1999.

Latin America and the Caribbean
Regional Antimicrobial Resistance Initiative

Acronyms

INRUD	International Network for Rational Use of Drugs
LAC	Latin America and the Caribbean
PRDU	Promoting Rational Drug Use
PURA	Promoción del Uso Racional de Antimicrobianos
RPM	Rational Pharmaceutical Management (project)
TOT	training-of-trainers
USAID	U.S. Agency for International Development
WHO	World Health Organization

Background and Strategy

The inappropriate prescribing of antimicrobials is thought to be a leading contributor to the emergence of bacterial resistance. There is a real risk of losing the valuable tools that antimicrobials represent in the fight against infectious diseases. In Latin America and the Caribbean (LAC) Region, instances of overprescribing, underprescribing, and unregulated sale and use of antimicrobials are well documented. In many countries of the region, attempts have been made to improve the use of antimicrobials and other drugs. However, it is unclear if or to what extent these interventions have been effective, since they have often been carried out without understanding the key determinants of antimicrobial use, and rigorous impact assessments are mostly lacking. Furthermore, in view of the great risk of losing the effectiveness of antimicrobials, a much more focused approach is needed.

The Rational Pharmaceutical Management (RPM) project received Infectious Disease Program funds from USAID's LAC Regional Bureau in 1998 to carry out a program of activities to improve the use of antimicrobials in the region. The program included two components: (1) introducing a conceptual framework for promoting the rational use of antimicrobials, and (2) strengthening the local capacity to develop and assess innovative approaches to improving the use of antimicrobials. These two program components were part of an integrated strategy for improving antimicrobial use in Latin America and the Caribbean, and contributed to USAID's strategic objective SO 5: "The threat of infectious diseases of major public health importance reduced." The first component targeted health providers and managers and was aimed at providing a practical, problem-based conceptual framework for improving the use of antimicrobials. The second component was designed to strengthen the research skills of groups involved in the design, implementation, and evaluation of interventions, with the objective of increasing regional research capacity, in particular at the hospital level.

Activities Achieved

1. Developed training materials on improving the use of antimicrobial drugs: Based on training materials from the International Network for Rational Use of Drugs (INRUD)-World Health Organization (WHO) course "Promoting Rational Drug Use" (PRDU), a set of course materials was developed in Spanish, focused on rational antimicrobial use. The resulting course was called "Promoción del Uso Racional de Antimicrobianos" (PURA) (Promoting Rational Antimicrobial Use), and the materials for it included 20 sessions, each including a trainer's guide and visual aides. The course introduces the problem of irrational use of antimicrobials and presents the conceptual framework for improving the use of antimicrobials. Several sessions explore in detail different practical interventions for achieving a more rational use of antimicrobials, following three main approaches—educational, managerial, and regulatory. All sessions include group exercises and promote interaction among the participants.

2. Conducted regional training-of-trainers (TOT) course: A regional TOT course was conducted in Santa Cruz, Bolivia, from May 29 to June 9, 2000. Nineteen health officials were trained in the PURA course. The participants represented seven countries of the region: Bolivia, Costa Rica, Ecuador, El Salvador, Nicaragua, Paraguay, and Peru. They included physicians, pharmacists, and health educators. As part of the course activities, the participants were grouped in teams to develop pre-proposals for intervention studies to improve the use of antimicrobials. Seven pre-proposals were developed and are currently being refined and expanded by the teams.

3. Developed training materials for Proposal Development Workshop: Based on the existing materials used in the Workshop for Developing Proposals for Improving the Use of Medicines, held in Indonesia in 1997, a set of materials was developed specifically for Latin America. These materials included sessions on proposal structure and content, research design and methodology, sampling techniques, data analysis, obtaining approval from Institutional Review Boards, and developing a budget and a timeline. The materials included lectures with overhead slides, as well as relevant supplemental readings.

4. Conducted Proposal Development Workshop: A Proposal Development Workshop was held in Mexico City, Mexico, from April 24 to May 4, 2000. In preparation for the workshop, the Joint Initiative on Drug Use Intervention Research (composed of the Applied Research in Child Health Project, INRUD, and WHO's Division of the Action Programme for Essential Drugs) issued a call for proposals for the region. Thirteen pre-proposals or letters of intent were received, and 10 study groups were selected following a standardized evaluation procedure. Twenty researchers (two per proposal) participated in the workshop, which introduced the materials described in item 3. The workshop included one-on-one technical support from the facilitators for the research groups to refine their proposals.

Future Steps

1. Further disseminate the conceptual framework for improving the use of antimicrobials, both at regional and national levels. This goal can be achieved by replicating the PURA course as opportunities and interest develop in increasing the number of trained persons. A shorter course format using the key sessions can also be offered, although the course would become much less comprehensive. For example, David Lee, with INRUD, conducted a two-day course on rational use of antimicrobials during a meeting of the Ibero-American Association for the Rational Use of Drugs held in San José, Costa Rica, in September 2000. The course materials developed by RPM will be made available for anyone who wants to replicate the course, fully or in part, at a regional or national level.

2. Continue offering technical support to the proposals for intervention studies developed at the workshop in Mexico, which need to undergo a final review before being approved. At the same time, sources of funding for these proposals need to be explored further. After the

intervention studies are carried out at a pilot level, those that show the most promising results can be rolled out, publicized, and replicated elsewhere.

3. Undertake demonstration projects at the regional level that follow the conceptual framework for improving the use of antimicrobials. One proposed activity is to offer technical support and guidance for the establishment of Drug and Therapeutics Committees in selected hospitals in the target countries. These committees would promote managerial and regulatory changes within their institutions to bring about improvements in the use of antimicrobials, for example, through the introduction and adaptation of the Standard Treatment Guidelines for common infections that the Pan American Health Organization is developing. The Drug and Therapeutics Committees will be created initially in two hospitals in each of four target countries and then expanded to all nine target countries.

Organization of Eastern Caribbean States

Executive Summary

Because of general funding constraints, the Organization of Eastern Caribbean States (OECS) country program was phased out beginning in 1995, followed by reduced core funding for fiscal year 1996–1997. On a final visit, Rational Pharmaceutical Management (RPM) project staff installed an upgrade of the inventory control and procurement software (INVEC)-2 program at five different country sites: Antigua, Dominica, Grenada, St. Lucia, and St. Vincent. Installation was accompanied by on-the-job training and troubleshooting as well as cleaning databases and providing more advanced training. During site visits for this upgrade, remote access software was installed that allowed RPM to provide program maintenance and support by modem. This mechanism provided useful experience for remote access maintenance of drug supply inventory management software for other RPM countries.

Acronyms

CMS	Central Medical Stores
ECDS	Eastern Caribbean Drug Service
HMIS	Health Management Information System [PAHO]
INVEC	inventory control and procurement software
MOH	ministry of health
MSH	Management Sciences for Health
OECS	Organization of Eastern Caribbean States
PAHO	Pan American Health Organization
RPM	Rational Pharmaceutical Management (project)
USAID	U.S. Agency for International Development

Program Overview

The Rational Pharmaceutical Management (RPM) project began work in the Organization of Eastern Caribbean States (OECS) to build on the success of the previous USAID-funded Management Sciences for Health (MSH) project, the Eastern Caribbean Regional Pharmaceutical Management Project (1986–1990), which established the Eastern Caribbean Drug Service (ECDS). Close contact with ECDS and other officials throughout the region helped the RPM project use existing relationships to expand and enhance ECDS capacities in RPM's priority technical areas.

RPM saw an opportunity to assist the OECS in its transitional efforts to identify new sources of supply and management for contraceptives. RPM assisted in the needs quantification of contraceptives and ensured that this information was communicated to ECDS and incorporated in subsequent tender cycles. In addition, RPM saw the potential for collaboration with the large Pan American Health Organization (PAHO) Health Management Information System (HMIS) for Community Health Services of Barbados and the Eastern Caribbean Countries Project.

Overall Strategy

RPM's basic strategy in the Eastern Caribbean was to take advantage of the successful USAID project that had established the ECDS pooled procurement system and to work in collaboration with PAHO. A project needs assessment completed in 1993 concluded that

- No drug registration system existed in the region, and many countries had outdated drug laws. The ECDS policy board intended, however, to harmonize legislation and improve registration.

- There was a need to improve forecasting and quantification of drug needs skills in most islands. Medical store staff needed more training in these areas in order to provide more accurate and timely information to ECDS for the regional tenders.

- The region needed better access to current drug information and needed to develop standard treatment guidelines. Because the region had a functional procurement and distribution system, the importance of ensuring rational drug use became more significant.

Because USAID did not provide contraceptive supplies to countries within the region after July 1994, ministries of health (MOHs) in each country had to take on responsibility for estimating, ordering, storing, and distributing contraceptives. The responsibility for estimating quantities and budget required was transferred from the MOH to the Central Medical Stores (CMS) in each island.

Program Activities

- RPM installed an inventory control and procurement software (INVEC)-2 program in four islands: Dominica, Grenada, St. Lucia, and St. Vincent and the Grenadines. The installation upgraded the original INVEC program in three islands and provided a relational database inventory management software program in St. Lucia for the first time. Staff from the ECDS installed the program in Antigua. RPM provided follow-up support and training to all these INVEC-2 installations to help ensure the smooth and continued functioning of the program and to increase the use of the program's reporting and management capabilities.

- ECPRO, the software that the Eastern Caribbean Drug Service used to manage its pooled procurement and annual tender, was upgraded. The new software package, ECPRO-2, was adapted to monitor orders and payments, and to develop reporting systems for the comparison of cost estimates with consumption.

- RPM and PAHO collaborated on a Report Writer software training course for regional participants.

- An ECDS staff member was established as an effective provider of INVEC-2 software support.

Major Accomplishments

- The INVEC-2 program was effectively installed in Antigua, Dominica, Grenada, St. Lucia, and St. Vincent and the Grenadines. This software helped the CMS of each island better track inventory and forecast drug needs.

- Twenty-two CMS, MOH, and ECDS staff members received advanced training in the R&R Report Writer Software for design and customization of INVEC-2 and ECPRO-2 reports.

- ECPRO-2 was developed and installed at the ECDS offices in St. Lucia, where it was used to manage the tender cycle. With the software, the ECDS is able to manage the annual tender process (with each tender cycle having an approximate value of $2.3 million). One full-time staff member manages the process with the assistance of two others.

Collaborations with Major Donors

The collaborations of RPM and PAHO HMIS staff targeted three basic areas:

- RPM trained four PAHO staff members in INVEC-2, the MSH inventory control and management software. PAHO staff learned both how to use the program and how to install and support it.

- RPM and PAHO cosponsored a Report Writer software training course for participants throughout the region (including 20 CMS staffers and people from the MOH and ECDS). This software was used to produce reports in INVEC-2 and in the HMIS project software.

- RPM made ECDS an effective provider of software support. Most of the INVEC-2 installations in the OECS region corresponded with ECDS first. The ECDS procurement officer observed the installation process both in St. Vincent and the Grenadines and in Grenada, provided the training in St. Lucia, and set up the program independently in Antigua.

Outcomes

The OECS region was originally considered a strong contender for long-term RPM assistance both because of the opportunities it presented and MSH's history in the region. However, because of the closing of the USAID Mission in Barbados and USAID's shift to field-support funding, the RPM activities in the region were cut back. In consultation with USAID staff, RPM decided to place the program in a "maintenance only" status after the four INVEC-2 installations were completed. Beginning in early 1995, RPM work in the OECS was limited to providing support and follow-up to the INVEC-2 installation sites.

In early 1996, an RPM staff member who had previous experience with RPM's installation of INVEC-2 within the OECS went to the region to check the INVEC-2 installations and computers in each of the five islands, to troubleshoot any problems, and to answer questions. Suggestions for improving the program were also solicited. In addition, an upgrade to the program was installed, and support procedures were reviewed. This last task was particularly important, as this trip was the last to the region during the RPM project. In general, INVEC-2 was at the time functioning well in each island, with the exception of Antigua. During this trip, Antigua's INVEC-2 program was updated and the configuration adjusted so that its program also worked well.

Needs at End of Project

The INVEC-2 installations in the OECS continue to need remote support; they also need to receive upgrades. ECDS staff members require periodic assistance in writing additional reports for ECPRO-2, as they find ways to use the program and its upgrades, and to refine its implementation.

Regional Economic Development Support Office

Executive Summary

In 1997, at the request of Regional Economic Development Support Office/East and Southern Africa (REDSO/ESA), the Rational Pharmaceutical Management (RPM) Project joined with the Family Planning Logistics Management (FPLM) project in assessing the condition of drug management and logistics systems in countries in East and Southern Africa, and in identifying the key issues that affected quality of health care. At subsequent regional meetings countries recognized the priority that should be given to logistics, to which REDSO/ESA responded by initiating the Regional Logistics Initiative (RLI), which focuses on documenting and disseminating best practices in logistics from within the region and on providing technical assistance to initiate logistics improvement.

RPM and FPLM jointly developed a work plan for the RLI in March 1999. In just over three years, to June 2000, REDSO/ESA and the African Bureau for Sustainable Development (AFR/SD) jointly financed the RPM component of the RLI program to the extent of $425,000.

The RPM strategy was to implement the program through training, direct technical assistance, and information dissemination to health sector representatives from countries in the region involved in decision making in drug management and logistics and to regional institutions. This was achieved through a number of activities, including a regional workshop on logistics held in March 1998; sponsorship of health personnel from three countries to the MSH Managing Drug Procurement course held in South Africa in October 1999; participation at the SOTA Conference in February 2000; and completion of a report, *Sexually Transmitted Infections: Drug Management Considerations for Sub-Saharan Africa*, which explores the cost of treatments for sexually transmitted infections (STIs) in sub-Saharan Africa by reference to country standard treatment guidelines (STGs) and international drug costs and discusses key procurement-related issues.

The project promoted better practices within the regions, in accordance with the RLI's guiding principles, primarily through the dissemination and application of the Cost-Estimate Strategy (CES) for Improving the Availability and Use of Reproductive Health Commodities. A workshop on the CES was conducted in May 2000 in Mombasa, Kenya, for 25 participants from Eritrea, Ethiopia, Kenya, Mozambique, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe. Of these participants, 15 were sponsored by REDSO through the RPM project. The success of this event owed much to the Kenyan and Zambian participants, who shared their experiences of field-testing CES in Kenya and implementing the methodology at the Coast Provincial General Hospital, Mombasa, and in Zambia. The RPM REDSO program had been involved with both of these applications of the CES methodology.

Although intended to be a collaborative effort with the FPLM project, implementation of the RLI initiative was hampered by a number of institutional and operational factors, some of which were overcome by the recruitment late in the program (November 1999) of a part-time RPM representative to work with the full-time FPLM staff based in Nairobi. The future success of the RLI would benefit from a more equal financial footing and level of effort for logistics as well as drug management and use issues to further the aims of REDSO/ESA in this area.

REDSO/ESA and the RLI have accomplished a great deal in terms of raising awareness among health sector managers of the issues of drug management and logistics, but there is further work to be done, especially in expanding the expertise of local educational and training institutions to continue capacity building in the region.

Acknowledgments

The U.S. Agency for International Development's Regional Economic Development Support Office/East and Southern Africa, Nairobi, Kenya, and the Africa Bureau for Sustainable Development, Washington, D.C, financed the RPM REDSO program. RPM would like to thank Mr. Gil Cripps, Health Financing Advisor, REDSO/ESA, and Mrs. Khadijat Mojidi, Senior Technical Advisor/Health, AFR/SD, for their advice, support, and cooperation during the implementation of the program.

RPM would also like to thank Dr. Margaret Gachara, Coordinator, Regional Logistics Initiative, Nairobi, Kenya, and other staff of the RLI Secretariat for their contribution to this collaborative effort.

Dr. Michael Thuo, Consultant, Nairobi, Kenya, and Mr. Oliver Hazemba, Consultant, Lusaka, Zambia, were key team members, who made a significant contribution to the implementation of the REDSO program through their expertise and local knowledge.

Acronyms

AFR/SD	Africa Bureau for Sustainable Development
CBOH	Central Board of Health (Zambia)
CPGH	Coast Provincial General Hospital
CES	Cost-Estimate Strategy
FPLM	Family Planning Logistics Management (project)
INRUD	International Network for Rational Use of Drugs
JSI	John Snow Inc.
MNH	Maternal and Neonatal Health (project)
MOH	Ministry of Health
MSH	Management Sciences for Health
REDSO/ESA	Regional Economic Development Support Office/East and Southern Africa
RH	reproductive health
RLI	Regional Logistics Initiative
RPM	Rational Pharmaceutical Management (project)
SO	strategic objective
STG	standard treatment guidelines
STI	sexually transmitted infection
USAID	U. S. Agency for International Development
ZIHP	Zambia Integrated Health Project

Program Overview

Background

At the Regional Quality of Care Conference, held in Mombasa, Kenya, in April/May 1997 and sponsored by the Regional Economic Development Support Office/East and Southern Africa (REDSO/ESA), participants from countries in the region identified logistics as a top priority for improving quality of health care. REDSO/ESA addressed this need by developing the Regional Logistics Initiative (RLI), which focuses on documenting and disseminating best practices in logistics from within the region and on providing technical assistance to initiate logistics improvement. Initially REDSO/ESA worked closely with John Snow Inc.'s Family Planning Logistics Management (JSI/FPLM) project to develop the Regional Logistics Initiative. The Rational Pharmaceutical Management (RMP) project of Management Sciences for Health (MSH) was brought into the program to complement FPLM's family planning logistics expertise with its drug management expertise, at USAID/Washington's suggestion. A Secretariat was established for the RLI in Nairobi, Kenya, in mid-1998. In March 1999, RPM and FPLM completed a joint work plan.

REDSO/ESA and the African Bureau for Sustainable Development (AFR/SD) jointly financed the program to the level of $425,000 over the period March 1997 to June 30, 2000.

Objectives

RPM's objectives for the REDSO program were in line with the focus areas of the Regional Logistics Initiative, namely to

- Build capacity in drug supply management
- Advise on the development of integrated logistics systems
- Advocate for efficient management and logistics systems
- Document and disseminate lessons learned and better practices in the region

These goals would be achieved through establishment of a pool of African consultants, development of a network of health personnel, and fostering of south-to-south collaboration.

Implementation Strategy and Major Activities

The RPM strategy was to implement the program through training, direct technical assistance, and information dissemination to health sector representatives from countries in the region involved in decision making in drug management and logistics and to regional institutions. The general focus of these activities was on policy, selection, and procurement of commodities for public health programs in health ministries. It was planned that there would be close collaboration with the JSI/FPLM project, RPM's partner in the REDSO/RLI. RPM's work would

contribute to USAID's strategic objective, SO2: Increased use of safe pregnancy, women's nutrition, family planning, and other key reproductive health interventions.

Principal activities conducted during the period of assistance were

- Development of RLI program
- Assessment of key logistics issues in East and Southern Africa countries
- Participation in regional meetings and workshops to disseminate best practices and promote the key role of logistics and drug supply in improving health care
- Enhancement of regional training capacity through curriculum development
- Preparation of a report on costs of drugs to treat sexually transmitted infections (STIs) in sub-Saharan Africa
- Conduct a regional workshop in the Cost-Estimate Strategy (CES)

Challenges Facing RPM REDSO Implementation

RPM was asked by REDSO to join with JSI/FPLM in the RLI after substantial effort by the latter to generate the interest of key stakeholders in the region and to develop momentum in logistics issues over a period of two years.

JSI/FPLM operated from a long-established field office in Nairobi, Kenya. RPM would not be able to support a full-time presence in the region and would be managing RPM participation from the RPM project office in Arlington, Virginia.

The RLI full-time coordinator was recruited independently of RPM and funded by FPLM.

The low level of funding from REDSO/ESA and AFR/SD enabled RPM to undertake only a limited subset of the originally proposed activities.

Chronological Activity Timeline

Table 1. Activity Timeline

Date	Activity
September 1997	Desktop regional logistics assessment
February 1998	Regional Logistics Workshop, Mombasa, Kenya
February 1999	Workshop and application of Cost-Estimate Strategy at Coast Provincial General Hospital, Mombasa, Kenya
March 1999	Joint RPM/FPLM work plan developed
June–July 1999	Workshop and application of Cost-Estimate Strategy in Zambia
October 1999	Sponsorship of regional health personnel to MSH Procurement Course
October 1999	Publication and dissemination of jointly designed RPM/FPLM brochure on the Regional Logistics Initiative
February 2000	Cost-Estimate Strategy showcased at REDSO Quality of Care Conference, Entebbe, Uganda
March 2000	Development of short-course curriculum in drug management for the Regional Centre for Quality of Health Care
May 2000	Regional Cost-Estimate Strategy Workshop, Mombasa, Kenya
July 2000	Desktop study on drug costs for the treatment of STIs in Africa

Program Accomplishments

Policy and Regulation

REDSO/ESA requested that both the Rational Pharmaceutical Management (RPM) project and the Family Planning Logistics Management (FPLM) project conduct a desktop assessment of the state of drug management and logistics in eight countries in the region. Components of RPM's pharmaceutical assessment tool were incorporated with FPLM's Composite Indicators to develop a methodology for obtaining appropriate information for the study. Four generic, or cross-national, issues emerged that were consistent with the overall objectives of the Regional Logistics Initiative.

- How to build and maintain sustainable (drug and contraceptive) logistics systems from donor assisted interventions.

- How to make (contraceptive and drug) logistics systems more effective and efficient within the context of health sector reform.

- How to build and maintain commitment—including the allocation of adequate resources—to logistics by program managers, policy makers, and donors.

- How to maintain effective coordination among all the partners (i.e., host government and donors) to ensure that inputs to contraceptive and drug logistics systems are managed rationally.

The findings of the study also led to the synthesization of issues into two themes—"better practices" and "common problems"—and confirmed the need for a regional workshop.

RPM and FPLM jointly conducted a Regional Logistics Workshop in Mombasa, Kenya, in February 1998. Representatives from seven countries in the region attended (Botswana, Eritrea, Kenya, Mozambique, Tanzania, Uganda, and Zambia). RPM presented technical sessions on the Procurement of Public Health Commodities, Issues in Financing, and Moving toward Sustainability and Policy Development for Logistics Improvement and Health Sector Reforms. These, together with FPLM presentations on Human Resources as a Logistics Component, LMIS and Management Support, Private Sector Logistics Methodologies Adapted to the Public Sector, and Stores Management, provided the participants with an opportunity to understand the key aspects of logistics in quality of care and to use this knowledge as a basis for developing country-specific action plans.

The workshop was also used as the basis for the establishment of a task force to further develop the Regional Logistics Initiative and resource group. It also initiated the development of a south-to-south network, membership details of which are recorded in a specially created database managed by the RLI. The workshop also produced draft country-specific logistics work plans.

Dr. M. Thuo (Kenyan consultant to RPM) represented RPM at the regional conference *Improving the Quality of Care: State of the Art 2000*, conducted by REDSO/ESA for policy makers and other governmental representatives; USAID Health, Population, and Nutrition officers; and cooperating agencies active in the region. The conference aimed to further establish the significance of drug management and logistics in achieving and maintaining quality of health care services by (1) disseminating better practices that improve the quality of health care, and (2) assisting in the expansion of usage of better practices throughout the region. The Cost-Estimate Strategy—a tool developed by RPM for improving the use and availability of reproductive health commodities—was demonstrated at the conference.

Management Information Systems

Implementing the Cost-Estimate Strategy

The Cost-Estimate Strategy (CES)—field-tested in Kenya in 1997—was applied at the Coast Provincial General Hospital (CPGH), Mombasa, to the services planned for a newly renovated maternity ward. RPM conducted a workshop in February 1999 to introduce staff from the CPGH to the methodology and to train them in its use. The CPGH staff successfully used the CES to cost the drugs, medical supplies, and equipment required to treat and provide a selected range of reproductive health conditions and services. This has led to improved procurement, heightened awareness of the cost implications of reproductive health (RH) commodities, and the development of a rational commodity budget for the maternity ward.

In addition, RPM supported the participation of a regional consultant, Mr. Oliver Hazemba, at the workshop so that he would develop expertise in the tool and be able to contribute to future dissemination and applications of the CES.

In conjunction with the RPM Zambia country program, RPM introduced and applied the Cost-Estimate Strategy in Zambia in June and July 1999. Mr. Oliver Hazemba was engaged to coordinate this activity with the Zambian Central Board of Health (CBOH) and Ministry of Health (MOH) and USAID's Zambia Integrated Health Project (ZIHP) with the objective of assessing the supply and cost of commodities for RH services. A team of RPM project staff members, CBOH and MOH officials, and others implemented the CES at 14 hospitals and 139 health centers in the 11 USAID-supported districts. Local experts identified 14 RH conditions for study, defined the standard treatment guidelines (STGs) for each condition, and established other survey parameters. Data collectors visited sites and the data were analyzed using the CES spreadsheet tool. Key findings include

- The three RH conditions and services with the highest costs per case were puerperal sepsis, family planning, and C-section.
- For 66 percent of conditions studied, treatment costs were estimated to be higher when supplies were purchased using local rather than international costs.
- Half of the estimated total drug and supply costs for addressing all 14 RH conditions, excluding family planning, were attributable to basic antenatal care.

As a result of the effort, donor agencies have used the CES data to help determine funding levels in country. The process as a whole has contributed to closer coordination between donors and organizations working in the RH sector. It also heightened awareness of and stimulated discussion about the real costs of offering RH services.

A report—*Assessment of Commodity Needs for Integrated Reproductive Health in Zambia: Applying the Cost-Estimate Strategy*—was published in July 2000.

Regional Cost-Estimate Strategy Workshop

In order to disseminate the CES in the region, a workshop was conducted in May 2000 in Mombasa, Kenya. Twenty-five participants—15 sponsored by REDSO through the RPM project—came from seven countries in the region, including Kenyans and Zambians who had agreed to share their experiences of field-testing CES in Kenya and implementing the methodology at the Coast Provincial General Hospital, Mombasa, and in Zambia. The countries represented were Eritrea, Ethiopia, Mozambique, Rwanda, South Africa, Uganda, and Zimbabwe. The objectives—fully achieved—were

- To demonstrate the utility of the Cost-Estimate Strategy for better informed decision making in reproductive health programs
- To present program managers and policy makers with an opportunity to review and discuss the benefits and outcomes of CES with implementers of the methodology in Kenya and Zambia
- To assist interested participants to identify, share, and refine their next steps in considering and planning for the introduction of CES to their country situation

When participants reported back on their deliberations for next steps, all recognized CES as a potentially useful tool. Several planned to promote the methodology to appropriate stakeholders and identified the need for financial support—primarily to come from ministries of health.

The proceedings from the workshop were published in November 2000.

CES Recognized as a Better Practice

One of the aims of the RLI is to identify better practices in drug supply and logistics management and disseminate these throughout the region. The CES has been recognized as such and a "better practice" flyer has been prepared for dissemination.

Human Resource Development

RPM sponsored the participation of a Kenyan, a Tanzanian, and a Zambian to the MSH Managing Drug Procurement course held in Durban, South Africa, in October 1999. The participants worked in the Medical Stores Coordinating Unit (the Kenyan Ministry of Health's central drug storage and distribution organization); the Central Medical Stores, Dar es Salaam; and the Central Board of Health, Lusaka, respectively. The course provided the participants with an understanding of different procurement methods, selection and cost analyses (ABC and VEN), tendering procedures, and contracting and negotiation skills.

Local consultants Dr. Michael Thuo (Kenya) and Mr. Oliver Hazemba (Zambia) were exposed to the CES and have become key practitioners of the methodology. Their expertise in CES should prove very useful to future activities in the region.

RPM provided technical input to the curriculum of the Regional Centre for Quality of Health Care at Makerere University course on Drug Management and Logistics for Public Health and provided a draft curriculum for a short course on Drug Management to the director of the center for discussion.

Program Management

In 1998 the Regional Logistics Initiative was more formally structured by the establishment of a Secretariat based in Nairobi, Kenya, and the recruitment of a full-time coordinator, Dr. Margaret Gachara, and other support staff. In November 1999, RPM recruited Dr. Michael Thuo to represent RPM on a part-time basis (funding was insufficient to place a full-time representative). Dr. Thuo had undertaken consultancies for RPM in the past and was well recognized in the region for his work in drug management.

A series of quarterly reports describing the implementation of the activities of both RPM and FPLM and outlining the future planned activities of the Regional Logistics Initiative were prepared in the month following the quarter reported on.

RPM and FPLM jointly developed a brochure for the Regional Logistics Initiative that described the objectives and focus of the RLI and was widely distributed to USAID missions, government representatives, and other appropriate organizations in the region.

Drug Information

A report, *Sexually Transmitted Infections: Drug Management Considerations for Sub-Saharan Africa*, was prepared that explores the cost of treatments for STIs in sub-Saharan Africa by reference to country standard treatment guidelines and international drug costs. Issues concerning the funding, procurement, and supply of STI drugs are discussed. The report was published in July 2000.

Activities Not Completed

It was planned to conduct technical assistance to a country in the region to apply the CES tool. Discussions took place with the Maternal and Neonatal Health (MNH) project to extend the application of CES in Zambia by using CES to assist in the development of national standard treatment guidelines. It was not possible to coordinate this with MNH before the closure of the RPM project.

A Rational Drug Use workshop planned to be held in Tanzania in 1999 was not implemented because (1) delays occurred in agreeing on work plans, (2) funds were unavailable, and (3) the International Network for Rational Use of Drugs (INRUD) Tanzania, in collaboration with INRUD Washington, organized a workshop on Promoting Rational Drug Use (May 1999) that lessened the need for a separate Tanzania-specific workshop.

Likely Needs at End of Project

Improved joint project protocol and a coordination mechanism are needed for the RLI Secretariat.

The CES tool is best implemented in a country situation with appropriate in-country technical assistance. Following the dissemination of the CES tool, further in-depth country assistance is likely to be requested from those countries wanting to apply the tool.

Quality of care can be improved through addressing logistical issues of distribution, storage, and management information systems, but further emphasis needs to be placed on the selection and procurement of reproductive health commodities and on rational drug use (which could not be adequately covered under the existing funding). Further activities in this area could be helpful to address these topics.

Lessons Learned

The program would have been better served had the basis for the partnership of the two projects in the Regional Logistics Initiative been that of an equal footing in terms of access to sponsoring organization(s), funding levels, programmatic decision making, and so forth.

Any future partners in the RLI need to recognize that advocacy and promotion of logistics and drug management issues form the core rationale for the initiative and to agree jointly on the scope of RLI activities.

The importance of drug management and logistics in the provision of quality health care has not been fully recognized within countries from the East and Southern Africa region. Or if the understanding of the relevance of these components does exist, the commitment of governments to establishing, improving, and maintaining efficient drug and logistics management systems is still not fully developed. Further efforts in advocacy and dissemination of better practices are required.

Given that there are success stories in health programs within the region, more can be achieved if there is greater south-to-south networking, cooperation, and exchange.

Bangladesh

Previous Page Blank

Executive Summary

Beginning in 1997, the Rational Pharmaceutical Management (RPM) Project provided assistance to the National Integrated Population and Health Program (NIPHP) in Bangladesh. NIPHP is a partnership of nongovernmental organizations (NGOs) that provides primary health care and family planning services through some 350 clinics. Each clinic manages a limited stock of drugs for sale to patients. RPM and NIPHP agreed to work toward three objectives:

1. Assist NIPHP to develop an Essential Drugs List (EDL) and standard treatment guidelines (STGs).

2. Assist NIPHP to implement Revolving Drug Funds (RDFs) in all of the clinics.

3. Assist NIPHP-affiliated facilities to rationalize drug use in the clinics

After presenting a three-pronged work plan, which was approved by NIPHP and USAID, RPM provided direct technical assistance and training to NIPHP—

- To conduct a case study and situation assessment

- To develop an EDL and STGs

- To train key NGO staff in rational drug use (RDU) principles

- To design and deploy three Monitoring-Training-Planning (MTP) modules to implement RDFs in each NGO

As a result, the NGOs and clinics are all permanently stocked with EDL drugs and all have functional RDFs that are generating modest excess revenues.

RPM also assisted NIPHP to create and apply MTP modules to improve RDU at the clinic level. After applying the first of these in August–September 1999, NIPHP was preparing to deploy the other two in early 2000.

Acknowledgments

Nasiruzzaman, USAID
Shabnam Shanaz, RSDP/Pathfinder
Peter Connell, UFHP/John Snow Inc.
Masud, Quality Insurance Partnership/Association for Voluntary Surgical Contraception (now EngenderHealth)
Salaudin, RSDP/Pathfinder
Sadia Parveen, UFHP/John Snow Inc.

Although these persons are not listed by name, RPM would like to acknowledge the support of the many individuals in the Bangladesh Ministry of Health and the members of the nongovernmental organization network who contributed to this project.

Acronyms

BRAC	Bangladesh Rural Advancement Committee
EDL	Essential Drugs List
ESP	Essential Services Package
INRUD	International Network for Rational Use of Drugs
JSI	John Snow Inc.
MO	medical officer (responsible in each clinic)
MOH	Ministry of Health [Bangladeshi]
MTP	Monitoring-Training-Planning
NGO	nongovernmental organization
NIPHP	National Integrated Population and Health Partnership
PD	project directors (in each NGO)
RDF	Revolving Drug Fund
RDU	rational drug use
RPM	Rational Pharmaceutical Management [Project]
RSDP	Rural Service Delivery Partnership [Pathfinder]
SDL	Standard Drug List
STG	standard treatment guideline
TA	Technical assistance
TD	*thana* director (responsible for rural clinics in a district or *thana*)
UFHP	Urban Family Health Partnership [JSI]
USAID	U.S. Agency for International Development

171

Program Overview

Background

In September 1996, USAID launched the National Integrated Population and Health Program (NIPHP). This program is implemented by seven nongovernmental organization (NGO) partners, each of which manages a different element of the program. Two of the partners, John Snow Inc. (JSI) and Pathfinder, coordinate the service-delivery components: Urban Family Health Partnership (UFHP) and Rural Service Delivery Partnership (RSDP). Through these programs, primary care and family planning services are provided in 350 clinics of 46 health service NGOs affiliated with UFHP and RSDP around the country. Each clinic manages a limited stock of drugs for sale to patients.

USAID/Dhaka requested that RPM assist NIPHP to implement revolving drug funds (RDFs) in all of the service NGOs and to improve drug use in the clinics. RPM responded by assisting NIPHP to develop an Essential Drugs List (EDL) and standard treatment guidelines (STGs) for approximately 20 of the most frequent conditions seen in the clinics. RPM also provided training to key NGO staff in rational drug use (RDU) principles and facilitated the design and deployment of three Monitoring-Training-Planning (MTP) modules to implement RDFs in each NGO. The NGOs have applied these MTP modules and all have functional RDFs as of February 2000. Indicators to assess and monitor RDF operation were developed and incorporated into a fourth MTP module to be applied in late 1999 in order for NGOs to evaluate their performance. A composite index of "satisfactory" RDF performance was developed for USAID R4 results reports.

RPM also assisted NIPHP in creating and applying MTP modules to improve RDU at the clinic level. These modules were designed in early 1999 and translated by NIPHP personnel for field-testing in mid-1999. The first of these modules was applied in NGOs and clinics in August–September 1999. Each module contained a performance indicator related to the objective of the module, and it was expected that clinics and NGOs would regularly monitor their performance using these indicators.

Objectives

- Assist NIPHP to develop a Standard Drug List (SDL) and STGs for all participating clinics
- Assist NIPHP to implement RDFs in all of the service NGOs and clinics
- Assist NIPHP-affiliated facilities to rationalize drug use in the clinics

Implementation Strategy and Major Activities

RPM's overall strategy was to assist NIPHP to develop and deploy tools to allow service-providing NGOs and clinics to implement revolving drug funds and improve RDU performance.

Major RPM activities included the following:

- Prepare a work plan. The initial RPM work plan presented to USAID/Bangladesh in February 1997 proposed a three-phase set of activities, lasting about two years.

  1. Initial information gathering and assessment (9 months). Key activities included gathering background information, estimating drug cost recovery capitalization requirements, assuring availability of start-up capital, measuring results obtained by existing NGO drug management operations, and clarifying potential regulatory problems.

  2. Design drug-management systems (12–18 months). Key activities included creating a drug management group to coordinate NIPHP's RDF and RDU efforts; proposing and designing models for drug cost recovery in both rural and urban settings; developing, testing, and revising required RDF manuals and training materials; proposing and designing methods for promoting rational drug use; and developing, testing, and revising required RDU training materials.

  3. Implementation, monitoring, and evaluation (during phase 2). Key activities included training NGO staff and implementing cost recovery systems, monitoring and evaluating results, training NGO staff and implementing systems to promote rational drug use, and monitoring and evaluating RDU results.

RPM identified inputs necessary to put the plan into action. These were—

- Seed capital to finance start-up of revolving drug funds. Using the Bangladesh Rural Advancement Committee (BRAC) model of physician-staffed clinics with $750 of capital per clinic, RPM suggested that 100 such sites would require about $75,000, without taking into consideration differences in service packages to be provided, delivery systems, and consumer demand.

- Local implementation costs. Although costs were not estimated in detail, RPM assumed that NIPHP partners would provide the costs out of their project funding for staffing the drug management group; conducting observation tours; carrying out training, workshops, and in-country travel; and providing materials.

- Technical support provided by RPM. RPM assumed that periodic, short-term technical assistance (TA) to the drug management group would be paid by USAID. TA was to focus on quantification of drug needs and capitalization requirements, assessment of cost recovery and RDU operations, design and testing of systems, and monitoring and evaluation of results. Services to be provided were—

173

- Experts in drug financing, procurement, and promotion of RDU
- Tested approaches to indicator-based assessment and computer software for drug needs quantification, management of competitive procurement, and analysis of prescribing practices
- Training opportunities, including visits to observe community interventions in RDU and participation in the International Network for Rational Use of Drugs (INRUD) courses on RDU

- Conduct case studies and situation assessment. RPM advisors carried out a detailed case study of the BRAC drug system including drug selection procedures, competitive procurement from qualified suppliers, and distribution chain from suppliers to regional distribution points through physician-staffed clinics and on to community-based health workers. The BRAC model became the basis for design of the NIPHP system.

  RPM also identified information to be collected for the situation analysis and assigned responsibility for specific data-collection activities to NIPHP partners, assisting the NIPHP partner responsible for operations research (International Centre for Diarrheal Disease Research, Bangladesh) to prepare a survey instrument to gather information on existing NGO drug supply operations.

- Develop an Essential Drugs List. RPM technical experts assisted in formulation of the NIPHP Essential Drugs List based on the Essential Services Package (ESP), which set forth the 18 components (conditions and diseases) for which NIPHP provides services. The ESP Essential Drugs List consists of 66 active ingredients in 83 presentations. The list specifies dosage and principal indications for use as well as side effects and contraindications.

- Assess revolving drug practices among NIPHP NGOs. RPM advisers prepared the research design and two questionnaires for the study. After the study had been conducted by UFHP and RSDP in a sample of their NGOS, RPM assisted in the analysis and interpretation of results, which were instrumental in estimating capitalization requirements.

- Develop standard treatment guidelines. RPM reviewed the NIPHP draft STGs and advised on optimal format and organizing principles in light of health care providers and needs of the ESP. The adviser also suggested what type of drug information should and should not be included in the STGs and assisted with preparation of the final document.

- Train key NGO staff in rational drug use (RDU) principles. Two activities were undertaken:

- A group of four NIPHP professionals participated in the INRUD RDU course offered in Nepal.

- An RPM team conducted training in RDU principles and practice for more than 60 clinic medical officers (MOs) and project directors (PDs).

- Design and deploy three Monitoring-Training-Planning (MTP) modules to implement RDFs. RPM introduced the MTP implementation methodology and designed the three RDF modules. RPM also assisted in preparation of the RDF management manual, which NIPHP used to implement the revolving drug funds in all 46 NGOs and their 350 affiliated clinics. The RPM adviser conducted training for NGO finance and administration managers and PDs on application of MTP in their organizations.

- Develop indicators to assess and monitor RDF operation. RPM advisers developed three performance indicators, which were incorporated into MTP modules in order to monitor RDF outcomes. In this way, monitoring data became available for central NIPHP offices to assess management and results of the funds in each NGO.

- Create and apply MTP modules to improve RDU at the clinic level. RPM conducted workshops for key NIPHP staff to create MTP modules on RDU. Three modules were designed, translated, and field-tested. One module was applied in late 1999.

- Design indicators related to the RDU objectives. Improvements in rational drug use by prescribers and dispensers were to be monitored by clinic staff and NGOs using indicators developed with RPM assistance. One indicator concerning use of standard prescriptions and the STG in diagnosing and treating was applied using the respective MTP module.

- Develop criteria for "satisfactory" RDF performance. RPM proposed eight criteria for determining satisfactory performance of RDFs for use in USAID's R4 results report. These were—

  1. Order quantities and trigger stock levels calculated within last 3 months

  2. Drug sales per month greater than or equal to one-third of initial stock level for the month

  3. Exemption/exoneration policy defined

  4. Policy on receipt of donated drugs defined

  5. Prices less than or equal to 10 percent of manufacturer's retail price

  6. All stocked drugs on the Essential Drugs List

7. Proportion of prescriptions actually dispensed greater than 50 percent of prescriptions issued

8. Zero days of stock-outs

Challenges Facing RPM Bangladesh Implementation

A series of conditions existed at the beginning of RPM work in Bangladesh that represented important challenges for implementation. Among these were—

- Multiplicity of actors: 7 partners in NIPHP
  46 health service NGOs
  350 clinics

  The challenge for RPM was to help NIPHP devise an implementation strategy that could quickly and inexpensively reach all levels and ensure basic RDF activities were carried out and RDU behaviors were adopted.

- Geographic diversity (rural and urban) and wide range of professional capability (physicians, paramedics) in NGO clinics. While RPM initially assumed that different approaches would be needed to deal with this diversity, the NIPHP partners were able to adapt the content and focus of the MTP modules to deal with the differences. As a result, the overall methodology was successfully applied in both rural and urban contexts.

- NIPHP focus on project directors and *thana* directors (TDs). Virtually all communications in the NIPHP system are directed through the PDs and TDs in the NGOs. NIPHP recognizes that their absorptive and response capacity has been frequently exceeded. This limitation was a constraint on the implementation methodology.

Chronological Activity Timeline

RPM activities in Bangladesh were initiated in 1996 with a brief visit by the RPM Director to reconnoiter the NIPHP project and establish feasibility of cost recovery for the NIPHP clinics. Subsequently, two activity streams were identified: one for creating revolving drug funds and one for rational drug use. These two streams were developed in 1998 and 1999 with close down of the RPM country program in early 2000.

Table 1. Activity Timeline

Date	Activity
September 1996	Initial reconnaissance visit to Bangladesh; assess feasibility of drug cost recovery for NIPHP NGOs
February 1997	Technical assistance to develop tentative work plan with two activity streams: revolving drug funds and rational drug use
November 1997	Technical assistance to organize NIPHP Drug Management Committee and identify data collection needs for RDF implementation
December 1997	Conduct case study of BRAC as model for cost recovery
March 1998	Training of four NIPHP participants in RDU at INRUD workshop in Nepal
June 1998	Develop Standard Treatment Guidelines and Standard Drug List
July 1998	Design MTP implementation strategy and prepare draft RDF modules Calculate drug and capital needs for RDFs
September 1998	Training in RDU for NGO project directors and clinic managers
October 1998	Training: introduction to MTP and RDF module for finance managers Roll out first MTP module and RDF manual (NIPHP began distributing RDF seed capital in January 1999)
July 1999	Monitor application of RDF modules by NIPHP and clinics; design RDU modules
February 2000	Supervise application of MTP modules and collect monitoring information on RDFs; close out RPM activities

Program Accomplishments

The accomplishments of the RPM-Bangladesh program can be grouped by technical activity areas as follows.

Financing

Revolving drug funds are operating successfully in all 360 clinics. Costs are being recovered and a modest, excess revenue is accumulating that will increase the financial sustainability of the NGOs. This program accomplishment was the result of three principal efforts.

- The BRAC case study provided important inputs for the design of the RDFs, including such aspects as negotiations with suppliers, use of an essential drugs list and prescribing guidelines, pricing and distribution policies, handling of sales receipts, and the like.

- The situation analysis of NGO experience with RDFs which revealed previous levels of capitalization, turnover ratios, costs and pricing as well as experience with unwarranted numbers of brand-name products.

- Finally, RPM with RSDP and UFHP used the NIPHP information system to estimate caseloads and establish epidemiological profiles so that STGs could be applied to calculate capital requirements for the RDFs. With this calculation, it was possible to accomplish the successful donation of seed capital by SMC.

Selection

The Essential Drug List is the foundation for the RDFs as well as RDU. Most doctors and paramedics were using drugs according to their clinical experience and those suggested by drug salesmen. As a program accomplishment, the EDL has improved drug selection by reducing the latitude for such behavior and has forced NGOs and clinics to concentrate their resources on the drugs that are truly necessary for primary care.

Procurement

All NGOs use suppliers selected by NIPHP on the basis of competitive bids. Suppliers have signed contracts to supply EDL drugs at preferential prices directly to the clinics ordering them. Consolidated payment is made monthly by the NGO headquarters. NGOs are ordering drugs by generic name.

Distribution

The key accomplishment of the program in this area is that NGOs do not stock and distribute drugs, thus reducing labor and capital requirements; rather, distribution is provided by the drug suppliers. This provision was built into the RDF manual as prepared by NIPHP with RPM assistance. Additions and amendments to the manual are being introduced to bring it up to date, for example, how to handle overstocking.

Rational Drug Use

In RDU, the principal accomplishment is that the standard treatment guidelines, which are the basis for daily prescribing practice, are being studied and applied during the appropriate MTP sessions. Key NIPHP staff who participated in the INRUD workshop on RDU are guiding the design of the MTP modules for RDU.

Program Management

The most significant accomplishment in this area is that RDF management has become an integral part of clinic and NGO programs. The RDF manual, along with the EDL and STGs, is the basic tools for project and thana managers. They have also learned to apply the MTP modules so that further topics can be developed and implemented using this tool to strengthen program management at the grassroots level.

Activities Not Completed

As of the close down of RPM activities in Bangladesh, two MTP modules for improved drug use had not been implemented by the NIPHP partners. Although RPM had completed the activities related to the deployment of these modules, the NIPHP staff person responsible for their completion took a leave of absence without completely apprising her replacement of her new responsibilities. The incompletely deployed modules were—

- Diagnosis and treatment of acute respiratory infections according to STGs
- Patient counseling to improve treatment compliance

The NIPHP is completing translation and field-testing of the first and will undertake a rewrite of the second before deploying it in mid-2000.

Likely Needs at End of Project

The USAID Mission in Bangladesh has suggested expanding the application of the NIPHP experience with RDFs and RDU to other Bangladeshi institutions including—

- The Ministry of Health (MOH). MOH service facilities provide centrally procured and distributed drugs. However, central financing has not kept up with demand and facilities are frequently out of stock.

- Non-NIPHP NGOs. Many other health NGOs operate in Bangladesh and may be able to apply the NIPHP model, both for organization of services and supply and use of drugs.

Discussions have been held about the possibility of using the URMES model (program and methodology developed in Ecuador for teaching health and rational drug use in primary and secondary schools) in Bangladesh.

Lessons Learned

The wide dissemination and application of MTP in 360 clinics with only a preliminary orientation to the methodology revealed several limitations that should be taken into consideration by NIPHP and other implementers of MTP in the future.

- MTP is not a one-time fix. Modules must be reapplied by clinic staff, at least whenever there is turnover of personnel. This induction of new staff will ensure that RDF operations are understood by all and RDU standards are applied uniformly.

- Sponsoring organizations (i.e., UFHP and RSDP) must motivate NGOs and clinics to apply the MTP modules by conducting follow-up to verify that commitments are fulfilled (i.e., monitoring checklists). NGOs must follow up with clinics.

- Translation and field-testing are especially important for producing effective MTP modules. Translators do not necessarily appreciate the degree of horizontal interaction and team-building aspects of the MTP sessions and may provide excessively "directive" instructions that undermine these principles.

- Doctors writing MTP modules tend to write for other doctors, using terminology and assumptions about medical education and experience (e.g., what is a generic name) that are not valid for nonmedical personnel. MTP modules written by doctors may lack key elements (e.g., list of generic names and equivalent brand names) for successful application by profit versus safety-net organizations.

Central Asian Republics

Executive Summary

Background

The Rational Pharmaceutical Management (RPM) Project was developed by the U.S. Agency for International Development (USAID) and has been implemented in more than 20 countries worldwide. The project provides technical assistance and training to public health specialists in improving the pharmaceutical sector. In the Newly Independent States (NIS), RPM has implemented programs in Russia, Ukraine, Moldova, and Kazakhstan.

From November 1998 to June 2000, RPM worked with Kazakhstan public health officials, regional pharmacy professionals, and the donor community to highlight the role of drug procurement and management in strengthening disease management. On request from the USAID Mission in Almaty, RPM provided short-term technical assistance, training, and facilitated policy dialogue in various aspects of drug management.

This report summarizes the RPM objectives, activities, and accomplishments of the technical assistance, followed by recommendations for further efforts in the region and lessons learned.

Objectives

The objectives of the RPM Central Asian Republics (CAR) program included—

- Increase local capacity in pharmaceutical procurement in order to—
  - Develop understanding of the drug procurement cycle and procurement techniques
  - Help local counterparts improve tuberculosis (TB) tender documents and processes
  - Observe TB tender and provide comments and recommendations

- Capacitate oblast-level managers in formulary system implementation approaches

- Capacitate oblast-level managers in conducting indicator-based pharmaceutical sector assessment and use of pharmaceutical indicators for monitoring performance and outcome

- Initiate dialogue about pharmaceutical policy options between national and oblast-level decision makers

Implementation Strategies

To achieve the set goals and objectives, RPM used a variety of implementation strategies. These included training workshops in drug procurement and cost-effective drug selection, hands-on technical assistance in developing standard bidding documents for national TB tenders,

observation of the national TB tender and provision of comments and analysis, an indicator-based pharmaceutical sector assessment, and a policy options workshop.

Cooperation with Other Projects

RPM was instrumental in bringing together experts from the CAR-based, USAID-funded projects and building upon local expertise developed by those projects. The RPM CAR activities were carried out in collaboration with the USAID ZdravReform Project implemented by Abt Associates, and some activities at various times were carried out in collaboration with Project HOPE, the Academy for Educational Development (AED), World Health Organization (WHO), and Centers for Disease Control and Prevention (CDC). Collaboration was approved and received firm support from the USAID/Almaty Mission.

Accomplishments

The following major accomplishments and results highlight RPM's impact in Kazakhstan.

- Forty-one pharmaceutical sector professionals from nine NIS countries were trained in competitive procurement practices.

- Standard bidding documents and drug specifications compliant with internationally accepted procurement standards were developed for the National TB Program.

- RPM and several counterparts made suggestions to improve the mix of TB drugs being procured. As a result 83 percent of the drugs procured through the 1999 TB tender were DOTS (Directly Observed Treatment, Short-course)-compliant, up from 26 percent in 1998.

- Despite higher drug quality standards, prices for first-line TB drugs were 1.5 percent lower than in 1998. RPM observed that the 1999 TB tender was transparent and followed standard norms and procedures.

- More than 100 health workers from throughout Karaganda Oblast representing major hospitals and family group practices were trained in cost-effective drug selection and formulary system implementation.

- A pharmaceutical sector assessment was conducted in Karaganda Oblast that identified gaps in the oblast's pharmaceutical system and suggested possible actions to correct those problems.

- The draft program for developing drug policy and reforming the Karaganda Oblast pharmaceutical sector was designed and approved by the Karaganda Oblast decision makers at a policy options workshop that followed the assessment.

Drug management in Kazakhstan has been strengthened at both the national and oblast levels by the capacity-building activities described above. To make the RPM efforts sustainable, the present report outlines recommendations for further reforms of the pharmaceutical sector, including development of national and oblast drug policies, further improvements in tender practices, establishment of drug information centers, and the implementation of drug procurement and use monitoring mechanisms.

Acknowledgments

The Rational Pharmaceutical Management (RPM) Project would like to extend special acknowledgment to the following persons (in alphabetical order) for their support of the RPM activities in the Central Asian Republics:

USAID/Almaty

Indira Aitmagambetova
Sherry Carlin
Mary Skarie
Kathrin Stratos

Academy for Educational Development (AED/Almaty)

Lusine Mishanina
Mikhail Zemskov

The Republic of Kazakhstan National Agency for Health

Serik Abdrahmanov
Erkin Durumbetov
Marua Omarova

Karaganda Medical Academy

Alexander Gulyaev

The USAID ZdravReform Project/Almaty, Abt Associates

Grace Hafner
Alexander Katsaga
Talgat Nurgozhin
Olga Zuz

Project HOPE/Almaty

Kestutis Miskinis
Michael Zeilinger

Karaganda Oblast Health Administration

Kanat Ermekbaev

Center for Health Purchasing Densaulyk

Nadezhda Khe

Acronyms, Initialisms, and Glossary

AED	Academy for Educational Development
Akimat	Oblast Administration
CAR	Central Asian Republics
CDC	Centers for Disease Control and Prevention
CHP	Center for Health Purchasing [*Densaulyk*]
DMIS	Drug Management Information System
DMTB	Drug Management for Tuberculosis
DRG	diagnosis-related group
DOTS	Directly Observed Treatment, Short-course
DUR	drug utilization review
EDL	Essential Drug List
ENI	USAID Bureau for Europe and the Newly Independent States
FDC	fixed-dose combination
FGP	family group practice
FTC	Formulary and Therapeutics Committee
GMP	good manufacturing practices
KNCV	[Royal Netherlands Tuberculosis Association]
IUATLD	International Union Against Tuberculosis and Lung Disease
MDRTB	multidrug-resistant tuberculosis
MIS	management information system
MoHES	Ministry of Health, Education, and Sport (from late 1999, the National Agency for Health)
MSH	Management Sciences for Health
NIS	Newly Independent States
NIT	National Institute of Tuberculosis
oblast	[comparable to a U.S. state]
PHC	primary health care
rayon	[comparable to a U.S. county]
RPM	Rational Pharmaceutical Management [Project]
SBD	standard bidding document
TB	tuberculosis
USAID	United States Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

Program Overview

Background

In August 1998 the USAID Europe and Newly Independent States (ENI) Bureau requested that the Rational Pharmaceutical Management (RPM) Project develop a country program on pharmaceutical management in the Central Asian Republics (CAR). Initial findings showed that there was interest in procurement training within the CAR public health sector. Furthermore, RPM determined that pharmaceutical procurement processes recently used in Kazakhstan did not conform to internationally accepted norms. This was evident in the flawed process and outcomes of the 1998 Kazakhstan national tuberculosis (TB) tender. As a result, RPM recommended that pharmaceutical procurement systems in Kazakhstan be strengthened to improve procurement techniques, competition, and transparency, and that special attention be given to bolster the TB drug procurement process.

In August 1999, on request from the USAID/Almaty Mission, RPM developed a country program that included training in cost-effective drug selection and procurement methods for *oblast*-level health managers. (An oblast is comparable to a U.S. state.) The program was concluded with an in-depth, indicator-based pharmaceutical sector assessment in Karaganda Oblast followed by a Pharmaceutical Policy Options Workshop.

Objectives

The RPM objectives and tasks in the CAR included—

- Increase local capacity in pharmaceutical procurement in order to—
  - Develop understanding of the drug procurement cycle and procurement techniques
  - Help local counterparts improve TB tender documents and processes
  - Observe the TB tender and provide comments and recommendations
- Capacitate *oblast*-level managers in formulary system implementation approaches
- Capacitate oblast-level managers in conducting an indicator-based pharmaceutical sector assessment and using pharmaceutical indicators for monitoring performance and outcome
- Initiate pharmaceutical policy options dialogue between national and oblast-level decision makers

Implementation Strategy and Major Activities

To achieve the set goals and objectives, RPM used a variety of implementation strategies, including—

187

- Training workshops in drug procurement and cost-effective drug selection
- Hands-on technical assistance in developing standard bidding documents (SBDs) for national TB tenders
- Observation of the national TB tender and provision of comments and analysis
- Training and hands-on assistance in conducting an indicator-based pharmaceutical sector assessment
- Financial support for collecting and analyzing the indicator data
- Dissemination of the assessment results, and assistance to local counterparts in developing the agenda for the policy options workshop
- Coordination of the USAID-funded projects in addressing the issues of pharmaceutical sector management
- Policy dialogue between the oblast and national-level governments
- Capacitation of oblast-level decision makers in developing a drug policy
- Dissemination of RPM materials on formulary system implementation and drug information developed during the RPM/Russia and RPM/Ukraine projects

The RPM training courses on drug selection and procurement were built around well-tested training modules based on the MSH/World Health Organization (WHO) book *Managing Drug Supply*. Use of Russian-language materials and manuals developed by RPM during the 1993 to 1999 activities in Russia, Ukraine, and Moldova helped build an understanding of the RPM methods and approaches. The list of publications and materials used in and developed for the CAR program is in Annex 1.

RPM was instrumental in bringing together experts from the CAR-based, USAID-funded projects and local counterparts. Because RPM did not have permanent representation in the CAR, from the very beginning it was the RPM strategy to collaborate with international projects and build upon local expertise they had developed. In the environment of short program time frames and the unpredictable political situation in the CAR, the strategy allowed RPM to be flexible and respond to the ever-changing situation. Almost all the RPM CAR activities were carried out in collaboration with the USAID ZdravReform Project implemented by Abt Associates, and some activities at various times were carried out in collaboration with Project HOPE, the Academy for Educational Development (AED), WHO, and the Centers for Disease Control and Prevention (CDC). Collaboration was approved and received firm support from the USAID/Almaty Mission.

88

Challenges Facing RPM CAR Implementation

The RPM Project faced some significant challenges as it implemented the Kazakhstan program, including the following:

- No mechanism exists for drug supply and supplier performance monitoring at the national or oblast level. Lack of the data impedes implementation of rational procurement mechanisms.

- Responsibilities for the implementation of the National TB Program are dispersed among various departments of the Ministry of Health, Education, and Sport (MoHES), and there is at present no mechanism to coordinate activities. Similarly, there is little harmonization of TB treatment policies and related activities between the MoHES and the National Institute of Tuberculosis (NIT).

- Frequent changes in the staffing and structure of public health management at the national level result in lack of institutional memory and consistency in political commitment. Identifying key health officials responsible for various aspects of the pharmaceutical sector was difficult.

- There is no permanent Tender Board in Kazakhstan; rather, every year different officials are appointed to conduct national tenders. Technical assistance in tendering procedures could not be sustainable.

- Geographic factors prevented RPM from wider involvement of national-level experts in RPM activities. (For example, the capital of Kazakhstan moved from Almaty to Astana, 1,200 kilometers away.)

Chronological Activity Timeline

RPM activities in the CAR began in 1994 with a reconnaissance trip by the RPM Director, and ended in May 2000 with a policy options workshop in Karaganda Oblast, Kazakhstan.

Table 1. Activity Timeline

Date	Activity
Feb. 1994	Reconnaissance trip to Kazakhstan
Nov. 1998	Reconnaissance and planning trip of the RPM Director to Kazakhstan and Kyrghyzstan
Jan. 1999	Regional CAR General Procurement Workshop in Alatau, Kazakhstan

Table 1. Activity Timeline (cont'd.)

Date	Activity
Apr. 1999	Hands-on technical assistance in standard bidding document development for the Kazakhstan national TB tender
June 1999	Training for Kazakhstan Tender Commission members in tender procedures
June 1999	Kazakhstan national TB tender observed and commented on by the RPM CAR Country Program Manager
Nov. 1999	Reconnaissance and planning trip to Karaganda Oblast, Kazakhstan
Jan. 2000	Workshop on cost-effective drug selection and procurement in Karaganda Oblast, Kazakhstan
Feb. 2000	Data collectors training seminar
Feb. 2000	Indicator-based pharmaceutical sector assessment in Karaganda Oblast, Kazakhstan
May 2000	Pharmaceutical Policy Options Workshop in Karaganda Oblast, Kazakhstan
June 2000	Project closed

Program Accomplishments

Increase Local Capacity in Pharmaceutical Procurement

Pharmaceutical procurement capacity at the local level has increased in three important ways:

1. By developing an understanding of the drug procurement cycle and procurement techniques

2. By helping local counterparts improve TB tender documents

3. By observing the TB tender and providing comments and recommendations

Developing an Understanding of the Drug Procurement Cycle and Procurement Techniques

Between 1994 and 1999 the Central Asian Republics implemented significant health sector reforms to improve the efficiency and quality of health care services in the region. These reforms included the privatization of retail pharmacies and wholesalers involved in the procurement and distribution of drugs, and the devolution of public-sector drug supply responsibilities from the national to the oblast level. As a result, local health authorities face decision-making and managerial responsibilities for which they have little training.

In November 1998, Management Sciences for Health (MSH)/RPM Project received funds from the USAID ENI Bureau to address these and other issues in the CAR. RPM kicked off its programming in January 1999 with a Regional General Procurement Workshop in Almaty. The workshop's target audience was specialists involved in drug procurement for public health, and an emphasis was placed on TB drugs. RPM invited more than 40 participants from the CAR,

Georgia, Armenia, Azerbaijan, Russia, Ukraine, and Moldova. The workshop was conducted in collaboration with Abt Associates, AED, and Project HOPE. The WHO sponsored the participation of seven health managers from Tajikistan.

Workshop Objectives

To achieve the program objective of developing local capacity in drug procurement, RPM developed the following workshop objectives:

1. Explain the basic structure and components of the pharmaceutical management cycle and the relationships of the components

2. Present the steps included in the drug procurement cycle and the four procurement alternatives (open tender, restricted tender, competitive negotiation, and direct purchase)

3. Highlight the components of a comprehensive quality assurance program and identify practical procedures for starting or improving programs

4. Illustrate the factors to consider in making drug selection for procurement decisions, using the example of antituberculosis drugs

5. Explain the need for, and essential components of, effective tender documents and identify ways to improve the documents

6. Present the criteria used to adjudicate drug tenders and the importance of transparency in the tender process; identify ways to make the tender procedures more transparent and objective

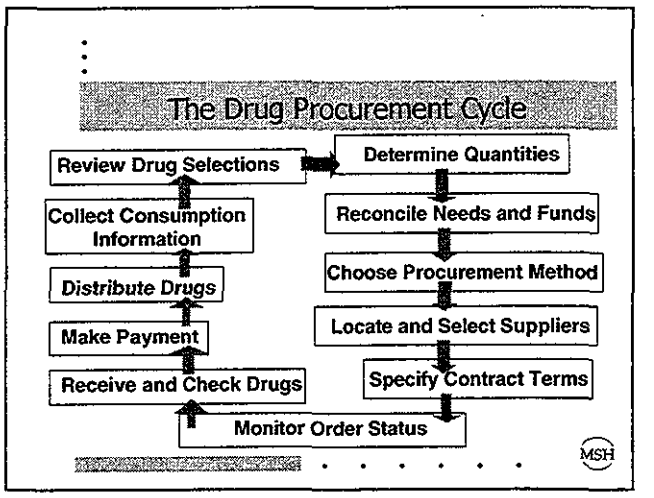
7. Demonstrate the elements of an effective drug supply contract and identify ways to improve the contracts

8. Review consumption and morbidity-based drug quantification methods

9. Outline pharmaceutical procurement problems in the Newly Independent States (NIS) and identify the required assistance to work on those problems

Mode of Implementation

The workshop was conducted using lectures, interactive presentations, small group activities, discussions, and informational materials. RPM staff, speakers from the USAID-funded projects ZdravReform and Project HOPE, and representatives from Kazakhstan, Kyrgystan, and Russia delivered presentations on drug procurement issues.



Presentations and activities were followed by discussions in which participants had the opportunity to share experiences and questions.

Outcomes

Participation

RPM trained 41 procurement specialists from nine NIS countries in modern methods of drug supply management. In their professional capacities, 41 percent of participants are responsible for drug procurement at the national level, and 36.3 percent operate at the oblast and city level. Three participants represented the private sector, and three represented nongovernmental organizations.

Evaluation

Results of the workshop evaluation revealed that participants believed the training and information on procurement methods would be useful in their future activities (8.4 points on a 9-point evaluation scale). The evaluation also showed that confidence and knowledge in drug supply elements increased.

Interaction

Participants from nine NIS countries had the unique chance to share and compare approaches to solving pharmaceutical supply management problems.

Regional Impact

Following the workshop, two participants from the Public Procurement Institute in Moscow designed a course on competitive drug procurement for procurement agencies in the Russian public health sector. The course was based on the materials provided by RPM at the workshop.

Outputs

Workshop Materials

RPM developed a package of workshop materials for the participants, including a Russian translation of "Managing the Tender Process" from *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.*

Proceedings

RPM published proceedings (Zagorski and Gabra 1999) shortly after the CAR General Procurement Workshop. The proceedings include a summary of problems with the CAR pharmaceutical sector identified by workshop participants, as well as an RPM proposal for further activities in the CAR.

Helping Local Counterparts Improve TB Tender Documents

Rates of TB, and particularly of drug-resistant TB, have reportedly reached epidemic levels in Kazakhstan. Public health officials and donors alike have expressed concern over the lack of TB drug availability and have dedicated significant time and resources to exploring methods of alleviating the spread of TB in the region. RPM proposed that more effective procurement practices and drug management could ameliorate the TB drug availability situation.

Recently, two important health sector policy initiatives were approved in Kazakhstan that pertain to TB drug management and availability.

1. In 1997 a National TB Program was adopted that declared WHO's Directly Observed Treatment, Short-course (DOTS) standards mandatory for treating tuberculosis. DOTS treatment guidelines have proven to be cost-effective and successful, and many countries have adopted this intervention methodology.

2. In 1998 the Law of the Republic of Kazakhstan on Public Procurement was passed, which requires the use of competitive practices when purchasing commodities with public funds. TB drug procurement would fall within this rubric.

The first Kazakh national TB tender using DOTS guidelines was conducted in August 1998 and reportedly resulted in the procurement of a large number of low-quality TB drugs that were then poorly distributed. Because there was no official reporting or documentation of the drug quality or the distribution effort, this report could not be confirmed. However, RPM reviewed the 1998 TB tender documents and discovered several significant deficiencies that could have resulted in the purchase of inferior drugs and services. In addition, the results could be attributed to the MoHES's limited capacity to conduct competitive procurement.

The RPM Project was asked to provide technical assistance in TB drug procurement to the Kazakhstan MoHES, USAID, the National Institute of Tuberculosis (NIT), and other parties involved in the Kazakhstan TB tender scheduled for June 1999. This work began with direct technical assistance provided by RPM in April and June 1999. RPM also observed the TB tender in June 1999, although the latter activity falls under RPM Objective 3.

Mode of Implementation

To meet the objective of improving TB tender documents and processes, RPM Senior Program Associate Michael Gabra visited Kazakhstan in April 1999 to provide direct technical assistance and hands-on training to parties involved in the TB tender scheduled for June 1999. Specifically, Gabra identified omissions of standard tender components from the 1998 TB tender document, incorporated the missing components into the 1999 draft TB tender document, reviewed the TB drugs chosen for the 1999 tender by the NIT, and submitted a draft generic standard bidding document (SBD) for pharmaceuticals to the MoHES.

To begin the process of familiarizing the parties with proper procurement techniques and to discuss issues of specific relevance to the TB tender, RPM met with representatives from the MoHES, NIT, USAID, WHO, and the ZdravReform Project. During this meeting the group discussed several topics related to the TB tender and to the pharmaceutical procurement system in Kazakhstan. The overarching concern expressed was that the tender document for the June 1999 TB tender be improved and adjusted to meet internationally accepted standards for pharmaceutical procurement. Recommendations produced at the meeting include—

- Full and coordinated implementation of the WHO DOTS strategy by the MoHES and NIT
- Reconcile the TB drugs recommended by WHO DOTS and those listed for purchase by the NIT, ensuring proper quantification of TB drug needs
- Support adequate pharmaceutical sector legislation and registration policies
- Modify the language of the TB tender document to ensure the quality of the drugs procured
- Improve the management, distribution, and monitoring of TB drugs

RPM made a thorough analysis of national procurement legislation and the 1998 TB tender documents. After the gaps had been identified, RPM suggested a set of additions and changes to the 1999 tender document to improve the procurement process and bring it into compliance with accepted international standards. A total of 21 additions and changes were suggested that addressed such important aspects of tendering as—

- Bidder eligibility
- Definition of domestic manufacture and priority
- Qualifications of manufacturer
- Bid bonds and performance bonds
- Product samples
- Technical specifications for each product
- Packing requirements
- Shelf life of goods and expiry date
- Analysis and inspection by the national laboratory
- Labeling requirements
- Good manufacturing practices (GMP) and other quality considerations
- Corrupt or fraudulent practices
- Primary and secondary awards and contracts

The Kazakhstan Tender Commission accepted 15 of the 21 suggested improvements. Two omissions, however, require close attention as they may have significant impact on product quality and availability.

1. The TB Tender Commission did not require that potential suppliers submit product samples for laboratory testing, nor did it allow enough time for the National Laboratory to perform tests had the samples been submitted. In a part of the world where TB rates are growing dramatically, largely because of reported poor drug quality, laboratory analysis of TB drugs is crucial.

2. The TB Tender Commission does not plan to sign contracts with second-best suppliers to secure an uninterrupted drug supply in case the winner defaults. Contracts in which the secondary supplier agrees to fix the award price for the duration of the contract is standard international practice and has proved to be very useful. In some countries awards are split between the winner and second-best supplier.

Outputs

RPM assistance led to the development of tender documents free of most of the major omissions found in the 1998 TB tender documents. With the additions proposed by RPM and accepted by the TB Tender Commission, the 1999 Kazakhstan TB tender documents are in compliance with internationally accepted standards (e.g., The World Bank's *Standard Bidding Documents: Procurement of Pharmaceuticals and Vaccines*, trial edition September 1993; reissued 1996 and 1997).

The following documents and materials were developed with RPM assistance:

- Generic standard bidding document template
- Instructions for bidders
- Drug specifications recommendations
- Spreadsheets for supplier prequalification
- Spreadsheet for tender adjudication
- Templates for tender protocols
- Contract template
- Principles of good procurement practices
- Job description for an in-house Kazakh procurement specialist

Observing the TB Tender and Providing Comments and Recommendations

Preparation for the Tender

Tender commissions in Kazakhstan are *ad hoc* bodies, and members sometimes have limited procurement experience. In the case of the 1999 TB Tender Commission, only two of the members had been involved in the 1998 TB tender and could rely on their previous experience.

Since many of the members of the MoHES Tender Commission were not familiar with tendering procedures and documents, RPM was asked to conduct a brief 1–2 day training to cover this gap. This training was conducted by RPM CAR Country Program Manager Andrei Zagorski in Almaty, Kazakhstan, in June 1999, one day prior to the actual national TB tender.

On the request of the Tender Commission, special attention was given to contracting suppliers for TB drugs. Correct contracting may ensure adequate supplier performance and drug quality. The following issues were covered during the training:

- Tender drug nomenclature and technical specifications
- Instruction for bidders and bidding documents
- Bid opening and evaluation procedure
- Tender adjudication process—
  - Preliminary examination
  - Evaluation and comparison of bids
  - Domestic preference
- Award of contract
- Signing of contract
- Drug supply quality assurance—
  - Supplier performance monitoring
  - Drug quality monitoring and reporting
  - Requirements for a Drug Management Information System (DMIS)
  - Types of reports required for rational drug management

In addition, RPM worked with the head of the Drug Policy Department of the MoHES, who is also the head of the TB Tender Commission, and recommended that the following additions be made to the final contracts with winning bidders.

- Prices should be fixed for the duration of the contract period.
- Drug specifications should be listed in a separate attachment (not simply a reference to the Instructions for Bidders).
- Packaging standards should be part of the contract.
- Drug quality requirements should include—
  - Supplier responsibility for laboratory tests
  - Quality certificates for each batch and lot
- Labeling requirements should be specified.
- Drug information format should be specified (contents and language).
- A delivery schedule should be developed and be part of the contract.
- Fines for late delivery or substandard quality should be identified and agreed upon.
- A clause on corrupt or fraudulent practices should be added.

The RPM consultant reiterated the recommendation that contracts should be signed with the second-best bidders to fix the price and quantities in case the winner defaults.

Regional Impact

At the request of the USAID Mission, the head of the Procurement Department of Fergana Oblast in Uzbekistan attended RPM training in preparation for the Fergana Oblast pooled competitive procurement.

The 1999 TB Drug Tender

As previously mentioned, the 1998 national TB tender reportedly resulted in the procurement of low-quality drugs at high prices. At the time of the tender there was significant controversy about transparency in the tender process and contract awards. To mitigate such problems in the 1999 TB tender, the USAID Mission in Kazakhstan requested that RPM assistance in developing tender documents and training in the tender processes be followed by observation of the actual TB tender. USAID also requested that RPM provide recommendations to the TB Tender Commission during and after the tender process.

The Republic of Kazakhstan allocated 274 million tenge to procure TB drugs for the National TB Program. At the exchange rate of one U.S. dollar (USD) to 132 tenge, this equaled $2,075,757. The TB tender took place in Almaty on June 22–23, 1999.

Mode of Implementation

RPM CAR Country Manager Andrei Zagorski observed the 1999 TB tender and provided comments and recommendations.

Tender Process

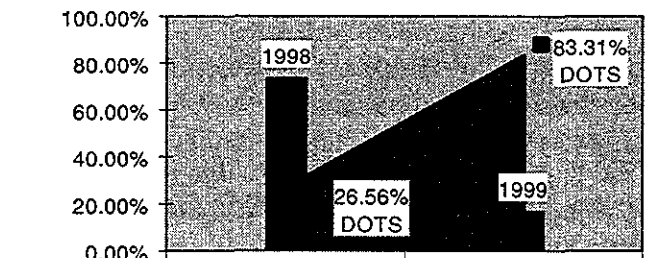
The 1999 TB tender was transparent and conducted in accordance with internationally accepted procedures. No complaints on the tender process were filed by any of the potential suppliers or observers.

Tender Outcomes

Drug Products Compliant with WHO DOTS Guidelines

Through the 1999 TB tender, Kazakhstan procured 10 TB drugs, 83.31 percent of which (by value) were first-line TB drugs, and 16.69 percent of which were second-line TB drugs used to treat drug-resistant TB. It should be noted that all the drugs procured through the 1999 tender are compliant with WHO DOTS standards.

Figure 1. TB DOTS Drugs in 1998 and 1999 Tenders



	1998	1999
DOTS Drugs	26.56%	83.31%
Other drugs	73.44%	16.69%

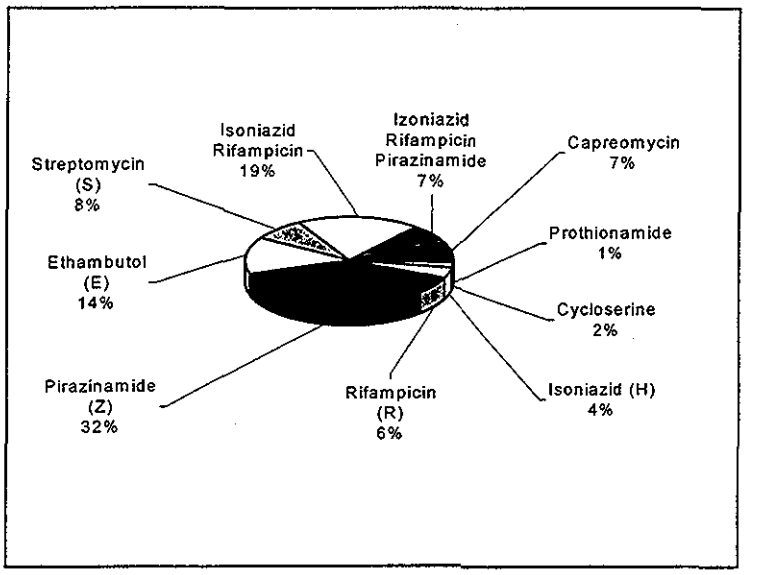
This was in contrast to the 1998 TB tender, which was expected to effectively initiate implementation of the WHO DOTS program, but failed to do so because of a lack of the drugs necessary to launch the program. For example, of all the drugs purchased in 1998, only 26 percent by value were in compliance with DOTS standards. The situation changed in 1999.

Figure 1 illustrates changes in the proportion of DOTS-compliant versus non-DOTS-compliant drugs in 1998 and 1999.

198

The mix of drugs in the 1999 TB drug procurement represents a considerable step toward rational TB drug use. Figure 2 illustrates the breakdown by value for each drug product of the 1999 TB drug tender. However, RPM was concerned that the MoHES would insist on direct, single-source procurement of fixed-dose combination (FDC) Myrin (HRE). In the 1998 TB tender, FDC Myrin accounted for 62.45 percent of funds allocated for the TB drugs, despite its noncompliance with DOTS standards. RPM suggested that the MoHES instead purchase vital first-line drugs with the remaining funds to be better equipped to effectively treat new TB cases.

Figure 2. Drugs Involved in the TB Tender 1999



Product Quality Standards Improved

The Drug Policy Department of MoHES informed RPM of significant problems with the quality of TB drugs procured through the 1998 tender. According to the department, TB facilities complained about late deliveries by suppliers, decomposition and malodor of tablets, and notably low efficacy of the products. These complaints, however, were not recorded officially, and it is not possible to identify the suppliers with poor performance.

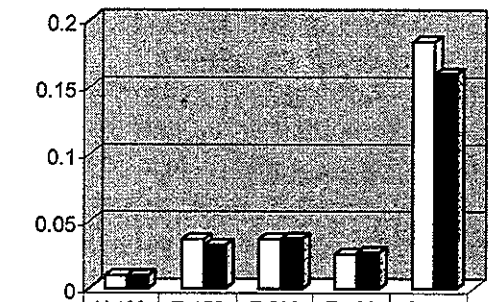
RPM determined that the deficient tender documents and drug specifications discussed above may have contributed to the low quality of TB drugs procured in 1998. For 1999, with improved tender documents, strict supplier prequalification criteria, and clear drug specifications, TB drugs were procured from manufacturers of high international standing, such as Novartis, GlaxoWellcome, Eli Lilly, and Sanavita. However, if drug quality standards are not enforced in contracts with suppliers and through supplier performance monitoring, there is no guarantee of drug quality even from reputable international suppliers.

Product Prices Reduced

Of the 15 potential suppliers that purchased tender documents, only 8 actually submitted bids. This was because new 1999 tender requirements called for higher drug quality standards (WHO GMP certificate, registration in the country of manufacture, pharmacopeial standards, etc.), so fewer suppliers were likely to qualify. With the reduced number of potential suppliers, the TB Tender Commission expected significantly higher prices than in the 1998 tender. However, the price of first-line TB drugs was actually reduced.

RPM compared the prices paid (in USD) for TB drugs for 1998 and 1999. Figure 3 illustrates the changes in prices (in USD) between the 1998 and 1999 TB tenders for first-line TB drugs.

Figure 3. First-Line TB Drugs: Price Comparison



	H 100	R 150	Z 500	E 400	S 1,0
1998	0.0096	0.037	0.037	0.0258	0.184
1999	0.0096	0.0325	0.0374	0.0269	0.160

Using 1998 and 1999 TB tender prices and 1999 drug quantities, RPM calculated that 1999 USD prices for first-line TB drugs were reduced by 1.5 percent from 1998 levels. This 1.5 percent price reduction could be attributed to larger pack sizes specified in tender documents (1,000-tablet bottles instead of 20- or 100-tablet blisters in 1998) and to larger quantities of products put on tender in 1999.

This price reduction suggests high cost-effectiveness of the 1999 TB tender, especially since the drugs will likely be of better quality and efficacy than those procured in 1998.

Capacitate Oblast-Level Managers in Formulary System Implementation Approaches

In November 1999, the MSH/RPM Project met with the USAID Mission in Kazakhstan to finalize the RPM CAR workplan. The USAID Mission provided RPM with funds for work at the oblast level. Karaganda was chosen as the work site to train hospital and family group practice (FGP) physicians in cost-effective drug selection, use, and procurement, and to conduct a pharmaceutical sector assessment and policy options workshop.

Workshop: "Cost-Effective Drug Selection and Formulary System Implementation in Oblast Hospitals and Family Group Practice"

The workshop was conducted from January 26 to 28, 2000, in Karaganda by the RPM Project in collaboration with the USAID/CAR ZdravReform Project, Karaganda Oblast Health Administration, and the Karaganda Medical Academy. Sixty-six invited participants represented major oblast hospitals and FGPs. The estimated total number of health workers who attended the workshop was more than 100.

Objectives of the Workshop

The objectives of the workshop were to give participants an understanding of the basic structure and components of the pharmaceutical management cycle, aspects of stepwise formulary system implementation, cost-control strategies, formulary-based drug procurement, and the important factors influencing drug quality and safety.

Topics:

- Drug Management Cycle
- Formulary Drug Selection based on:
  - Cost-effectiveness
  - Efficacy
  - Safety
- Formulary-Based Procurement
- Competitive Procurement
- Rational Drug Use

The main emphasis was on the necessity of developing a working mechanism of cost-effective drug selection for use and procurement in various public health settings and medical insurance.

Mode of Implementation

The workshop objectives were achieved through lectures, discussion, and provision of materials, including the MSH/RPM-developed *Manual for the Development and Maintenance of Hospital Drug Formularies* and *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals,* a Russian-language version of the United States Pharmacopeia's *Drug Information for the Health Care Professional*, and a reference on drug synonyms. Presentations were delivered by MSH RPM staff, a speaker from the USAID ZdravReform Project, representatives from the Karaganda Oblast Health Administration, and academicians from the Karaganda Medical Academy. Presentations were followed by discussions in which participants were given a chance to share their experiences and questions.

Outcomes

Karaganda Oblast has been a pilot site for a number of USAID projects, and it is anticipated that future projects will continue to address existing problems in the development of drug policies, rational drug selection, use, and procurement. The workshop exposed a large audience of oblast health workers to modern methods of addressing pharmaceutical sector problems, thus laying the foundation for the USAID-sponsored technical assistance to come.

The workshop was very well received, and was covered by local radio and TV stations. Interviews were given by the head of the Oblast Health Administration Dr. Ermekbaev, RPM CAR Country Manager Andrei Zagorski, ZdravReform Project consultant Dr. Nurgozhin, and Dr. Khe, head of the Oblast Center for Health Purchasing Densaulyk. The speakers outlined objectives of the workshop, the forthcoming pharmaceutical sector assessment, and the role of USAID-funded projects in health reform in the Republic of Kazakhstan.

Capacitate Oblast-Level Managers in Conducting Indicator-Based Pharmaceutical Sector Assessment and in Using Pharmaceutical Indicators for Monitoring Performance and Outcome

Pharmaceutical supply systems in many countries have inefficient or ineffective drug management procedures that negatively affect the availability of drugs and cause irrational use of those drugs that are available. As a result, negligence in the pharmaceutical sector often results in the failure of health sector reforms. No matter how well trained a medical staff may be, if drugs are not available or not affordable to patients, the health system suffers.

In Kazakhstan, a country that is transitioning to a market economy, there are many gaps in supplying drugs for public health, and the government needs possible options for ameliorating these problems. This pharmaceutical sector assessment measures the extent of the supply gaps, provides information for identifying possible solutions, and serves as a baseline against which to measure any subsequent interventions.

Assessment Objectives

The Karaganda assessment had the following objectives:

- Identify areas of irrational drug management in the pharmaceutical supply system with respect to selection, procurement, distribution, and use of drugs, including aspects of finance, policy, and law, as they affect drug management.
- Provide data that will give the USAID Mission an understanding of the pharmaceutical sector problems encountered in Karaganda Oblast.
- Provide Karaganda Oblast officials with a report on the status of the local pharmaceutical sector and identify options to address problems identified in the assessment.
- Describe the public/private-sector relationship and identify opportunities for increasing the role of the private sector.

The study team comprised Andrei Zagorski, RPM CAR Country Manager, and Marina Semenchenko, Senior Program Associate, both of MSH.

Data collectors consisted of physicians, pharmacists, and interns provided by the Center for Health Purchasing (CHP) Densaulyk and by the Karaganda Medical Academy. Their role was to collect data at selected oblast and *rayon* (county) health facilities and pharmacies.

The assessment report was written by RPM staff and reviewed internally by RPM and externally by the Oblast Health Administration and CHP Densaulyk.

Methodology

Assessment objectives were achieved through collection of background information, document review, structured interviews with key informants, structured collection of indicator data, and ABC/VEN analysis of procurement drug lists.

Tools

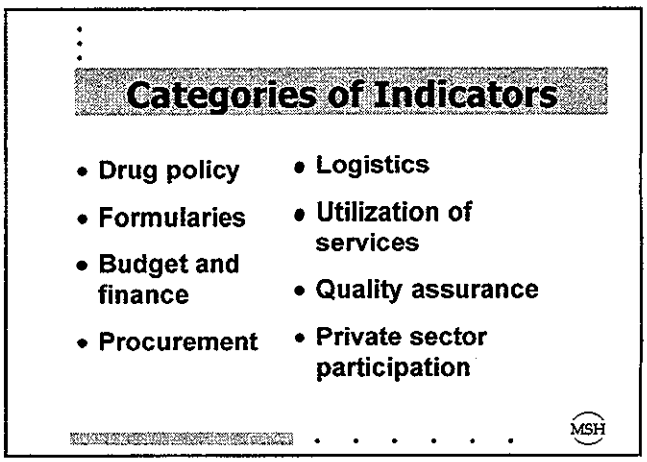
The assessment tools used in Karaganda Oblast were developed by modifying the structured questionnaires used in earlier RPM assessments in Russia. The indicators and sample forms contained in MSH's *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* were used for the collection of indicator data. The tracer drug lists were established in collaboration with Karaganda Oblast pharmaceutical experts during the Data Collectors Training Workshop, conducted in Karaganda in January 2000, prior to the assessment. The assessment tool contained the following components:

- Questionnaires used to interview key informants at the Oblast Administration, Oblast Health Administration, and health facilities

- Data collection forms, including—
  - Drug Use Data Form
  - Inventory Data Form
  - Stock-out Data Form
  - Price Comparison Data Form
  - Tracer drug lists

Pharmaceutical Indicators

The indicators used in the assessment are standardized measurements of a local pharmaceutical system. RPM has field-tested these indicators in several countries and regions, and used them to conduct three oblast assessments in Russia. Indicators can be used to compare the effectiveness and performance of health systems between countries or oblasts, or alternatively they can serve as baseline data against which the results and impacts of reforms and interventions can be measured within one health system. The latter was the purpose of the present assessment.



The assessment was the first systematic indicator-based survey conducted in Kazakhstan. It is expected that the indicator data will be used as a reference to measure future performance of the national pharmaceutical sector and of the health sector reforms implemented by Kazakhstan within the framework of USAID-funded projects.

Tracer Drugs

A number of indicators used in the study were measured using tracer drug lists. The indicators related to procurement, stock management, drug availability, and drug prices. Although ideally, data would have been collected on all drugs flowing through the system, such a thorough investigation would have required greater time and effort than was available. Therefore, prior to the assessment, two standard tracer drug lists were developed—one for the hospital survey and the other for the survey of primary health care (PHC) facilities and private pharmacies.

The lists were developed by local and RPM experts. The selected drugs represented major therapeutic categories. The drugs were not necessarily the most safe and efficacious from the point of view of international evidence-based practice, but rather those commonly used in the oblast. Drugs were identified by generic names. All selected drugs were also on the Kazakhstan Essential Drug List (EDL). To facilitate data collection based on the tracer drug lists, RPM provided data collectors with the latest edition of the reference *Synonyms of Pharmaceuticals.*[1]

Selection of Assessment Sites

Sites for the survey were selected in collaboration with the Oblast Health Administration, which suggested focusing on those facilities that were its top priority of interest. These facilities comprised the seven largest public hospitals at the oblast and rayon levels, and five PHC facilities (including state and private FGPs, and an independent private polyclinic). All those facilities served an urban population (83 percent of the total oblast population). Some data were collected at a small private hospital and are used for illustrative purposes in the report. Note, however, that these figures are not included in the indicator data. In addition, the assessment results do not reflect the situation in the pharmaceutical sector in rural areas.

Data on drug prices and availability were also collected at 25 randomly selected retail pharmacies in Karaganda and Jezkazgan cities and at the private drug wholesaler Pharmacia.

Data Collection and Processing

The assessment data collection was performed February 1–15, 2000, by 20 data collectors trained by RPM. Data collectors gathered quantitative data and interviewed key informants at the facility level. Computer specialists from CHP Densaulyk then entered the data into Excel spreadsheets, calculated the indicators, and generated summary tables and graphs. Interviews with key informants at the oblast administrative level and collection of background information were performed by the RPM staff.

[1] *Synonyms of Pharmaceuticals* by G. Shashkova, V. Lepakhin, G. Kolesnikova. Russian Center "Pharmedinfo," Moscow, 1999.

Key Assessment Findings

A summary of key assessment findings is as follows:

- Karaganda Oblast does not have a clearly defined oblast-specific drug policy that would address all aspects of the drug supply system including selection, procurement, distribution, and use of pharmaceuticals.

- Existing oblast financial mechanisms do not ensure availability and affordability of essential drugs for patients in the public health sector.

- Lack of specific drug formularies for exempt patients is an impediment in ensuring the availability of vital drugs in the face of diminishing health budgets.

- Reimbursement to hospitals based on diagnosis-related groups (DRGs) is seriously undermined by the lack of accepted and approved standard treatment guidelines.

- Oblast competitive drug procurement procedures are not transparent and lack mechanisms to ensure drug quality and supplier compliance with contract prices.

- The latest version of the national EDL and accompanying manual developed by the USAID ZdravReform Project are not available at oblast facilities, and they are not followed by physicians in their prescribing practices.

- The national EDL and FGP formulary do not perform their function of ensuring that cost-effective, efficacious, and safe drugs are procured and used for treatment.

- Drug prices and treatment costs are not controlled and are very high at all levels of the oblast health system. A decrease in the number of patient visits to PHCs and in hospitalization rates, along with an increase in overall morbidity in 1999 as compared to 1998, may be attributed to the high costs of drug therapy.

- The lack of drug price control policies make pharmaceuticals very expensive in the private retail sector.

- Serious gaps were identified in stock management and pharmaceutical services in hospitals.

- There are no mechanisms in the oblast to control drug use at all levels of care. As a result, polypharmacy is a general trend that results in irrational treatment, expensive for both patients and the oblast health system.

- The oblast health management information system (MIS), currently being developed by local experts, may serve as a basis for the development of a drug management information system (DMIS) that would assist the oblast in the development of its drug policy and control.

- Evidence-based, unbiased drug information is not available to prescribers or patients.

Policy Options and Possible Interventions

Based on the assessment findings, RPM suggested a number of interventions and activities to address the identified gaps. The proposed suggestions were grouped as short, medium, and long term.

Short-term activities are those that the Oblast Health Administration could conduct without external technical assistance, relying only on local capacity. Such interventions could be developed and implemented in one to six months.

Medium-term activities and interventions may require some technical assistance from international experts, but, if properly managed by the oblast, may also build upon existing local expertise. It will take more time to implement these interventions, up to approximately two years.

Long-term interventions include systemic changes to the pharmaceutical sector, and these will require changes in oblast legislation, as well as extensive technical assistance and international expertise.

It should be noted that the suggested activities were intended to serve as a point of departure for discussion at the policy options workshop, rather than as concrete recommendations.

Short-Term Activities

- At the Oblast Administration level, revise tender documents and include pharmaceutical specialists as permanent members of the Oblast Tender Board.

- Establish a Formulary and Therapeutics Committee (FTC) at the Oblast Health and facility levels (hospitals and FGP associations), and develop the FTC policies and procedures as outlined in the MSH/RPM *Manual for the Development and Maintenance of Hospital Drug Formularies*. The Russian language edition of the manual is available in the oblast.

- Initiate pilot formulary drug selection at health facilities that have Karaganda Medical Academy departments (for example, Oblast Clinical Hospital, Oblast Children's Hospital), and two FGP associations (one in Karaganda based upon Medical Academy departments, the other a private practice in Jezkazgan).

- Using the technical expertise of the oblast CHP Densaulyk staff and RPM assessment tools, develop a set of pharmaceutical outcome and performance indicators. Incorporate the pharmaceutical indicator data collection process into the existing CHP MIS network.

- Use pharmaceutical indicators to initiate outcome and performance monitoring of drug procurement and prescribing, and to ensure compliance with the EDL and eventually with pilot formulary lists.

- At the PHC level, working with two existing FGP associations, initiate prescribing by international nonproprietary name.

- Disseminate the latest versions of the national EDL and accompanying manual developed by the USAID ZdravReform Project, and drug information and management materials provided by RPM.

- Develop a formulary list of drugs for exempt patients.

Possible Outcomes

- It is expected that controlled selection, procurement, prescribing, and use will increase technical and operational efficiency and health outcomes of health facilities in pilot sites.

- Pharmaceutical indicator data will allow the Oblast Health Administration to analyze performance, trends, and changes in the sector and have a basis for deciding on corrective measures. Data collected from pilot sites may help to gain support of other facilities in the oblast.

Medium-Term Activities

- Disseminate results of short-term interventions in pilot sites.

Elements of a Formulary System

Drug policy and legislation	Drug utilization review programs
Active formulary committee monitoring	Adverse drug reaction reporting and
Updated formulary list	Drug quality assurance program
Drug information services	Ongoing training

- Develop a schedule and initiate implementation of a formulary system[2] at the oblast and facility levels.

[2] *Formulary system* is a process whereby the medical staff of an institution, working through a Formulary and Therapeutics Committee, evaluates and selects from the numerous available drug products those that are considered most efficacious, safe, and cost-effective. A formulary system is a mechanism to streamline procurement activities, minimize institutional costs, and optimize patient care. Essential elements of a formulary system include a functional formulary committee, drug policies and legislation, a constantly revised and updated formulary drug list, drug information services, ongoing drug utilization review programs, reporting mechanisms for adverse drug reactions

- Establish an oblast Drug Information Center.
- Implement drug utilization review (DUR) in pilot sites.
- Develop and implement standard treatment guidelines that include specific drug treatment based on the oblast drug formulary for use in DRG-based reimbursement mechanisms.
- Establish mechanisms of reporting adverse drug reactions and drug product quality problems.
- Establish a DMIS.

Possible Outcomes

The activities described above are expected to improve the performance of the health system within its existing legal boundaries. With implementation of the proposed interventions, pharmaceuticals should become more affordable to patients and will be safer and more efficacious. Implementation of the proposed interventions does not require systemic changes in drug legislation and finance. However, other necessary reforms of the pharmaceutical sector may require systemic changes in legislation, finance, and organization.

Long-Term Interventions

- An oblast drug policy that addresses all aspects of drug selection, procurement, distribution, and use should take the shape of an enforceable law.
- The formulary system should become the core of pharmaceutical sector management.
- New mechanisms for health financing should be developed to guarantee access to health services, including pharmaceuticals, to the majority of the population. Financing mechanisms should be performance-based, create incentives to providers to perform adequately, and develop competition between health facilities.

Assessment Output

RPM produced the Karaganda Oblast Pharmaceutical Sector Assessment Report, which served as the basis for discussions at the Pharmaceutical Policy Options Workshop conducted in May 2000.

---

and drug quality problems, feedback mechanisms, and ongoing training and education of prescribers and medical staff.

Initiate Pharmaceutical Policy Options Dialogue

In February 2000, the MSH/RPM Project conducted an indicator-based pharmaceutical sector assessment in Karaganda Oblast. The assessment data were analyzed and a report was developed during March–April 2000. The report presented assessment findings, identified gaps in the Karaganda Oblast pharmaceutical system, and suggested possible courses of action to correct problems in each area. The suggested activities were intended to serve as a point of departure for discussion at a policy options workshop that was conducted by RPM in Karaganda Oblast on May 25–26, 2000.

Policy Options Workshop

The workshop was conducted on May 25–26, 2000, in Karaganda, by the Rational Pharmaceutical Management Project in collaboration with the USAID/CAR ZdravReform project, Karaganda Oblast Health Administration, CHP Densaulyk, and the Karaganda Medical Academy. The workshop was the last RPM CAR activity.

The workshop discussions and activities were built around the findings of an indicator-based pharmaceutical sector assessment conducted by RPM in Karaganda Oblast in February 2000. The assessment report was translated into Russian, and 100 copies were disseminated among participants prior to the workshop.

Participants

Ninety-two invited participants represented the USAID/Almaty Mission, National Agency for Health, the Government and Parliament of Kazakhstan, Ministry of Economy, Oblast Administration (*Akimat*), Oblast Health Administration, the Karaganda Medical Academy, Center for Health Purchasing Densaulyk, directors of major oblast hospitals, and FGPs. The estimated total number of health workers who attended the workshop was more than 100.

Objectives

The workshop sought to accomplish the following:

- Discuss the results of the indicator-based pharmaceutical sector assessment and use the data and information to guide decision making
- Familiarize the national-level decision makers with pharmaceutical sector problems and oblast and sector needs to address these problems
- Discuss the basic structure and components of the pharmaceutical management cycle, and the components' relationships

- Identify drug policy components and discuss existing gaps and requirements
- Define the components and role of the formulary system in drug sector management and steps for its implementation
- Discuss the role of the MIS in decision making and discuss existing gaps
- Identify possible alternatives for pharmaceutical sector financing
- Draft a plan and steps for oblast drug policy development
- Draft a plan and steps for formulary system implementation
- Assess existing resources and identify pilot sites for formulary system implementation at the hospital and PHC levels

Mode of Implementation

The workshop objectives were achieved through wide plenary discussion of the assessment results and the development of implementation approaches in four work groups (Drug Policy Options, Pharmaceutical Sector Finance Options, Management Information System, and Formulary System Implementation).

Presentations on the assessment results were delivered by MSH/RPM staff, speakers from the USAID ZdravReform Project, representatives from the Karaganda Oblast Health Administration, and faculty from the Karaganda Medical Academy.

Work group activities were facilitated by RPM staff, the ZdravReform Project, Oblast Health Administration, and CHP Densaulyk.

Outcomes

The workshop resolution drafted by the Drug Policy Work Group follows.

The workshop work groups drafted proposals for the Oblast Administration (Akimat) and the Oblast Health Administration on a number of activities for improving pharmaceutical sector efficiency. Those proposed activities included development of an oblast drug policy, implementation of a formulary system, and establishment of a DMIS and drug information center.

Oblast Health Administration and Akimat also discussed the necessity of a special study to evaluate the feasibility and economic viability of establishing insurance-based financial mechanisms for the pharmaceutical sector.

DRAFT
Resolution of Policy Options Workshop
Karaganda Oblast Health Administration

May 25–26, 2000

The Karaganda Policy Options Workshop members discussed the results of a pharmaceutical sector assessment. The assessment was conducted jointly by the USAID Rational Pharmaceutical Management Project, the Karaganda Oblast Health Administration, CHP Densaulyk, the Karaganda Medical Academy, and the USAID ZdravReform Project. The assessment identified existing problems in the oblast pharmaceutical sector and outlined possible options for sector reforms.

In accordance with the laws of the Republic of Kazakhstan, Karaganda Oblast has the right to develop its own drug policy provided that it does not contradict national legislation.

Oblast Drug Policy

The oblast drug policy identifies the pharmaceutical sector objectives, sets priorities and outlines strategic approaches, defines principles of relationships between the public and private sector, and allows collaboration with nongovernmental organizations and international donors.

The Aim of Oblast Drug Policy

The main aim of the oblast drug policy is to ensure the availability of vital and essential drugs to the population.

Elements of Oblast Drug Policy

- Legislation and regulation
- Economic strategies for the drug supply system
- Drug management information system
- Human resources development mechanisms
- Formulary system

Objectives of Oblast Health Administration in Drug Policy Development

In order to achieve the aim of the oblast drug policy, the Oblast Health Administration needs to develop objectives for each element of the policy, as well as strategies and mechanisms for its

implementation. To accomplish this, the following objectives are to be met in order to improve management efficiency and optimize pharmaceutical sector activities.

Legislation and Regulation

- Develop oblast regulatory acts in support of drug policy and the formulary system
- Develop a proposal on changes in national drug policies for the government
- Develop implementation strategies and establish enforcement mechanisms

Economic Strategies for the Drug Supply System

- Develop measures to increase competition in the oblast drug market
- Guarantee the rational use of funds for the procurement of vital drugs, including for exempt patients, through the development and implementation of restrictive drug lists (formularies)
- Explore opportunities for alternative funding sources for the drug supply (for example, through pharmaceutical insurance mechanisms, copay programs, and the private sector)
- Improve tender documents and procedures
- Develop a proposal at the national level to establish mechanisms for reinvesting monies saved in the oblast public health sector back into the sector

Drug Management Information System

- Establish a center for unbiased evidence-based drug information for prescribers and patients
- Develop and maintain a database on postmarketing drug monitoring, adverse drug reactions, and drug quality problems
- Develop and implement ongoing monitoring of the pharmaceutical sector based on performance and outcome indicators

Human Resources Development Mechanisms

- Identify the scope of work and responsibilities for a clinical pharmacologist position in health facilities whose job would pertain to drug selection and use processes
- Evaluate existing resources and develop training programs for oblast prescribers in rational prescribing and use in conjunction with the Karaganda Medical Academy, and with assistance from international projects
- Develop a network for exchanging experiences in pharmaceutical sector reforms with other oblasts and countries

Formulary System

- Optimize drug selection, procurement, and use on the basis of the oblast drug formulary and specific drug formularies of health facilities

Implementation Strategies

Step 1

- Establish a drug policy development work group
- Assign responsibilities for the development of drug policy elements
- Develop a plan and timeline for the development of the drug policy
- Analyze existing oblast and national legislation and regulation pertaining to the pharmaceutical sector and identify needs in legislation development
- Approve principles of a formulary system as the main strategy of the oblast drug policy
- Establish an Oblast Formulary and Therapeutics Committee (FTC)
- Establish an Oblast Drug Information Center
- Select pilot sites (hospitals and FGPs) and establish facility FTCs

Step 2

- Develop and approve the FTC policies and procedures
- Develop and approve principles, criteria, and mechanisms for formulary drug selection
- Develop and approve mechanisms of drug formulary use in pilot facilities for prescription and procurement
- Improve existing competitive procurement methods, including the following:
  - Review and improve standard bidding documents (SBDs)
  - Develop drug specifications to guarantee drug quality and safety
  - Develop mechanisms for domestic production support
- Explore opportunities for legislative support of nongovernmental, nonprofit drug purchasing groups (one such group could be established at the Karaganda Hospital Association, another at the Jezkazgan Association of Family Group Practices)

- Develop a proposal at the national level to establish a body for state control and monitoring of the pharmaceutical sector to ensure the quality and legality of drugs
- Develop a proposal at the national level to improve drug registration and licensing mechanisms in order to increase competition on the drug market
- Discuss the results of pilot formulary implementation oblastwide

Step 3

- Approve and implement a formulary system as the basis for drug policy and pharmaceutical sector management oblastwide. The key elements of a formulary system are as follows:

- Functional FTCs at the oblast and facility levels
- Existence of written policies and procedures that define the principles of drug selection, procurement, and use
- Existence of a regularly updated restrictive oblast drug list (formulary)
- Competitive drug procurement based on the formulary
- Formulary-based drug prescription in health facilities of all levels
- Reimbursement of health services (pharmacotherapy component) based on the use of formulary drugs
- Existence and availability of sources of unbiased evidence-based drug information
- Ongoing drug utilization review (DUR) programs
- Existence of reporting and monitoring mechanisms for adverse drug reactions and drug quality problems
- Existence of feedback mechanisms
- Ongoing training programs for prescribers and patients

- Finalize and pass the oblast Law on Drug Supply

Likely Needs at End of Project

General

All activities planned for RPM in the CAR were completed. This section of the report discusses the likely needs of the CAR after the end of the project that pertain to general issues of the pharmaceutical sector, and, separately, to TB drug management. USAID and donor support may be required to assist Kazakhstan in achieving the goals and objectives of the pharmaceutical sector reform.

Oblast Level

- Oblasts may require assistance in developing their drug policies. In Karaganda, the Oblast Health Administration seems to have a good understanding of the elements of a drug policy and the required implementation efforts. However, oblast decision makers do not have previous experience in such an activity. Oblast policy makers would certainly benefit from international experience. One option would be a to organize a study tour to a country with similar public/private-sector relationships.

- Karaganda Oblast has all necessary prerequisites for the implementation of a formulary system (the RPM guidelines, political will, and experts in clinical pharmacology). However, because drug formulary development is a lengthy and technically complicated activity, some technical assistance may be required.

- Standard treatment guidelines are key to ensuring the correct use of drugs in a health system. Karaganda Oblast has the political will to develop standards, but it lacks experience. The oblast will benefit from hands-on assistance from internationally acknowledged experts.

- In order to ensure transparency in drug procurement, major technical assistance may be required to help the oblast develop drug-specific SBDs, drug specifications, and drug supply contracts. In 1999, RPM assisted Kazakhstan in developing tender documents for a national TB tender. However, not all recommendations were taken into account by the Tender Board, and the documents are not available at the oblast level. The tender process is another area that requires assistance. As the RPM experience showed, hands-on assistance in conducting a tender is effective, but for consistent results such assistance requires the presence of an observer or consultant at a series of tenders.

- Karaganda Oblast and national-level experts expressed a desire to establish state-controlled drug supply mechanisms as an alternative to private mechanisms. This, however, is not likely to solve the problem of affordability of pharmaceuticals at the facility level, but may instead be a step back to a command economy. International assistance may be required to help the oblast establish relationships with the private sector or establish nongovernmental independent drug procurement groups, (e.g., through existing hospital and FGP associations).

- There is a strong belief at the oblast and national levels that the establishment of a medical insurance system may solve the problem. There are, however, certain prerequisites for establishing an insurance system, including the existence of enforceable drug formularies and treatment standards, the readiness and ability of the population to pay insurance premiums, and so forth. Both oblast and national-level decision makers may benefit from an in-depth survey of the economic viability of establishing insurance mechanisms and follow-up training.

- The existence of sources of unbiased evidence-based drug information is a prerequisite for activities aimed at improving prescribing and drug use practices. Currently neither the oblasts nor the national government has the means or experience to establish drug information centers. To establish drug information services, assistance will be required in obtaining sources of unbiased drug information (reference manuals, access to the Internet, etc.), training in drug information development and use, and equipment. The RPM experience in developing drug information centers and information materials in Russia may be used.

National Level

- The current drug registration system does not create a favorable environment for competition in the drug market. Drug registration is a source of hard currency for the country, and as such it does not serve the social goals. It is lengthy and expensive, making it impossible for many manufacturers, especially those producing good quality generic products, to enter the market. This leads to the development of monopolies for certain drugs, an increase in the number of illegal (nonregistered, smuggled) drugs on the market, and a rise in prices. International assistance may be necessary to prove to the national government that inexpensive, effective

drug registration will, in the long run, bring more revenues to the state and make quality drugs more affordable to the population.

- Discussions with the oblast decision makers and physicians showed that there are few incentives for health workers to reform the health sector. A reduction in the number of hospital beds or a decrease in the length of hospitalization washes funds out of the health system. Whatever funds oblasts save due to health reforms are not reinvested in health, but are taken out and used by the government for other purposes. Such a situation undermines international efforts to implement health reforms in Kazakhstan and may be responsible for increasing resistance (proved by the RPM assessment) to reforms in primary health care. Assistance in the form of international projects may be required to develop an understanding of the problem at the national level.

TB Drug Management

Further Needs in Operations Research

Kazakhstan and other Central Asian Republics have been implementing DOTS for a number of years. However, according to statistics, the morbidity rate has not changed favorably.

Often, necessary TB drugs are not available. Furthermore, when drugs are available, they are often used irrationally. These two issues, drug availability and use, undoubtedly contribute to the TB morbidity and mortality seen in the CAR.

An indicator-based assessment of TB drug management is useful to (1) help identify the causes of poor availability and use, (2) design drug management interventions, (3) convince decision makers to take action, and (4) measure progress.
RPM has developed a tool for such an assessment, the *Drug Management for Tuberculosis Manual* (DMTB).

Selection

RPM experience in Kazakhstan has shown the value of technical assistance to ensure that TB drugs selected for tenders are those that are needed for DOTS implementation. In general, the selection process has been fairly opaque (i.e., done behind closed doors). This has resulted in the procurement of a large number of non-DOTS drugs and TB drugs for multidrug-resistant TB (MDRTB). One way to address the problem could be an open discussion of drug selection at the national level with participation of top international TB experts (KNCV, IUATLD, CDC, WHO).

Another issue related to the selection of TB drugs, but not confined solely to TB drugs, is drug registration. Currently the drug registration procedures are expensive and lengthy, and do not allow easy access to inexpensive, high-quality generic TB drugs. This limits the selection and keeps prices high. Training and technical assistance are required in drug registration.

Because TB treatment is under government control and is centralized, it creates a good opportunity to work on a TB facility drug formulary. At this point, as RPM assessment data suggest, patients have to pay out-of-pocket for a large number of irrationally prescribed drugs, medical supplies, and food.

Procurement

As the RPM experience has shown, technical assistance in TB procurement should be ongoing for at least several years to become truly sustainable. Tender documents should be reviewed and improved, and tender procedures should be observed (in order to provide hands-on assistance and develop local capacity in tendering). More attention should be given to drug supply contracts.

Two important components of good procurement practices are monitoring of supplier performance and reporting of drug quality problems. A database on suppliers and drug products should be developed and maintained to provide information for supplier prequalification. Ideally, to meet the national TB program drug requirements it may be advisable in the future to move from open to restricted tenders.

During the Karaganda assessment RPM learned that oblasts conduct their own TB drug procurements, separate and apart from national TB drug procurements. The feasibility of eliminating duplicate procurements should be explored.

Distribution

Anecdotally, a significant waste of TB drugs occurs down the distribution pipeline. Improper storage and handling can also be damaging to drug quality. A special study of the distribution system down to the rayon TB facility level should be conducted.

Use

The DMTB assessment tool includes several indicators to study the degree of compliance of prescribers and patients with accepted treatment standards. An assessment may show if problems exist. There are, however, many drug use issues and potential problems that may be overlooked by prescribers and medical staff, and may not be detected during a short, one-time assessment. It is not safe to assume that a TB facility complies to standards unless there is an ongoing mechanism to check this, and take corrective action when needed. One such essential mechanism to ensure the proper use of drugs is an ongoing drug utilization review program.

TB Drug Management Information System (TB DMIS)

There is a great need in Kazakhstan for drug management information systems at all levels of health care. The National TB Program, however, may require a separate DMIS, since it is a separate vertical program. Establishing a DMIS is not easy, though, and will require much technical assistance, training, and the provision of equipment.

Lessons Learned

Project–Related Lessons

- The implementation methods selected for RPM activities were effective for achieving the immediate goals set by USAID. Specifically, targeted, short-term technical assistance is a cost-effective programmatic method when the expected output or outcome is a document (tender documents), participation in a one-time process (drug tender), or training in general issues (drug procurement). However, sustainability of RPM efforts will largely depend on the willingness of local decision makers to accept RPM recommendations to establish drug management mechanisms for national and oblast health programs.

- A pharmaceutical sector indicator-based assessment is a powerful tool that helps to identify drug management deficiencies, identify possible solutions, and initiate a policy options dialogue. When local experts are involved at every stage of the assessment, beginning with planning, it also helps create stakeholders. RPM, however, had a chance to conduct such an assessment and the resulting policy options workshop only at the very end of project, and thus was unable to build on its results and outcomes. An assessment and a policy options workshop should precede any activities aimed at reforming the pharmaceutical sector.

- Collaboration with several USAID-funded organizations and WHO proved to be very successful. RPM did not have significant previous experience working in the CAR, and benefited from the experience and technical expertise of Abt ZdravReform and Project HOPE. In preparation for the regional workshop in 1999, communication and leveraging with WHO allowed for a better understanding of procurement problems in the CAR.

- Subcontracting the Academy for Educational Development (AED) to organize the January 1999 Regional General Procurement Workshop helped avoid many problems that otherwise could have occurred if the workshop had been organized from the United States. AED's excellent skills in providing logistical support and bringing together participants from 10 countries are commendable.

- The idea of a regional workshop proved to be fruitful. Participants were very interested in sharing their experiences with each other and learning about approaches used in other NIS countries to solve procurement problems. It is advisable that such workshops be conducted regularly.

Pharmaceutical Sector–Related Lessons

- In the CAR, even the presence of good and reasonable health policies and strategies that affect the drug supply does not guarantee the easy implementation of reforms due to lack of enforcement mechanisms.

- Deficiencies in drug registration mechanisms and the lack of unbiased drug information in the CAR may impede future activities and interventions in improving drug selection, procurement, and drug quality assurance.

- Despite the efforts to shift the focus of the health systems in the CAR to primary health care, hospitals remain important venues for improving drug management.

- The increasing role of nongovernmental professional associations and the private sector in delivering pharmaceutical sector services to public health systems presents many opportunities and challenges.

- Kazakhstan may benefit from the specialized training of oblast procurement specialists in aspects of pooled procurement.

National TB Program–Related Lessons

- Short-term technical assistance was sufficient to empower the TB Tender Commission. As a result, the 1999 national TB tender was conducted according to international competitive procurement standards.

- It is difficult to plan and implement any changes in the National TB Program without the data from an in-depth survey of the TB drug management system.

- The National TB Program may face significant difficulties without oversight from the National Agency for Health on drug selection for TB treatment, procurement, distribution, and use.

- Improvements in the drug component of the National TB Program may stall in the future without reliable survey data on the prevalence of MDRTB and data on the quality of TB drugs on the Kazakhstan market.

Annex 1. Reference Documents Produced and Tools and Manuals Used

Reference Documents Produced during the Project

Adams, I.C., Gabra, M.S., Savelli, A.V., Zagorski, A. *RPM Central Asian Republics Final Report.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, August 1999.

Gabra, M. *RPM Kazakhstan Trip Report, Visit to Almaty, Technical Assistance in Development of Tender Documents.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, April 1999.

Savelli, T. *RPM Trip Report, Kazakhstan and Kyrghyzstan, October 1998.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, October 1998.

Savelli, T. *Trip Report, Reconnaissance Trip to Kazakhstan, February 1994.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, February 1994.

Zagorski, A. *Central Asian Republics: Final Report of the Rational Pharmaceutical Management Project.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 2000.

Zagorski, A. *RPM Trip Report to Kazakhstan, November 1999.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, November 1999.

Zagorski, A., Gabra, M. *Workshop Proceedings: CAR General Procurement Workshop. Kazakhstan, Almaty, Alatau, January 1999.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, January 1999.

Zagorski, A., Semenchenko, M. *Karaganda Oblast, Kazakhstan, Pharmaceutical Sector Assessment, February–March 2000.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, March 2000.

Zagorski, A., Semenchenko, M. *Proceedings: Pharmaceutical Policy Options Workshop, May 2000.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 2000.

Zagorski, A., Semenchenko, M. *Workshop Proceedings: Cost-Effective Drug Selection and Formulary System Implementation in Oblast Hospitals and Family Group Practice, Kazakhstan, Karaganda, January 2000.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, [Draft] February 2000.

Tools and Manuals Used during the Project

Management Sciences for Health (MSH). *International Drug Price Indicator Guide.* Arlington, VA: MSH, 1999.

Management Sciences for Health in collaboration with the World Health Organization. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.* 2d ed., Revised and Expanded. West Hartford, CT: Kumarian Press, 1997.

Management Sciences for Health/Rational Pharmaceutical Management (RPM) Project. *Rapid Pharmaceutical Management Assessment: An Indicator-based Approach.* Arlington, VA: MSH/RPM, July 1995 (also available in Russian).

Moore, T., B. Bykov, T. Savelli, and A. Zagorski. *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.* Arlington, VA: Russia Rational Pharmaceutical Management Project/Management Sciences for Health, January 1997 (also available in Russian).

Savelli, A.V., H.O. Schwarz, A. Zagorski, and A. Bykov. *Manual for the Development and Maintenance of Hospital Drug Formularies.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, 1996 (also available in Russian).

U.S. Pharmacopeial Convention, Inc. *USP Dispensing Information—Volume I: Drug Information for the Health Care Professional.* Englewood, CO: Micromedex, 1999 (also available in Russian).

Ecuador

Executive Summary

The Rational Pharmaceutical Management (RPM) Project's objectives for the Ecuador program were to—

1. Improve availability of and access to essential drugs through Ministry of Health (MOH) services

2. Improve drug use by prescribers and the public

3. Define and refine national drug policy

The implementation strategy consisted of—

- Forming strategic alliances with all organizations seeking to improve drug supply and use

- Assisting the MOH to design and implement a decentralized drug management system (DDMS) based on an assessment of public-sector drug management

- Conducting dialogue with the MOH to revise drug policy

- Supporting allied organizations to develop drug management and rational drug use (RDU) activities using their own resources and methodologies

RPM initiated work in Ecuador with the Management Sciences for Health (MSH)-World Bank evaluation of the State Center for Drugs and Medical Supplies (CEMEIM) conducted in 1994 and the rapid assessment of the drug system conducted by MOH-RPM-FASBASE (World Bank) in 1995. RPM's country program was designed to develop and apply the recommendations of these two studies: decentralize drug management and implement cost recovery.

The principal activity of the RPM/Ecuador porgram was support of the Ministry of Health's efforts to decentralize drug procurement and distribution. Work was conducted in close collaboration with the Directorate of Sanitary Control (DSC) and the Provincial Health Directorates and in coordination with international organizations, including the Pan American Health Organization (PAHO), UNICEF, Belgian Technical Cooperation (BTC), and the World Bank.

The first phase of work consisted of a rapid pharmaceutical assessment using RPM's indicator-based methodology, adapted to the health district level. An assessment was carried out in eight health districts by district staff trained by RPM. The assessment report convinced the MOH to decentralize drug management to the health district level. The MOH adopted the DDMS as official policy in October 1997.

In November 1996, the Directorate of Sanitary Control decided to apply the decentralized model progressively in all provinces of the country by assigning implementation responsibility to

international agencies interested in improving drug management, including RPM, PAHO, and BTC. The strategy was initially applied by RPM in three provinces, Imbabura, Tungurahua, and Morona Santiago, using the Monitoring-Training-Planning (MTP) methodology to implement decentralized programs, and was expanded to an additional seven provinces by the end of 1998.

In August 1999, the DSC conducted an assessment of the drug management situation in all provinces of the country and determined that the DDMS was operating well in those provinces where RPM had assisted. As a result, the DSC requested RPM to assist implementation in the remaining 12 provinces, including those which had initially received assistance from PAHO and BTC.

The second principal activity was the improvement of hospital drug management. This activity began with a five-day workshop at the Hospital Eugenio Espejo (HEE) in September 1996. In December, it became clear that the participants had not completed tasks assigned during the workshop. Therefore, in March 1997, RPM began to adapt the MTP modules that had been used to successfully implement the DDMS in health districts for use in hospitals. In June, the new modules were applied by the MOH and IESS hospitals in Ibarra and, for the next 12 months, they carried out the complete drug management series of modules.

The third principal activity of RPM/Ecuador was to improve rational drug use through primary schools. The URMES model *(Uso Racional de Medicamentos en Escuelas)* was developed to teach primary school children about common childhood diseases, how to recognize and prevent them, and how to cure them with appropriate medicines. The model is being applied in more than 200 schools in four provinces of the country. Evaluations have shown significant knowledge and behavioral changes in students, teachers, and parents.

A fourth activity of RPM/Ecuador was support to other organizations in their attempts to improve drug management in the country. These organizations included Fundación Terapia, the Central University, Association of Latin American Pharmaceutical Producers (ALAFAR), and UNICEF as well as the World Bank projects—FASBASE and MODERSA—and the Holanda-Ecuador project of PAHO's Essential Drugs effort. RPM's support included—

- Sponsoring a drug-seller survey by ALAFAR
- Supplying hardware and United States Pharmacopoeia Dispensing Information (USP-DI) materials to the Drug and Poison Information Center
- Providing printed forms to FASBASE-supported health districts and service units
- Strengthening hospital drug management in a MODERSA-supported hospital
- Subcontracting with Fundación Terapia to improve rational drug dispensing by drug sellers

The accomplishments of the RPM/Ecuador program were—

1. Enunciation of the decentralized drug management policy
2. Promulgation of the System of Financial Administration of Institutional Pharmacies
3. Development of MTP modules to improve drug management in health districts and hospitals
4. Application of MTP modules by local MOH personnel in 10 provinces and three hospitals
5. Development of the URMES model and its application in primary schools of four provinces
6. Training of private drug sellers to improve dispensing practices in two provinces
7. Organization and operation of a Drug and Poison Information Center
8. Increased availability of essential drugs in MOH facilities
9. Partial to total cost recovery for drugs in most MOH subcenters
10. More than $74,000 of additional resources leveraged to support drug management and RDU

225

Acknowledgments

Dr. Eduardo Zea, Director of Sanitary Control, Ministry of Public Health, 1995–96
Dr. Nelson Valle, Director of Sanitary Control, Ministry of Public Health, 1997–98
Dr. Ximena Chiriboga, Director of Sanitary Control, Ministry of Public Health, 1999
Dr. Oscar Luzuriaga, Director of Sanitary Control, Ministry of Public Health, 2000
Lic. Mauricio Larrea, Mayor of Ibarra
Ing. Argentina Vergara, Directorate of Sanitary Control, Ministry of Public Health
Dr. Lorena Ruiz, Directorate of Sanitary Control, Ministry of Public Health
Dr. Marcelo Lalama, Fundación Terapia

RPM consultants:

Dr. José Avecillas
Lic. Hernán Silva
BF Carlos Proaño
Dra. Yolanda de Grijalva
Ing. Iván Grijalva
Ing. Neyda Espín

Acronyms

ABC	analysis system to determine highest- and lowest-consumption products
ALAFAR	Association of Latin American Pharmaceutical Producers
BTC	Belgian Technical Cooperation
CEMEIM	State Center for Drugs and Medical Supplies (acronym in Spanish)
CEPAR	Center for Population and Responsible Parenthood (*Centro de Estudios de Paternidad Responsable* in Spanish)
CIMET	Drug and Poison Information Center (acronym in Spanish)
DDMS	decentralized drug management system
DMU	Drug Management Unit
DSC	Directorate of Sanitary Control
FASBASE	World Bank project to strengthen health districts
HEE	Hospital Eugenio Espejo
MODERSA	World Bank project to modernized the health sector
MOH	Ministry of Health [Ecuadoran]
MSH	Management Sciences for Health
MTP	Monitoring-Training-Planning
NGO	nongovernmental organization
PAHO	Pan American Health Organization
RDU	rational drug use
RPM	Rational Pharmaceutical Management [Project]
SINAFA	National Pharmaco-therapeutics System (acronym in Spanish)
SO	strategic objective
UNICEF	United Nations Children's Fund
URMES	*Uso Racional de Medicamentos en Escuelas Saludable*
USAID	U.S. Agency for International Development
VEN	system of classification of drugs according to their importance in saving lives, pharmacological effectiveness, and safety

Program Overview

In the mid-1980s, the Ecuadoran Ministry of Health (MOH) centralized drug purchases and distribution for all MOH facilities in a quasi-autonomous State Center for Drugs and Medical Supplies (CEMEIM). Poor management of procurement and receivables led to chronic losses and frequent stock-outs, both at central and regional warehouses and in service delivery units for which CEMEIM was the only supplier. Disillusion with CEMEIM grew with time and a search for alternatives began in the early 1990s.

In 1994, FASBASE (a World Bank–funded project to strengthen basic health services) requested that Management Sciences for Health (MSH) assist in the evaluation of CEMEIM and assess alternatives for its restructuring, including design of a cost-recovery component. The report recommended formation of a public-private corporation to negotiate drug prices and proposed a decentralized design for drug procurement at the health district level. The design was not implemented at that time; however, FASBASE began efforts to strengthen the administrative and financial capacity of some health districts with an eye to decentralizing drug management. RPM began to support those efforts in October 1995, after MOH representatives participated in an RPM-sponsored rapid drug assessment workshop in Bolivia and requested replication of the workshop in Ecuador. As a result of the second workshop, RPM developed a country program with the MOH, which evolved in three phases.

1. Pharmaceutical management assessment in MOH health districts and design of a decentralized drug management model (October 1995–March 1996)

2. Development and implementation of the Monitoring-Training-Planning (MTP) methodology and materials to implement the model (April–June 1996)

3. Application of the decentralized drug management system (DDMS) (November 1996–August 1998)

RPM also developed three other lines of work to complement the MOH program:

- A primary school–based health education program to improve drug use by the public

- Assistance to MOH and IESS hospitals to improve drug management and rational use

- Support to a variety of initiatives by individual organizations aimed at improving drug use

Objectives

RPM's objectives for the Ecuador program were—

1. Improve availability and access to essential drugs through MOH services

2. Improve drug use by prescribers and the public

3. Define and refine national drug policy

Implementation Strategy and Major Activities

Besides contributing to USAID's global strategic objectives, RPM's Ecuador program was designed to contribute to the USAID/Ecuador mission's strategic objectives(SOs):

SO B1–Improve the quality of primary and secondary services
SO B2–Expand access to primary health care services

RPM's implementation strategy consisted of—

- Forming strategic alliances with all organizations seeking to improve drug supply and use
- Assisting the MOH to design and implement a decentralized drug management system based on an assessment of public-sector drug management
- Conducting dialogue with the MOH to revise drug policy
- Supporting allied organizations to develop rational drug use (RDU) activities using their own resources and methodologies

RPM's work in Ecuador began in 1994 with the MSH-World Bank evaluation of CEMEIM and the indicator-based rapid assessment of the drug system conducted by MOH-RPM-FASBASE (World Bank) in 1995. RPM's country strategy was designed to develop and apply the recommendations of these two studies: decentralize drug management and implement cost recovery.

Subsequently, in 1998 the RPM midterm evaluation recommended that RPM develop a "District Drug Management Package," which was, in effect, the objective of the Ecuador program. In the course of implementing the principal program activities, including *Uso Racional de Medicamentos en Escuelas Saludable* (URMES) and the decentralized drug management system, baseline studies were prepared that formed the basis for outcome monitoring in accordance with the recommendations of the midterm evaluation.

The principal activity of the RPM program in Ecuador from 1995 through 2000 was to support the Ministry of Health in drug procurement and distribution. During this period, RPM worked closely with the MOH and international organizations, including the Pan American Health Organization (PAHO), UNICEF, Belgian Technical Cooperation (BTC), and the World Bank, to design and implement a DDMS that would shift drug procurement and distribution from the central level to the health districts. The DDMS was designed and implemented in collaboration with the Directorate of Sanitary Control (DSC) and the Provincial Health Directorates using the

Monitoring-Training-Planning methodology developed by RPM to implement decentralized programs. The principal phases of implementation of this activity were—

- Assessment—Application of the RPM indicator-based rapid assessment methodology in 12 provinces, 1995–96
- Design of the new system—Participatory, interinstitutional drafting of a manual for DDMS followed by field tests, 1996
- Design and production of manual and operational materials with official sanction, 1996–97
- Development of implementation methodology—Design and testing of five MTP modules in three provinces, 1996–97
- Implementation of the five MTP modules in 10 provinces with three-fourths of the country's population, 1997–98
- Evaluation—Self-evaluations conducted by districts and provinces in 1998, followed by a national assessment conducted by the MOH in 1999
- Institutionalization—Policy reform to promulgate the DDMS and adoption of the MTP methodology and modules to implement it by the MOH, 2000

The outcomes of the first three phases, through 1996, were health district staff trained to conduct a rapid pharmaceutical assessment making use of RPM's methodology adapted to the health district level, a report of the rapid drug management evaluation in the eight pilot health districts, a manual to expand the use of the assessment methodology along with eight trainers to apply it, a new decentralized drug management system for health districts with a corresponding procedures manual, and a training package for implementation and expansion of the new system.

In November 1996, a multilateral strategy was developed with DSC to apply the decentralized model progressively in all provinces of the country by assigning implementation responsibility to international agencies interested in improving drug management in Ecuador, including RPM, PAHO, and BTC. The strategy was initially applied by RPM in three provinces, Imbabura, Tungurahua, and Morona Santiago, and ultimately led to expansion of the DDMS to 100 health districts of 10 provinces by the end of 1998.

As a result of continuous dialogue with MOH officials and a series of workshops sponsored by the National Health Council, RPM, FASBASE, and MODERSA, in October 1997 the MOH officially adopted the DDMS in a policy pronouncement. In 1998, the CEMEIM was officially disbanded and, in 1999, replaced by a Drug Management Unit (DMU) charged with negotiating prices for drugs purchased by the public sector, thus finalizing the policy reform in response to RPM's recommendations from 1994 and 1996 and completing the process initiated with implementation of the DDMS during the previous two years.

In August 1999, the DSC conducted an assessment of the drug management situation in all provinces of the country and determined that the DDMS was operating better in those provinces where RPM had assisted. As a result, in January 2000 the DSC requested RPM to assist with implementation in the remaining 12 provinces, including those which had initially received assistance from PAHO and the BTC. Because of the proximity of the end of project, RPM could not respond to the request. However, the DSC contracted ex-RPM consultants to continue this work.

The second principal activity of the RPM program in Ecuador was assistance to improve hospital drug management. In June 1996, the Director of Hospital Eugenio Espejo (HEE) requested USAID assistance to strengthen the drug management system of the hospital. RPM designed and conducted a five-day workshop for 26 hospital staff in September 1996 in which participants mastered techniques to prepare a hospital drug formulary, conduct VEN and ABC analyses, and prepare drug policies and drug information monographs. All participants expressed a firm commitment to develop a hospital formulary manual for the HEE. However, a follow-up workshop held in December 1996 revealed that those tasks had not been completed, at least in part because of management instability and lack of supervision.

As a result, in March 1997 RPM began to adapt for hospital use the MTP modules that had been used successfully to implement the DDMS in health districts. In June, the new modules were applied by the hospital staff in the MOH and IESS hospitals of Ibarra and, during the next 12 months, the complete drug management series of modules was carried out with the following outcomes:

- Operational Pharmacology Committees
- Standard treatment protocols for the most frequent pathologies
- Hospital drug formulary
- Plans to modernize the institutional pharmacy
- Cost recovery

These eight modules were later used in 21 hospitals in Peru to improve drug management.

The third activity of RPM/Ecuador was the development of a public education program to improve rational drug use through primary schools. Under the USAID Health Sector Reform Project, the Centro de Estudios de Paternidad Responsable (CEPAR) and the Healthy Communities Initiative of PAHO promoted the establishment of county health committees in three municipalities of the country. One of these, Ibarra, proposed a "healthy schools" project, and RPM collaborated with the municipality to develop an "add-on" curriculum for primary school children to learn about common childhood diseases, how to prevent them, and how to cure them with appropriate medications. The URMES model was the result. After trials in 8, and later 21, schools, the model was applied in schools in four provinces of the country.

A fourth activity of RPM/Ecuador was support to other organizations in their attempts to improve drug management and rational drug use in the country. These organizations included Fundación Terapia, the Central University, Association of Latin American Pharmaceutical Producers (ALAFAR), and UNICEF as well as the World Bank projects—FASBASE and

MODERSA—and the Holanda-Ecuador project of PAHO's Essential Drugs program. RPM's support ranged from sponsoring a drug-seller survey by ALAFAR to supplying hardware and United States Pharmacopoeia Dispensing Information (USP-DI) materials to the Central University in order to start the Drug and Poison Information Center. RPM also provided printed forms to FASBASE-supported health districts and service units in order to apply the DDMS and assisted application of the hospital drug-management modules in Hospital Enrique Garcés, a MODERSA-supported hospital. Finally, Fundación Terapia was subcontracted by RPM to apply the "Farmacia 2000" program to private drugstores in an effort to improve rational drug dispensing by drug sellers.

Challenges Facing RPM/Ecuador Implementation

The principal challenge facing RPM/Ecuador during the entire implementation period has been the instability of central and provincial staff. Since 1994, there have been five presidents of the country and five ministers of health, seven Directors General of Health and as many Directors of Sanitary Control. With each change of minister, the provincial authorities were changed, along with many of the health district chiefs. Virtually every minister and/or director general had a new drug program to introduce, with the result that most drug management activities already under way were halted, changed, eliminated, or ignored. Under these conditions, much of RPM's effort went into briefing new officials and convincing them that continuity was important.

A further challenge was the continued high inflation rate, which has increased the price of drugs faster than personal incomes or government budgets. Revolving drug funds in MOH facilities lost significant capitalization during the last three years because governmental accounting practices did not allow revaluation of stocks to recover inflation losses.

A third challenge to RPM implementation was the geographic division of labor between projects such as UNICEF's "Bamako" initiative (Esmeraldas and Sucumbios provinces), the Holanda-Ecuador project of PAHO (Loja, Zamora, and El Oro provinces) and the APS (Primary Health Care) project of BTC (Cañar, Los Rios, and Napo provinces). In the latter case, BTC asked RPM to apply the MTP methodology in order to implement the DDMS in project provinces. In the former cases, UNICEF and PAHO asked that the MOH and RPM not conduct drug management activities in project provinces. The result was that archipelagos were formed where each international organization conducted project activities as it wished without regard for (incipient) MOH policy and procedures.

Chronological Activity Timeline

Table 1. Activity Timeline

Date	Activity
1994	MSH-World Bank assessment of CEMEIM resulting in recommendations for reform and decentralization of drug management
March 1995	MOH Director of Sanitary Control participates in RPM Rapid Assessment workshop in Bolivia; requests RPM assistance to replicate workshop
October 1995	RPM conducts Rapid Assessment workshop in Ecuador for 15 MOH central and district staff and FASBASE officials
1995–1996	Indicator-based, rapid assessment of drug system conducted in 10 provinces by MOH and FASBASE staff
May 1996	RPM facilitates design of decentralized drug management system by MOH with participation of FASBASE, PAHO, BTC
August 1996	First four Monitoring-Training-Planning modules to implement decentralized drug management system developed and tested
September 1996	RPM assists indicator-based, rapid assessment of hospital drug system in Hospital Eugenio Espejo, Quito
1996–1997	Indicator-based, rapid assessments of drug system conducted in 11 health districts of Imbabura and Morona-Santiago provinces by local MOH staff with RPM assistance
January 1997	Hospital Eugenio Espejo conducts follow-up of rapid assessment with RPM assistance
March 1997	RPM and Municipality of Ibarra design, apply, and evaluate URMES model in eight primary schools
March 1997	MTP modules applied in Imbabura and Morona-Santiago provinces
August 1997	RPM supports Central University, ALAFAR, and Metropolitan Hospital to organize and operate the National Drug and Poison Information Center
September 1997	RPM designs MTP modules for hospital drug management; modules applied in MOH and IESS hospitals of Ibarra
October 1997	RPM agrees to MOH requests that MTP application be expanded to 10 provinces; contracts and trains three field coordinators
October 1997	RPM and PAHO advise MOH on alternatives to centralized drug procurement via CEMEIM
November 1997	ALAFAR conducts drug-seller assessment in private pharmacies of Ibarra with RPM guidance and support
1997–1998	Five MTP modules applied by provincial and district MOH staff in 100 health districts of 10 provinces
March, August 1998	Fundación Terapia applies "Farmacia 2000" program to improve private dispensing practices of private drug sellers, under contract to RPM
1998	URMES program applied in 21 primary schools of Ibarra
July 1998	RPM assists CARE's APOLO Project to improve drug management using MTP methodology
1998	URMES applied in all primary schools of Sucumbios province
October 1998	CEMEIM is formally disbanded and a Drug Management Unit is formed in MOH to negotiate drug prices for decentralized purchasing
November 1998	RPM conducts field trial of Integrated Management of Childhood Illness drug assessment manual
1998	RPM and FASBASE assist MOH to develop system for financial administration of institutional pharmacies, including software
1998–1999	RPM assists MOH to include contraceptives in Essential Drugs List as part of transition from donated to purchased commodities

Table 1. Activity Timeline (cont'd.)

February 1999	MOH holds National Pharmaceutical Management Seminar with support from World Bank and participation of RPM and PAHO
August 1999	MOH evaluates operation of the Decentralized Drug Management System and requests RPM support to expand MTP application to remaining provinces
1999–2000	RPM conducts antibiotic-use study in two hospitals of Quito
January 2000	RPM assists application of MTP modules in Enrique Garcés Hospital in Quito with MODERSA (World Bank) financing
April 2000	RPM agrees to MOH request that RPM support implementation of the MOH's financial administration system in all provinces.
May 2000	URMES applied in primary schools of Duran, Guayas province
June 2000	RPM assists MOH to design national contraceptive logistics system based on decentralized drug system

Program Accomplishments

Drug Policy

In late 1999, the Minister of Health of Ecuador stated that the MOH had reformed drug policy following RPM recommendations regarding CEMEIM and decentralization of drug management. In effect, from 1994 to 1999, the MOH designed the DDMS as the fourth component of the National Pharmaco-therapeutics System, SINAFA, and implemented it in two-thirds of the health districts of the country.

In 1998, as a further application of SINAFA and in response to need for policy definition regarding cost recovery and revolving drug funds, the MOH developed the System of Financial Administration of Institutional Pharmacies. The system was officially promulgated later that year and authorized by the National Controller's Office for implementation. After extensive trials in Tungurahua province, national implementation began in 2000.

Both of these policy developments derived directly from RPM evaluations and assessments and subsequent dialogue with MOH officials. The actual implementation of these policies was assisted and supported by RPM.

Decentralized Drug Management

The RPM/Ecuador program developed the Monitoring-Training-Planning (MTP) self-teaching modules as an implementation tool that has proven useful in a variety of situations. The MTP modules have been used by health districts, hospitals, and primary schools to implement a whole spectrum of programs. Some examples follow.

1. Health Districts

The first phase of the DDMS was implemented in less than a year by provincial and district staff in 10 provinces with more than three-quarters of the total population and two-thirds of the health districts. RPM coordinators assisted provincial MOH teams to apply the MTP modules, which covered the following subjects:

- The Health Area Pharmacology Committee
- The Health Area Drug Warehouse and Supply System
- Drug Stocks and Sales in Health Centers and Subcenters
- Good Prescribing Practices, Standard Treatments, and the Hospital Formulary

Two additonal modules were developed but only partially applied:

- Financial Management of the Drug System and Cost Recovery
- Self-Evaluation of Drug Management in Health Districts

Self-evaluations by the provincial teams and districts in 1998 found that functioning pharmacology committees were selecting drugs and developing standard treatments and formularies and that decentralized procurement and cost recovery were taking place in most of the districts that had participated in the implementation. An all-province, indicator-based evaluation done by the MOH in 1999 revealed that more essential drugs were in stock and fewer stock-outs occurred in those provinces that had participated in the RPM-assisted DDMS implementation. Cost recovery was being achieved, at least partially, in 80 percent of the districts in those provinces.

2. Hospitals

The MTP modules originally designed to train district-level health care staff were adapted for use in hospitals. Eight MTP modules were applied by hospital staff in two provincial-level hospitals in Imbabura province. More than 100 persons participated in the process during a 12-month period. The modules they applied were—

- The Hospital Pharmacology Committee
- Drug Selection and Analysis
- Standard Treatments and the Hospital Formulary
- The Hospital Pharmacy
- Good Dispensing Practices
- Participation of the Patient in Treatment
- Drug Use Studies
- Self-Evaluation Based on Indicators

Hospital management has assessed the outcomes of this process and reports that—

- The most frequent treatments have been standardized in most services.
- A hospital formulary has been prepared to guide selection of drugs for procurement.
- The hospital pharmacy has been relocated to provide 24-hour outpatient service as well as attending hospital cases.
- Training is under way to install the MOH's System of Financial Administration of Institutional Pharmacies.

3. Nongovernmental Organizations—Project Apolo

   RPM assisted CARE to conduct MTP sessions with six health-service nongovernmental organizations (NGOs) that were subjects of USAID's Project Apolo, an effort to strengthen private-sector, primary health care initiatives. As a result of these sessions, one of the NGOs reported reducing its drug stocks from more than 800 items to less than 200. Others reported undertaking efforts to standardize treatments among physicians in their facilities.

Rational Drug Use in Schools, URMES

URMES (RDU education) has been used to teach proper drug use to some 23,000 children in 232 schools of Imbabura, Guayas, and Sucumbios provinces. These primary schoolchildren learned about common childhood diseases, disease prevention, and appropriate drug use. More than 300 community volunteers (teachers and parents) were trained and supervised through a series of 10, MTP-based modules about topics such as scabies, colds, malaria, malnutrition, anemia, and diarrhea.

Evaluations showed significant improvements in knowledge about the diseases, prevention, and treatment by students, teachers, and parents. Because children buy their activity workbooks, the program is largely self-financing. Organizations in the Philippines, Nicaragua, and Peru have expressed interest in the model and are seeking donors or local sponsors to support local implementation. Two schools in Lima, Peru, have tested the model with favorable results.

Training for Private Drug Sellers

The Fundación Terapia's "Farmacia 2000" is being adopted by the Association of Drugstore Owners and has given rise to an initiative by the College of Pharmacists and two universities to professionalize drugstore clerks in order to improve dispensing practices and reduce self-treatment by clients.

Drug Information System

The CIMET, or Drug and Poison Information Center, is operated by the Central University and ALAFAR and currently handles two to three consultations per day. It is staffed by volunteers (primarily pharmacology students) and uses hardware and some software donated by RPM. The Technological University of Chimborazo is studying the feasibility of establishing a third cooperating center under the CIMET.

Evaluation Results

The internal RPM evalution, conducted in March 1998, found that virtually all health districts had working pharmacology committees and district-level drug warehouses with drug distribution to service sites; most were recovering drug costs, either partially or totally. The evaluators expressed surprise at how everyone interviewed around the country "was speaking the same language" regarding drug management and rational drug use.

The all-province, indicator-based MOH evaluation of August 1999 found that most health districts still had functional pharmacology committees and were recovering costs. However, a disturbing number had experienced stock-outs and expressed uncertainty about how to deal with confusing MOH pronouncements regarding charges for services and exemption from payment.

Leverage of Other Funds and Resources

RPM/Ecuador negotiated agreements with the MOH and USAID to use $60,000 of mission Child Survival funds assigned to the MOH to cover local implementation costs of the DDMS, including training and supervision expenses as well as printing of forms and training materials. The central MOH has provided two full-time counterparts to work with RPM, and the provinces and districts fielded some 400 provincial and district staff to participate in and conduct the MTP sessions to implement the DDMS.

The Municipality of Ibarra budgeted $7,000 for the URMES program in 1998 and parents of Ibarra schoolchildren contributed another $2,000. In Sucumbios province, the ÑanPaz Foundation financed another $7,000 of training and logistics costs for implementation of URMES in all schools of the province; parental contributions covered about 50 percent of the cost of materials.

Activities Not Completed

1. Expansion of the DDMS to the remaining 12 provinces was programmed for 1999–2000 but changes of government and central MOH managers caused confusion regarding policy and indecision over operational procedures. The MOH is currently in the process of contracting

ex-RPM consultants to work with central-level functionaries to expand the DDMS to the remaining provinces using MTP modules and to apply the System of Financial Administration of Institutional Pharmacies in all provinces and districts.

2. A National RDU Congress was planned for late 1998 or early 1999. Again, governmental instability caused the indefinite postponement of this activity.

Likely Needs at End of Project

After the RPM program closes in Ecuador, the following are likely needs for the future.

- National coverage of DDMS—health districts and MOH hospitals. On the basis of expressions by MOH and MODERSA officials, it is their desire that the DDMS be implemented in all health districts and provincial hospitals. Indecision is, so far, paralyzing action to put the plan into effect.

- Operationalization of preferred supplier mechanisms and negotiated prices for decentralized procurements. The MOH's Drug Management Unit is charged with selecting suppliers and negotiating favorable, uniform prices for all MOH (and, perhaps, all public sector) service units. As yet, the DMU has not achieved its objective and will probably require technical assistance to do so.

- Monitoring and evaluation of the DDMS in MOH units. Continued self-evaluation of DDMS performance is necessary to monitor and improve drug management and use, as well as cost recovery and financial sustainability of the system. Although indicators have been defined and used in isolated instances, a fully functional monitoring system needs to be put into place.

- Certification of functional units. As an outcome of the monitoring system, performance of well-operated districts and units should be recognized. This objective has been stated many times by the MOH, the Quality Assurance Project, and RPM but no concrete steps have been taken. Technical assistance will be necessary to organize a certification entity and make it operate effectively.

- Integration of family planning commodity logistics into the DDMS. With the elimination of donated family planning commodities, the vertical supply system of the MOH will undoubtedly be decentralized. In theory, these commodities can be managed as part of the DDMS. However, a number of conflicting laws and regulations must be harmonized and confusion resolved in order for this to happen. Technical assistance will be needed to facilitate the process.

- Clarification of cost-recovery criteria and exemption policy for MOH units. This topic is related to the previous one and similar technical assistance will be required to sort out the confusion and resolve conflicting policies and regulations.

Lessons Learned

1. Experience has amply demonstrated that pharmacy and therapeutics committees are frequently mere formalities and usually do not do the things they were set up to do. RPM/Ecuador showed that assigning monthly tasks is a good way to keep them operating and producing results.

2. Tools alone are not enough. A rational pharmaceutical management system consists of more than tools. RPM/Ecuador showed hospitals, health districts, and NGOs how to organize to use tools effectively and build a drug management system.

3. Local drug management is a vital part of decentralization. As the MOH decentralized, there was a tendency to ignore drug procurement and distribution. In fact, local management of drug supplies is one of the first management and financial functions that districts and service units can and should undertake for themselves.

4. Training alone does not lead to implementation. The MOH and other collaborators recognized this lesson and have moved to adopt other implementation methodologies to achieve changes in behavior or performance.

5. Private sector drug sellers need help. Private drug sales in Ecuador are 5 to 10 times the value of drugs procured and dispensed by the public sector, and the degree of irrationality in the private sector is probably also significantly greater. RPM/Ecuador experience suggests that important gains can be made with private drug sellers to improve their financial viability and rationalize their drug sales and dispensing.

6. Misperceptions about quality are an important obstacle to adoption of generics. RPM/Ecuador has observed that prescriber resistance to generic drugs is rooted in the perception that generics are inferior products of questionable therapeutic value. Future projects should address this question head-on and assist MOHs to conduct adequate verification of drug quality and publication of results.

7. Prescribers must be part of the formulary process. Top-down formulary development that ignores prescribers' professional capacity and local therapeutic conditions is likely to fail, at least as far as adherence to the formulary is concerned.

Honduras

Executive Summary

At the request of the U.S. Agency for International Development (USAID), in 1998 the Rational Pharmaceutical Management (RPM) Project began providing assistance to the National TB Control Program (TBP) of Honduras to strengthen the drug supply system for antituberculosis drugs. RPM developed a one-year workplan to provide technical assistance to the TBP that included the following goals—

- Review TBP procedures for specifying and quantifying anti-TB drugs and identify purchasing, stocking, and distribution bottlenecks.
- Provide recommendations to alleviate the TB drug supply problem, including strengthening the information system to monitor stocks at peripheral units.
- Suggest measures to improve dispensing and consumption of anti-TB drugs by patients.
- Help develop community-based strategies to support the TBP.

RPM's implementation strategy was based on the development and application of tools to strengthen drug management and patient treatment compliance. This was enhanced by the design of a community volunteer program that would increase community support for the program while improving case identification and directly observed treatments at the local level.

Principal activities conducted during the period of assistance were—

1. Review anti-TB drug selection and procurement procedures
2. Assess the anti-TB drug stock information system
3. Organize national TB volunteer program
4. Advise on operations research to improve case detection and patient treatment compliance

The outcomes and products of these activities were—

1. Recommendations to the Ministry of Health (MOH) on selection and procurement. For example, anti-TB drugs should be procured with a longer shelf life. The TBP should monitor stock levels at regional warehouses in order to avoid surpluses and shortfalls. TBP should issue clear instructions regarding management of the "reserve treatment."
2. A visual "case detection" graph for health facilities to visually determine whether they are detecting the expected number of TB cases.

3. A prototype individual treatment box for which the TBP has requested detailed designs and cost estimates for production.

4. A prototype wallet-sized patient identification card so that patients can receive treatment away from their home facility. The TBP has printed these cards and has begun implementing them in MOH clinics.

5. Volunteer organization plan based on TB patients who have completed treatment. An annual program cycle for the volunteer organization was designed and prototype materials were prepared.

6. A drug stock information system for the central and regional levels based on Epi-Info. The system has been tested at the central level and regional data entry began in May 2000.

Acronyms

DOTS	Directly Observed Treatment, Short-course
EPI	Expanded Programme on Immunization
HATL	Honduran Antituberculosis League
MOH	Ministry of Health (*Secretaria de Salud)*
RPM	Rational Pharmaceutical Management [Project]
SO	Strategic Objective (USAID)
TB	tuberculosis
TBP	Tuberculosis Control Program
USAID	U.S. Agency for International Development
WHO	World Health Organization

Acknowledgments

Dr. Noehmi Paz, Director, National Tuberculosis Control Program
Lic. Tomasa Sierra, Assistant Director, National Tuberculosis Control Program

Program Overview

As of the writing of this report, Honduras is categorized by the World Health Organization (WHO) as a country that has not adopted a standard WHO TB control strategy but is reporting tuberculosis (TB) prevalence and treatment information to the WHO. The Honduras National TB Control Program (TBP) has a procedural manual and training program, has adopted elements of WHO's "directly observed treatment, short course" (DOTS) strategy for diagnosing and treating tuberculosis, and is implementing DOTS in selected, high-prevalence health districts. In 1997, the TBP changed the treatment regimen from mono-drug antituberculosis (anti-TB) preparations to compound drug preparations, with the result that several of the drugs from both regimens either expired or were in short supply.

In 1998, USAID/Tegucigalpa requested RPM assistance to strengthen the drug supply system for anti-TB drugs and thus avoid future shortages or expirations. After an initial reconnaissance visit in March 1999, RPM developed a one-year workplan to provide technical assistance to the TBP to assess the anti-TB drug supply system and recommend improvements that would help ensure uninterrupted supplies. The workplan proposed that RPM would—

- Review TBP procedures for specifying and quantifying anti-TB drugs and identify purchasing, stocking, and distribution bottlenecks
- Provide recommendations to alleviate the TB drug supply problem, including strengthening the information system to monitor stocks at peripheral units
- Suggest measures to improve dispensing and consumption of anti-TB drugs by patients
- Help develop community-based strategies to support the TBP

Objectives

RPM's objectives for the Honduras program were to—

1. Ensure the appropriateness and adequacy of TB drug selection and procurement procedures
2. Improve the anti-TB drug stock information system
3. Strengthen TB treatment compliance

Implementation Strategy and Major Activities

RPM's implementation strategy with the TBP was to assist the development and application of tools that strengthen drug management and patient treatment compliance. These tools were—

- Anti-TB drug management information system
- Patient treatment identification cards
- Anti-TB drug dispensing boxes

Another aspect of the strategy was to assist the TBP to design a community volunteer program that would increase community support of the program while improving case identification and directly observed treatments at the local level, which is a cornerstone of the WHO TB treatment strategy. The WHO reports that—

- DOTS is recommended by the WHO as the best way to detect and cure infectious TB patients.

- DOTS not only involves direct observation of treatment but also requires political commitment, microscopy services, reliable drug supply, and monitoring systems.

- Patients treated with DOTS do not need to go to hospital. They can stay with their families and go back to work in a few weeks.

- With DOTS, trained health workers and community volunteers can be used to deliver treatment.

- DOTS achieves cure rates as high as 95 percent. Even in economically devastated areas, DOTS works.

- DOTS is one of the most successful health interventions of the 1990s: in the last three years 1 million TB patients have been treated with DOTS.

RPM activities in Honduras supported USAID's SO 5: "the threat of infectious diseases of major public health importance reduced." RPM activities also supported the achievement of USAID/Honduras' Intermediate Result 3.5, "Improved delivery of TB prevention and control."

Principal activities conducted during the period of assistance were—

1. Review anti-TB drug selection and procurement procedures. Review the purchasing specifications and tendering process used by the Ministry of Health and suggest improvements to ensure adequate quality, quantity, delivery times, and shelf life of anti-TB drugs.

2. Assess the anti-TB drug stock information system. Review the stock information system operating in area warehouses and analyze the flow of stock information to the central

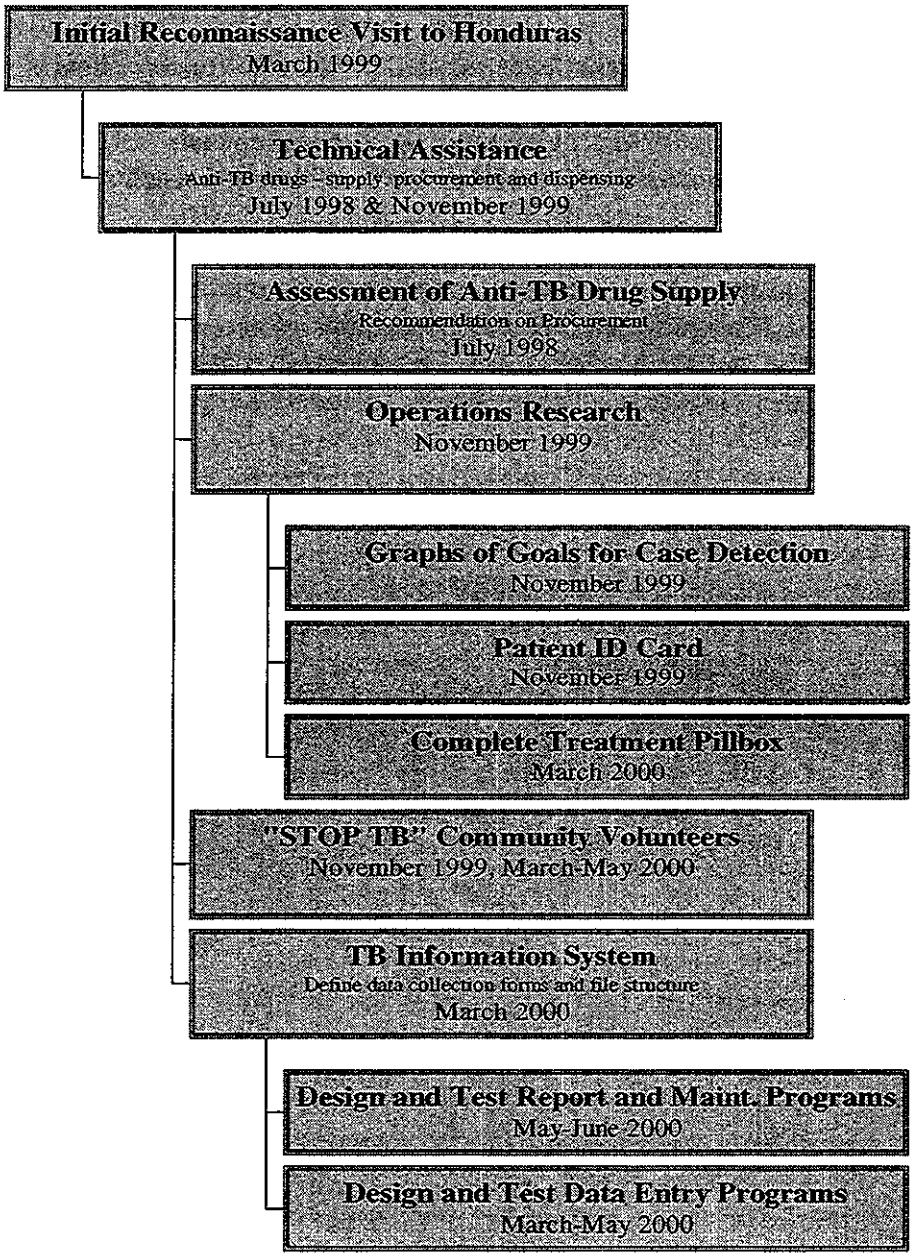
level. Design a processing and reporting system to analyze drug stock information, case identification, and treatment outcomes.

3. Organize a national TB volunteer program. RPM assisted the TBP to conceptualize a national TB volunteer program in July 1999 during discussions with the Honduran Antituberculosis League (HATL). RPM provided follow-up planning and recommendations to get the volunteer program under way and to help define its institutional home.

4. Advise on operations research to improve case detection and patient treatment compliance. This included a design for graphical representation of case detection goals as well as patient identification cards that would allow TB patients to receive treatment at any MOH facility. RPM also suggested an initial design for individual patient drug dispensing boxes.

Figure 1 depicts the chronological order of major RPM activities in Honduras.

Figure 1. Chronological Activity Timeline



Challenges Facing RPM Programming in Honduras

The principal challenge facing the RPM Honduras program was the fact that the TBP depends on the Central Pharmacy and Special Procurement Office of the MOH to purchase drugs for the program and report stock levels. These two units function rather autonomously and have traditionally been unresponsive to TBP requests for information or modification of procurement specifications or tender procedures.

Program Accomplishments

Antituberculosis Drug Supply and Procurement Assessment

During RPM's initial reconnaissance visit in March 1999, RPM observed that the supply of anti-TB drugs had stabilized after the 1996–97 adjustment period, which resulted from changes in the treatment regimen. As mentioned previously, the regimen had changed from mono-drug tablets to double- and triple-drug preparations. In 1996, in order to use up drugs from the old treatment regimen, the TBP purchased some drugs to complement them. However, the program also purchased drugs for the new treatment schedule, which were finally consumed after the remaining stocks of the old regimen were exhausted. Because of this delay and the 23-month shelf life of the drugs for the new regimen, some of these expired in July 1999.

The principal problem observed initially by RPM was the relatively short shelf life (two years) specified by the central pharmacy for purchasing anti-TB drugs. While a two-year shelf life may be appropriate for drugs with fast to normal turnover, the distribution and therapeutic regimen of the TBP made for slow turnover. Therefore, the two-year shelf life became excessively limiting for the following reasons—

- Testing and certification takes up to three months after arrival at central warehouse.
- Stocks remain in central warehouse until requisitioned by regional offices—generally three to nine months later.
- Stocks remain in regional warehouses until requisitioned by district offices—generally three to six months later.
- Health districts issue complete treatments to patients upon confirmed diagnosis. Treatment lasts six months.

The total time anti-TB drugs are on the shelf is 15—24 months. Any minor miscalculation or delay in the system causes drugs to become subject to expiry. As a result, the regional offices will not accept stocks from the central warehouse with a shelf life of less than 9 months since these are likely to expire further down the distribution chain due to inherent delays in the distribution and treatment process. On the other hand, most anti-TB drugs will last up to five years, so the 24-month shelf life specified by the MOH's central purchasing office was unnecessarily short.

Finally, it is estimated that, since the mid-nineties, the MOH has only been detecting about 70 percent of the expected new cases. However, drugs are purchased for 100 percent of the new TB cases expected to be found in the country. This has led to a chronic overestimate of annual requirements that, presumably, is taken into account in the estimate of net requirements for the following year. Nevertheless, there are regions of the country where the detection rate is less than 50 percent of expected and, up until 1998, anti-TB drugs were distributed from central stocks based on expected cases. Under these conditions, drugs accumulated in some regional

warehouses to the point where they exceeded one year's consumption and became at risk of expiration. The program had no way of detecting these surpluses in order to redistribute them to other regions.

On the basis of these findings, RPM recommended to the Central Pharmacy and Special Procurement Office that anti-TB drugs be procured with a longer shelf life, up to five years if possible. As of May 2000 this recommendation had not been acted upon. RPM also recommended that the TBP collect monthly information on stock levels at regional warehouses in order to monitor surpluses and shortfalls. This recommendation was accepted but regional reporting has been spotty and the central level does not have necessary analytical capacity. RPM's recommendations are presented [in Spanish] in Annex A.

Rational Drug Use

The TBP follows the practice of dispensing the complete, six-month treatment to the MOH clinic nearest each confirmed TB case. This practice generally seems to work well and MOH staff directly observe treatments. The treatments are usually dispatched in a cardboard box or plastic bag by the Regional Health offices and the health districts label these with the patient's name for distribution to the responsible clinic. Each time the patient visits the clinic, a dose is removed from the box, which allows fairly precise control of the number of doses delivered. However, if a patient does not appear for treatment, the clinic is not immediately aware of his or her absence. Furthermore, the bags and boxes are improvised and the containers sometimes quite undependable.

RPM recommended systematizing treatments by developing individual drug treatment boxes that would hold and organize the patient's complete treatment, with patient identification and a calendar to be checked off when doses were administered in order to observe days of treatment and days missed. A prototype box was prepared and the TBP requested detailed designs and cost estimates for production.

A nurse at the "Las Delicias" health center in Morazan Province shows how treatments are kept in cardboard boxes. This is a well-organized center and the treatment boxes are uniform in size and shape and well labeled. RPM designed boxes, based on this concept, to contain TB treatments for individual patients.

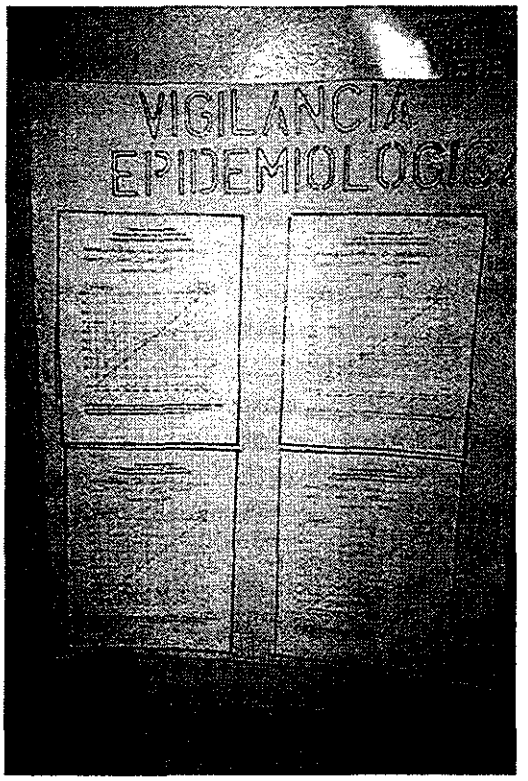
Another aspect of rational use in the DOTS strategy is direct observation of treatment. DOTS is still in the process of being implemented in Honduras but it is foreseen that direct observation of treatment in rural areas will have to be based on community volunteers whose recruitment, training, and supervision will be the responsibility of the Health Areas. No tools exist for managing such a volunteer group although they are mentioned in the TBP Action Plan.

RPM recommended that community volunteers be organized, consisting of patients who had completed treatment. An annual program cycle for a volunteer organization was designed and prototype materials were prepared and discussed with members of the Honduran Antituberculosis League, which might sponsor the program. Both the Peace Corps and the UN Volunteers were contacted to support the development and implementation of the volunteer program and both organizations expressed strong interest. The Peace Corps (Crisis Corps) began recruiting an experienced health professional to design the program and organize the volunteer system.

A third concern that impacts rational use is that there are patients who, after beginning treatment, feel notably recovered after two months and begin to search for work away from their communities. They frequently miss treatments at the responsible MOH clinic and no mechanism existed to easily identify the missing patients or to shift their treatment to a new site.

RPM designed a prototype wallet-sized patient identification card that could be presented at any MOH facility in Honduras to receive treatment and have the patient's doses and records transferred from the home facility. The TBP has printed these cards and has begun implementing them in MOH clinics.

Finally, as mentioned above, case detection was a significant, limiting factor in rationally ordering and distributing drugs, since some regions only detected 50 percent or fewer of expected cases. However, there was no way for clinics or districts to quickly determine whether they were adequately detecting cases. RPM recommended devising a visual "case detection" graph with the number of annual expected cases as 100 percent of goal and one-twelfth of that as the monthly goal, accumulated from one month to the next (like the Expanded Programme on Immunization coverage graph). With such a tool, health facilities can quickly and visually determine whether they are on track for their expected caseload and take whatever measures are needed to improve detection, such as school campaigns, to locate chronic coughers.



At the same clinic in Morazan Province, the charts show the number of TB cases detected versus the clinic's coverage goal for 1999. Most months are filled in. The charts were designed by RPM to stimulate clinic staff to identify potential TB cases. The charts are being applied in many MOH facilities.

Drug Distribution

An important source of drug expiration problems is the "reserve treatment" that each clinic is issued in order to respond quickly to a newly identified TB case. The reserve treatment policy stipulates that a complete six-month treatment be held in each clinic for the next confirmed TB case. Once diagnosed, the patient receives treatment from the "reserve" and a new "reserve treatment" is sent from the Health District offices. If no cases are detected, the reserve treatment remains in "excess" and may expire. In some instances, the reserve treatment was not being used to begin therapy of new patients, leaving the reserve treatment unused and at risk of expiration.

RPM recommended issuing clear instructions to treatment facilities that a new patient is to take the "reserve treatment" and that the new issue to the patient from the district is supposed to become the new "reserve treatment." This recommendation was implemented by the TBP.

Management Information System

The information system being utilized by the TBP is manual and oriented to case control and monitoring of treatments by cohorts, as per Pan American Health Organization recommendations. It does not incorporate any stock management functions, such as estimating requirements, monitoring stocks, managing distribution, and dispensing. The Central Drug Warehouse is supposed to send monthly stock status reports for both the central warehouse and regional warehouses to the TBP, but it did not do so from October 1998 until March 1999. This made it impossible to adjust stock allocations among regions.

RPM met with Central Drug Warehouse representatives and recommended that national and regional stock levels of anti-TB drugs be reported monthly. RPM also assisted the TBP to analyze these reports and make allocations accordingly. However, as of June 2000, stock reporting from the Central Drug Warehouse continued to be irregular.

RPM designed a drug information system based on Epi-Info for the central and regional levels. RPM also designed procedural guidelines [in Spanish] for stock reports and analysis (see Annex B). The system has been tested at the central level and some regional data entry began in May 2000. The system is to be installed on USAID-donated computers during the third quarter of 2000.

Activities Not Completed

One of the operations research projects, the creation of TB treatment pillboxes, was initiated by the TBP but never reached actual implementation. RPM had planned to follow up on this work but implementation delays caused these activities to extend beyond the end of the RPM Project.

The TB Information System has not been operationalized at the regional level and data entry has only tentatively begun at the central level, as of June 2000. Software and hardware installation must be completed nationwide and training conducted for the system to become operational.

The "STOP TB" Volunteers is an attractive vision which the Honduran Antituberculosis League will try to implement once the League is formally restructured. The Peace Corps is committed to recruiting a TB health professional to begin the work.

Likely Needs at End of Project

After the RPM Project closes in Honduras, several activities could be helpful to complete the activities initiated by RPM. These include the following:

- Follow up on procurement recommendations to ensure that the Special Procurement Office at the MOH adopts and applies them.
- Complete the design and production of treatment pillboxes.
- Install the TB Information System software in USAID-donated computers located in Regional Health offices and conduct appropriate training in operation of the hardware and software.

- Organize the "STOP TB" Volunteers which, in spite of RPM's design work and contacts, does not have a formal, institutional sponsor nor organizational resources. Additional work will be required to develop an annual volunteer coordination program for the organization and to design and produce the materials for the program to function.

Lessons Learned

Written recommendations alone are not enough to achieve results. Consultants leave recommendations in written reports with the assumption that the collaborating institutions want to use them. However, this may not be enough to achieve results. Consultants must follow through with local counterparts to ensure that they feel ownership of the recommendations. Then, further follow-up is necessary to help capaciatate those persons to take the action desired. Finally, in a third stage, the outcomes of actions must be assessed. While this should be the primary responsibility of local counterparts, additional TA is often necessary to carry this through.

Annex A. Recommendations for Anti-TB Drug Management, July 1998

1. Abastecimiento de Medicamentos. El abastecimiento de medicamentos antífimicos, luego de un período de desajuste en 1996-1997 a raíz del desabastecimiento de medicamentos y de la introducción del nuevo esquema de tratamiento con grageas triples, parece haberse estabilizado. El principal problema detectado en el abastecimiento es la vida útil tan corta con la que se piden los medicamentos.

   Por un lado y de cara a los desajustes mencionados, en 1996 el PNT se abasteció tanto de medicamentos del esquema antiguo (mediante préstamos ante la demora en la adquisición de medicamentos para ése año en un afán para apoyar al nivel operativo en dar respuesta a la población demandante como del nuevo. Como resultado, los medicamentos del nuevo esquema fueron consumidos después de agotar los stocks del esquema antiguo. Como los primeros llegaron con vida útil de tan solo 23 meses, se caducaron en Julio de 1998, antes de ser consumidos.

   Por otro lado, los medicamentos antituberculosos pueden durar hasta 5 años. Es decir, no hace falta solo pedirlos con vida de 24 meses, como es costumbre en Proveeduría de la Secretaría de Salud.

   Finalmente, la programación anual de medicamentos a nivel del País se basa en el tratamiento de todos los casos esperados en el territorio nacional. Se reconoce que existe un sobregistro nacional de 30% de los casos. Puesto que solo se puede tratar a los casos. Detectados, es lógico que persistan excedentes de un año para otro el cual sé en una reserva aproximada para 6 meses. La programación para el siguiente año toma en cuenta estos sobrantes y los deduce de las cantidades a pedirse. Sin embargo, hay regiones donde la tasa de detección es baja: menos que el 505 de los casos esperados. Cuando se despachan los medicamentos con base en la programación de casos esperados a estas regiones, las cantidades pueden sobrepasar el consumo de un año y peligra el vencimiento si los medicamentos no tienen una vida útil mas larga (o si el programa no tiene forma de detectar los excedentes y redistribuirlos a otras regiones).

   RECOMENDACIÓN: Se debe pedir los medicamentos antituberculosos con vida útil de 5 años.

   RECOMENDACIÓN: Se debe recabar y visualizar datos mensuales de stocks y consumo en las regiones.

2. Administración de Tratamientos: La práctica de despachar todo el tratamiento para un paciente hasta la unidad que vigilará su terapia parece funcionar bien. Las Regiones de Salud colocan todo el tratamiento tanto de la fase inicial como de la fase de sostén, en una bolsa o una cajita que las áreas rotulan con el nombre del paciente bajo tratamiento. Cada vez que él

asiste al servicio, se le entrega su dosis desde su apartado. Esto permite controlar las dosis entregadas con mucha precisión. Sin embargo, las cajitas y bolsas son improvisados y algo precarios.

La estrategia de Tratamiento Acortado Estrictamente Supervisado TAES, (DOTS en inglés) hace incapié en que el paciente. El TAES esta en vías de implementación en Honduras.

A medida que se implemente el TAES en zonas rurales dispersas, la administración de tratamientos se basará en voluntarios comunitarios cuyo reclutamiento, capacitación y supervisión caerá sobre las áreas de salud. No existen herramientas para manejar el programa con voluntarios, sin embargo el PNT contempla en su Plan de Acción la incorporación de éste recurso en el Control de la Tuberculosis.

Vale recalcar que los pacientes hombres que se recuperan notablemente en los primeros dos meses de tratamiento, salen en busca de trabajo para mantener a sus familiar y, frecuentemente, son perdidos para la segunda fase de sostén o tratamiento intermitente. No existe un sistema de identificación de pacientes en tratamiento ni transferencias de ellos a otras unidades donde pueden continuar su tratamiento.

RECOMENDACIÓN: Conseguir cajas o estuches de plástico para sistematizar el despacho de los medicamentos desde la región hasta el área o UPS.

RECOMENDACIÓN: Establecer un programa de reclutamiento y capacitación de colaboradores comunitarios con base en claros principios de organizaciones de voluntariado - poco tiempo, trabajo en equipo, resultados visibles, reconocimiento abundante.

RECOMENDACIÓN: Establecer un carnet de identificación de pacientes en tratamiento que, al reverso, reproduce el formulario TB-4 (un calendario de tratamientos de primera y segunda fase) para que el paciente pueda atenderse en otro servicio y éste pueda notificar al servicio que inicio el tratamiento sobre su evolución y término.

3. **Tratamiento de Reserva**. Cada UPS mantiene un "tratamiento de reserva" con el fin de iniciar la quimioterapia inmediatamente después de detectar un caso mientras hace el pedido el cual se convierte en reserva. El problema puede originarse cuando no se detecten casos y no se consume el "tratamiento de reserva" dejándolo inmovilizado y en peligro de caducar. Es importante que la UPS detecten los casos de tuberculosis en sus Areas Geográficas de Influencia.

RECOMENDACIÓN: Recalcar que el "tratamiento de reserva" se convierte en el "tratamiento definitivo" del próximo paciente y que el nuevo pedido se convierte en reserva.

4. **Detección de Casos.** El PNT ha detectado que el actor mas limitante del programa en muchas áreas es la detección de casos que, en algunas regiones no llega al 50% de los casos esperados en la población (1 en 1000 habitantes): En realidad la captación de casos es pasiva de entre los pacientes que acuden a los servicios de la SS con sintomatología respiratoria no brindándose una atención integral al paciente. A pesar que el personal de salud conoce la meta de detección ésta no es visible como recordatorio ni tampoco proyectada a la población general. La supervisora de sector en Sabanagrande mencionó que las metas numéricas son difíciles de monitorear.

   RECOMENDACIÓN: Investigar la posibilidad de realizar campañas de identificación de personas con síntomas respiratorios. Si los voluntarios involucran a las escuelas, los niños ayudarían a identificar personas de su familia o la comunidad con los persistente. El Día Internacional de la Tuberculosis es una excelente oportunidad para tal campaña.

   RECOMENDACIÓN: Imprimir gráficos de alcance de metas como la que se presenta en el Anexo A e incluirlos en los módulos del programa (en especial, el Módulo 1, "Detección y Diagnóstico").

5. **Sistema de Información:** El sistema que utiliza el PNT esta orientado al control de casos y evolución de tratamientos por cohortes. No contempla el manejo de los medicamentos - programación, stocks, dispensación. El Almacén Central, que debería enviar al PNT informes mensuales sobre stocks, no lo hizo entre Octubre 1998 y marzo 1999. Esto dificulta cualquier manejo de los medicamentos disponibles. (No se detectó ningún informe antes de Octubre 1998). El Almacén Central recibe informes de stocks y movimientos desde las regiones pero no los hace extensivos al PNT.

   RECOMENDACIÓN: El Almacén Central debe enviar al PNT un formulario los informes de stocks nacional y regionales de insumos y medicamentos antituberculosos. (El Programa siempre lo solicitan por escrito y la respuesta es ocasional).

Annex B. Procedural Manual for TB Inforamtion System, May 2000

Manual del Sistema de Informacion de Tuberculosis - SIT

Departamento de VIH/SIDA/TB, Honduras
Secretaria de Salud

CONTENIDO

INTRODUCCION III-100
QUE ES EL SIT III-100
REQUERIMIENTOS PARA EL SIT III-102
COMO INSTALAR EL SIT III-102
COMO INICIAR EL SIT BAJO EPI-INFO III-102
CONVENCIONES EN EPI-INFO III-103
SECUENCIA DE PROCESOS III-103
Mantenimiento del archivo de UPS III-105
Inicialización de Archivos en Diskette III-107
Ingreso de Datos del Período III-109
Verificación de Datos Ingresados y Listado de Datos III-115
Consolidación de Archivos III-117
Informes III-119
Respaldos III-121
CONSIDERACIONES ADICIONALES III-122

INTRODUCCION

Este manual está dirigido a las personas que instalarán y operarán el SIT a nivel de Región o Area de Salud. Tiene como propósito indicar los pasos que se debe seguir para operar el sistema con éxito.

El manual está estructurado en la secuencia que debe observar el operador. Los pasos a seguir están ilustrados al comienzo de cada capítulo como una cadena de cajitas. Estas muestran, en forma figurada, los pasos previos y posteriores al que se describe en el capítulo. Se debe tener en cuenta la secuencia indicada ya que, de otra manera, los resultados pueden ser impredecibles.

QUE ES EL SIT

1. ¿En qué consiste? El SIT es un paquete de programas y archivos de datos escrito para el sistema EPI-INFO que permite automatizar el Sistema de Información del Programa Nacional de Control de Tuberculosis (PNT) de la República de Honduras. Hasta el 2000, el PNT ha utilizado formatos impresos para recolectar y trasmitir la información del programa desde las UPS hasta los niveles de región y nacional. La consolidación y análisis de esta información en los diferentes niveles han sido engorosos y, a veces, demorados. El SIT

permitirá simplificar y agilizar estos procesos a la vez que dotará a los niveles regionales y distritales de herramientas de monitoreo que facilitarán el control y mejoramiento del programa.

El EPI-INFO, a su vez, es el sistema de información creado por los Centers for Disease Control de los EEUU para investigación epidemiológica. EPI-INFO ha tenido una diseminación y aceptación amplia entre el personal de los ministerios de salud del mundo y, siendo de dominio público, puede ser libremente copiado y distribuido. El SIT aprovecha estas caracteristicas de EPI-INFO para desarrollar las funciones de ingreso, verificación y análisis de datos que maneja el PNT, es decir para:

- Examenes de laboratorio
- Identificación de casos
- Seguimiento epidemiológico de casos
- Resultados de tratamientos por cohortes
- Inventario y movimientos de medicamentos antifímicos

2. ¿Cómo funciona? El SIT se monta sobre la instalación de EPI-INFO en el disco duro de la computadora del PNT regional o en la del Area. Ahí residen los programas del SIT y los archivos maestros de datos en los cuales se consolidan la información mensual o tremestral del nivel en cuestión.

En el Area o Región, para cado período, los datos son ingresados inicialmente en diskette hasta verificar que sean correctos y completos; a continuación, se consolidan los datos en los archivos maestros. El Area y la Región analizan los datos consolidados en forma de los indicadores definidos por el PNT, lo que permiten establecer la situación y los avances en detección y curación de casos de TB así como el rendimiento de los laboratorios y la situación de los medicamentos.

Luego del análisis, se envian los datos en un diskette al nivel superior donde son consolidados con los datos de otras instancias del mismo nivel y se repite el proceso de análisis. Finalmente, se repite todo el proceso para el siguiente período.

3. ¿Quién es responsible? Los coordinadores del PNT de nivel regional y distrital son los responsables de la instalación y operación del SIT, así como del ingreso de los datos, el análisis de la información y la trasmision de los datos verificados al nivel superior. Ellos deben coordinar y colaborar con el epidemiologo.

4. ¿Cuándo hay que hacer los procedimientos? El PNT ha establecido que las Areas preseenten informes a la Región en forma mensual y que las Regiones informen al nivel central en forma trimestral. Puesto que no todas las Areas cuentan con computadoras, los datos mensuales se pueden presentar en formatos impresos manuales o en forma electrónica (diskettes). El nivel regional debe ingresar los datos mensuales al SIT y proporcionar los informes respectivos a las Areas, a fin de que estas analicen su situación y los avances y tomen las medidas pertinentes. El nivel regional debe enviar los informes trimestrales al nivel central en diskette, dentro del calendario previsto por el PMT.

REQUERIMIENTOS PARA EL SIT

1. Equipo. Se debe contar con una computadora con disketera de 3.5" y disco duro con un espacio libre de 5 MB. El sistema operativo bién puede ser DOS o Windows. Se necesita una impresora.

2. Instalaciones. Las instalaciones incluyen electricas y ambientales. Las eléctricas deben considerar dos aspectos básicos: provisión de tierra y un estabilizador de corriente con cortapicos. Si os apagones son frecuentes, se puede necesitar una fuente de fuerza ininterrumpida (UPS) de unos 500 W.

   En cuanto a lo ambiental, es recomendable instalar el equipo en un lugar cerrado (para evitar polvo) y con aire acondicionado (tanto para mantener la pureza del aire como para la comodidad del operador y para evitar el recalentamiento del equipo).

3. Capacitación. Los operadores deben conocer lo básico de operación del equipo (encendido, arranque, apagado de todos los dispositivos y accesorios) y los aspectos de operación como son: navegación en Windows, estructura de archivos, cómo utilizar diskettes – insertar, formatear, copiar, como enviar documentos a la impresora. Además, es necesario dominar el ingreso y manipuleo de datos bajo EPI-INFO.

COMO INSTALAR EL SIT

1. EPI-INFO. Instalar según instrucciones.
2. SIT. Copiar todo el diskette de SIT al directorio EPI6.
3. CONFIG.SYS. Incrementar el número de FILES y BUFFERS a 40 en el archivo CONFIG.SYS.

COMO INICIAR EL SIT BAJO EPI-INFO

El paquete de software de EPI-INFO funciona bajo el sistema operativo DOS. Sin embargo, la gran mayoría de computadoras trabajan con el sistema operativo Windows. Felizmente, Ud puede cerrar Windows e iniciar otra sesión en DOS. (No es conveniente abrir una ventana de DOS bajo Windows, optando por el ícono de MS-DOS en el menú de Programas, ya que puede existir confusión sobre los dispositivos de discos a utilizarse). Esto se hace moviendo la flecha o puntero de Windows al botón "Inicio" en la esquina izquierda inferior de la pantalla y hacer "clic" con el botón izquierdo de su ratón. Se abre el menú de inicio. Mueva la flecha arriba hasta la opción "Apagar" y haga "clic." Se abrirá una lista de opciones, una de las cuales es "REINICIAR EN MS-DOS." Haga "clic" en el círculo de la opción y luego en el botón "Aceptar." La pantalla se volverá negra y, luego de unos segundos, aparecerá un mensaje que indica que está en DOS y podrá regresar a Windows al escribir "EXIT".

A diferencia de Windows en él que se navega con el puntero "flecha", DOS se basa en comandos y movimientos del cursor en sentido horizontal y vertical. Los comandos se escriben digitando letras y números en el teclado y el cursor se mueve con las flechas verticales y horizontales. En

los siguientes parrafos, los comandos se señalan en **negrita** y las teclas con nombres propios se identifican entre flechas, ej <ESC>.

Una vez que Ud haya reiniciado en sistema DOS, puede invocar el SIT de la siguiente manera (oprima <RETURN> después de cada linea de caracteres):

cd \EPI6
TB

CONVENCIONES EN EPI-INFO

- <F10> para salir de cualquier programa
- Cuando se ingresan datos, si el campo (espacio de entrada) se llena, el cursor salta al siguiente campo. Si no se llena, habrá que aceptar con <ENTER>.
- Si se equivoca en la entrada de datos y los datos erroneos quedan grabados, se puede regresar a los registros anteriores con la tecla <F7> o avanzar a los registros siguientes con la tecla <F8>.
- Una vez ubicado el registro erroneo, mueva el cursor al campo a corregir y digite el valor correcto, dando <ENTER> para aceptar el nuevo dato.

SECUENCIA DE PROCESOS

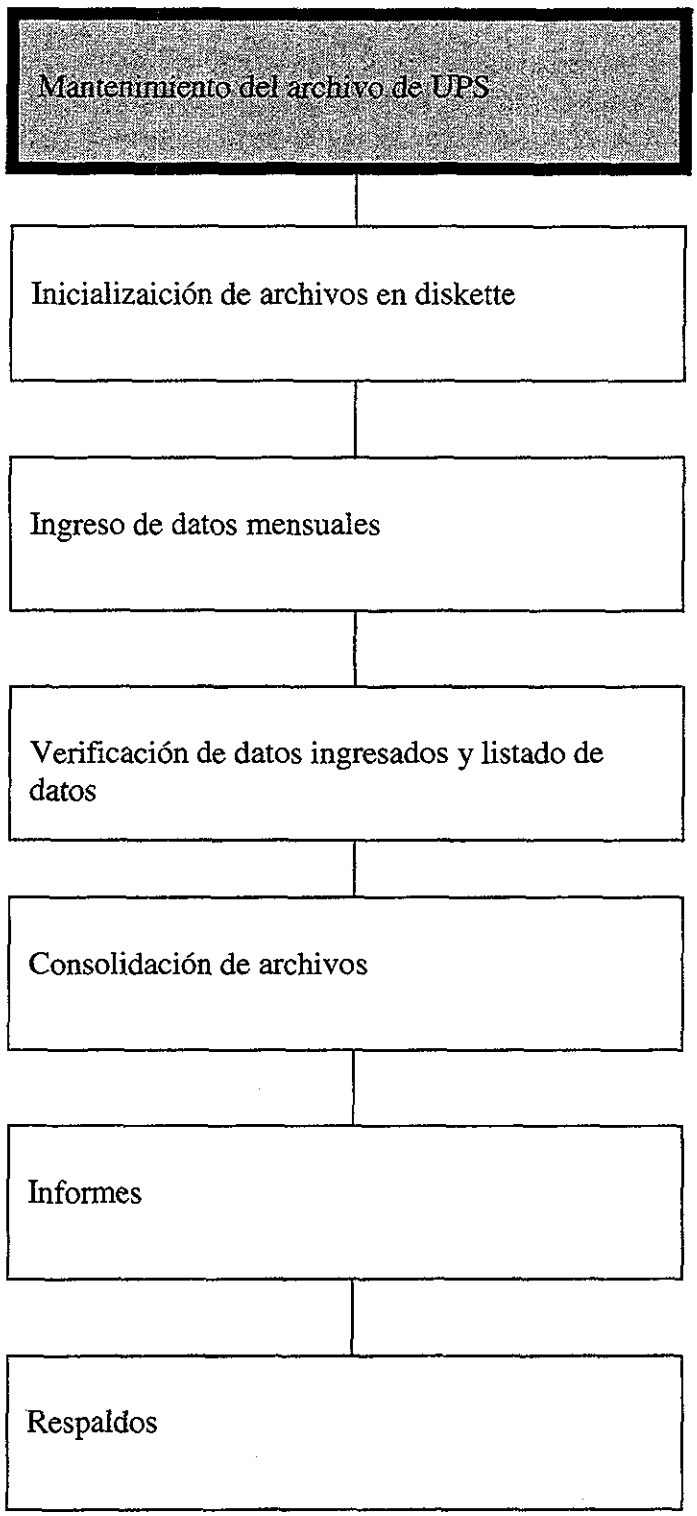
Inmediatamente, verá una pantalla que identifica el sistema ***EPI-INFO 6*** y proporciona una serie de opciones en la barra de menú que aparece en la fila superior de la pantalla. La segunda opción es "Tuberculosis." *Mueva el cursor con la flecha la derecha hasta resaltar la opción y oprima* <RETURN> (o con el puntero del ratón y haga clíc). Se abrirá un menú secundario bajo la opción "Tuberculosis" que proporciona las siguientes opciones:

1. Mantenimiento del archivo de UPS
2. Inicializaición
3. Ingreso de datos
4. Verificación de datos
5. Consolidación de archivos
6. Informes
7. Respaldos

A continuación, se explicará cada una de las opciones en la secuencia que debe ejecutarse. El flujo de actividades está señalado en la cadena de casillas dibujada en la siguiente página. La casilla resaltada indica que, en los siguientes parrafos, se explicarán las instrucciones para esa actividad.

Las actividades señaladas en la cadena de casillas representan el proceso mensual o trimestral que se sigue para ingresar toda la información sobre tuberculosis para el Area o Región y producir los informes respectivos.

Es menester indicar que el ingreso de datos se realiza en diskette. Por esta razón, el operador del SIT debe contar con un diskette en blanco para comenzar el proceso. Puede usarse un diskette nuevo o "formatear" un diskette usado. Si fuera necesario "formatear" un diskette, lo puede hacer en Windows o bién, dando el comando **FORMAT** en DOS.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

MANTENIMIENTO DE UPS

Este procedimiento permite actualizar la información de las Unidades Productoras de Servicios, UPS. El sistema de información de tuberculosis cuenta con una base de datos de las UPS, proporcionada por la Oficina de Estadística de la Secretaria de Salud con vigencia de abril de 2000. La información que contiene la base de datos se refiere a la ubicación geográfica de la UPS (códigos de departamento y municipio) y su relación con la estructura de la Secretaria (números de Región y Area a las que pertenece) ademas de la identificación de la unidad (codigo y nombre).

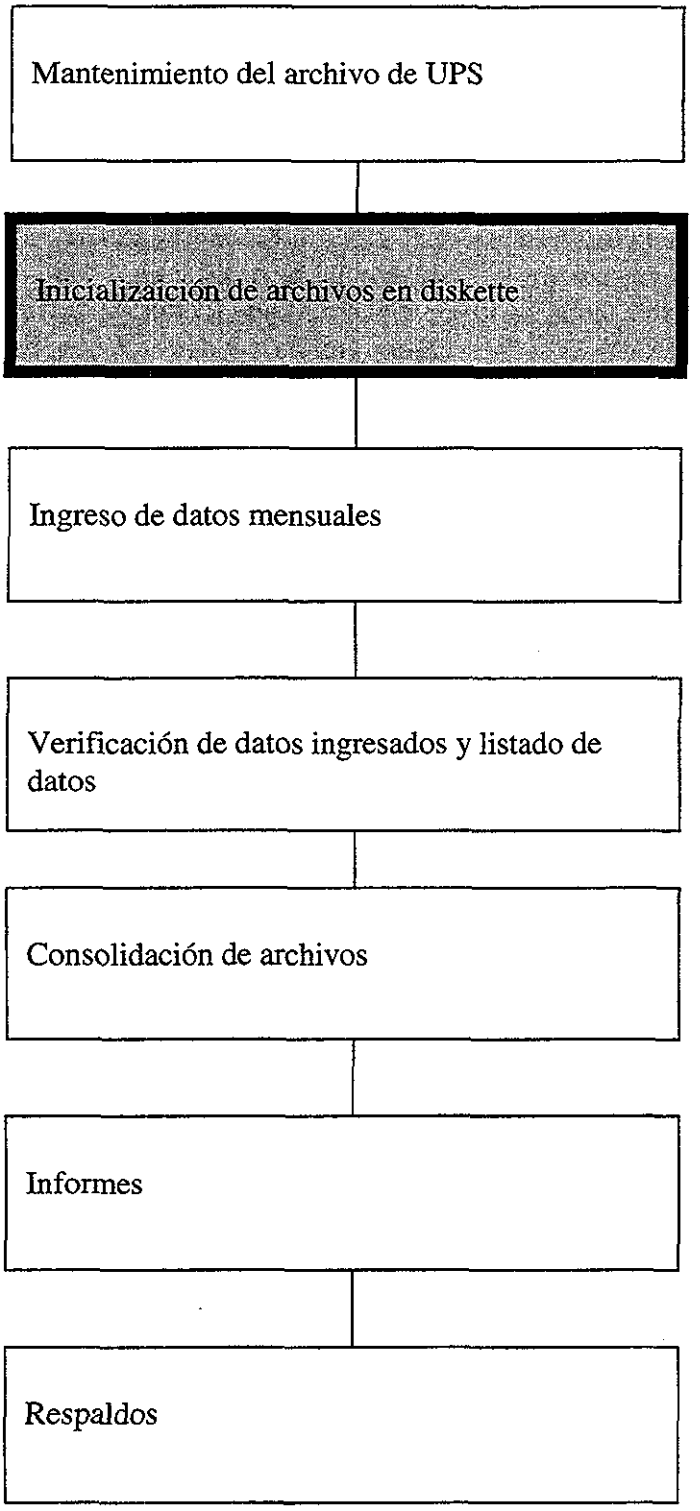
Para garantizar la funcionalidad del sistema, es imprescindible ingresar los datos para las variables: REGION, AREA, DEPTO, MUNIC, NOMBRE y UPS. La variable UPS tiene los mismos valores que CODIGO que, a su vez, se compone de CODOGO2 y una cifra de validacion, VALI. Por lo tanto, se puede reconstruir estas tres variables a partir de UPS. También se recuerda que las regiones 3 y 4 enumeran sus áreas comenzando con cero (ej. 0, 1, 2 .. 7) mientras las demás regiones comienzan con 1.

Se debe modificar la información contenida en este archivo solamente cuando se habilita una nueva UPS en la Región/Area. Para ello, se deber recabar la información mencionada en el parrafo anterior. Al ingresar a este procedimiento, se verá la siguiente pantalla.

```
Este archivo corresponde a RUPS.dbf del Depto de Estadistica
de la Secretaria de Salud, version de Abril, 2000, eliminados
los registros que corresponden al IHSS y consultorias dentales

REGION   _
AREA   _
DEPTO   __
MUNIC   __
CODIGO   ____
CODIGO2   ____
VALI   _
NIVEL   __
NOMBRE   ____________________________
SECTOR   _
INACTIVO   _
NUMERO   _
UBICACION   ___
UPS   ___
```

Ingrese los datos para la nueva UPS y cuando llegue a la última linea, aparecerá la pregunta en inglés "*Write data to disc (Y/N/Esc)?*" ("Grabar los datos en disco (S/N/Esc)?"). Si los datos son correctos, oprima "Y" y aparecerá una nueva pantalla en blanco en la cual puede ingresar datos de otra UPS. Si no hay mas UPS, oprima <F10> para terminar. Las opciones "N" o "<Esc>" devuelven el cursor a la primera casilla para corregir o confirmar los datos.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

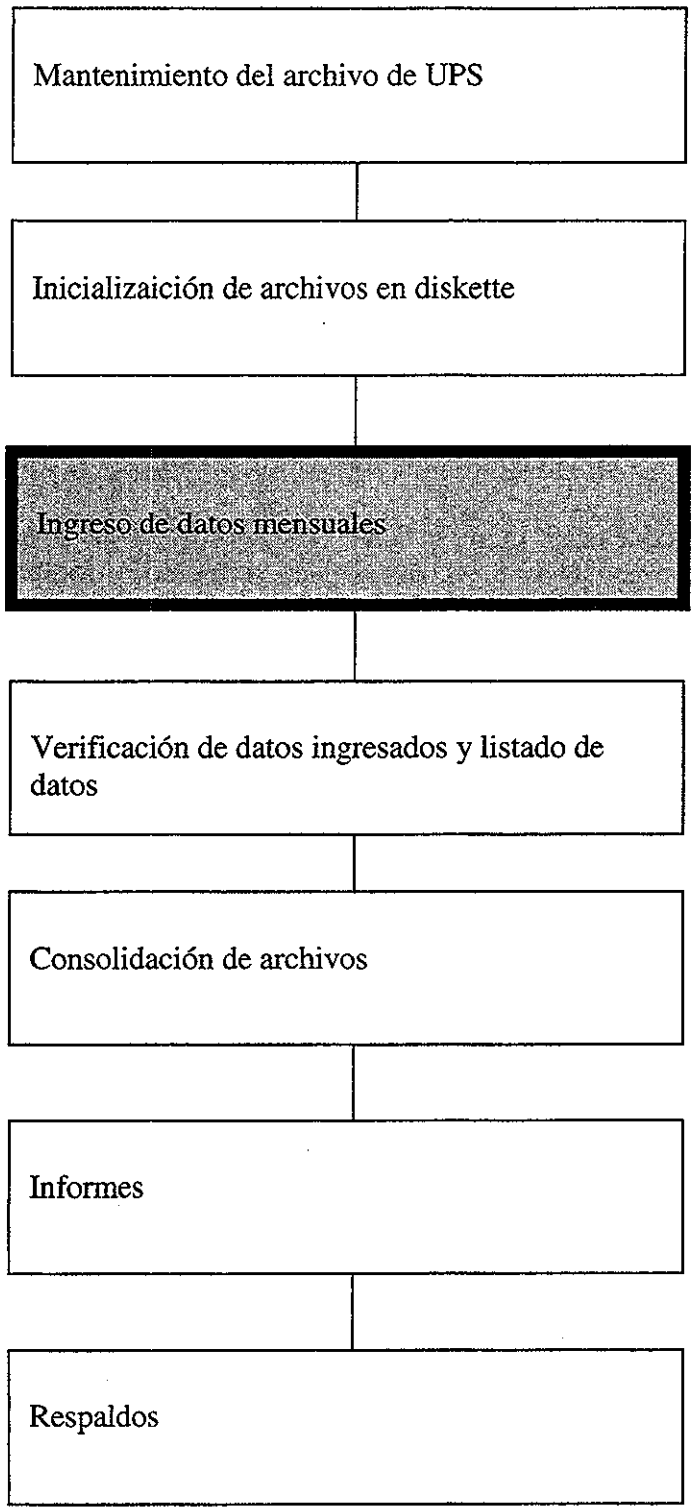
265

Inicialización de Archivos en Diskette

Como ya se dijo, el ingreso de datos mensuales y/o trimestrales se hace en diskette. Esto quiere decir que, antes de comenzar el registro de datos de un área o región, se debe contar con un diskette en blanco.

El ingreso de los datos para cualquier período comienza con la preparación del diskette de datos. Al seleccionar la operación Inicialización de Archivos en Diskette, aparecerá un mensaje en la pantalla que indica insertar un diskette nuevo en el lector y oprimir <ENTER> para continuar. A continuación, el programa pide que se ingrese REGION TRIMESTRE y AÑO sin espacios. Por ejemplo, datos de la Región 3 para el segundo trimestre del año 2000 se ingresarían como "3200." Inmediatamente, se copian varios archivos al diskette desde el disco duro de la computadora, todos con un prefijo de tres letras, un guión y el código de REGION, TRIMSTRE y AÑO seguido por el sufijo .REC (ej. CAS-3200.REC. Estos archivos estan vacios y pueden recibir los datos del mes o trimestre. Además, se construyen algunos archivos de parametros con información que requieren los programas del sistema durante la entrada o procesamiento de datos.

Una vez terminada la operación, aparece el menú principal.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

Ingreso de Datos del Período

Cuando se selecciona esta opción, aparece un submenú para el ingreso de los cinco diferentes tipos de información:

1. TB-1. Datos sobre producción de laboratorio (baciloscopias realizadas, baciloscopias positivas, cultivos realizados).
2. TB-2. Datos sobre produccion de actividades de detección de casos (números de sintomáticos respiratorios, casos baciloscopía positivos, número de baciloscopías de control, etc).
3. Casos nuevos y recaidas. Desglose de datos epidemiológicos por edad y sexo.
4. Seguimiento de tratamientos por cohortes. Información sobre resultados de tratamientos en cohortes cuyo tratamiento se inició hace un año.
5. Medicamentos. Registra información sobre cantidades de medicamentos antifímicos en el inventario de la Región (o Area) y los movimientos (entradas y salidas) durante el período.

Seleccione la subopción para los datos que desea ingresar, y luego de unos segundos, aparecerá una pantalla de entrada de datos. El formato de cada pantalla sigue el diseño de los formularios del PNT con la excepción de la información de identificación en el encabezado que, en la pantalla, es mas reducida. Al ingresar el código de Area o UPS, el siguiente espacio se llena automaticamente con un REGISTRO único compuesto del TRIMESTRE/AÑO/AREA o UPS, según el caso. (Estos datos fueron registrados en la Inicialización, paso anterior). A diferencia de los formularios, será necesario ingresar un dato en cada espacio de la pantalla, aun cuando este sea cero. Es decir, no se admiten espacios en blanco.

En las siguientes pantallas, los espacios donde se registra datos se muestran con signo de numeral (#) para datos numericos o con subraya (____) para datos alfanumericos. Los datos numericos deben consistir de digitos entre 0 y 9. No se acepta letras. Cuando se llega a la última linea, aparecerá la pregunta en inglés "*Write data to disc (Y/N/Esc)?*" ("Grabar los datos en disco (S/N/Esc)?"). Si los datos son correctos, oprima "Y" y aparecerá una nueva pantalla en blanco en la cual puede ingresar datos de otra Area o UPS. Si no hay mas Areas o UPS, oprima <F10> para terminar. Las opciones "N" o "<Esc>" devuelven el cursor al primer campo de la pantalla para corregir o confirmar los datos.

Para el Informe Mensual de Laboratorio, TB-1, se debe contar con los resultados consolidados de cada Area de Salud de la Región para todo el período en custión, es decir sumar los datos de todos los laboratorios de cada Area a fin de ingresarlos en forma resumida.

Bajo el título SINTOMATICOS RESPIRATORIOS, hay espacios para ingresar los resultados de la primera y segunda muestra. Ademas, se reportarán los resultados de CULTIVOS al final de la página.

INFORME MENSUAL DE LABORATORIO TB-1

AREA ## REGISTRO _____

==========

SINTOMATICOS RESPIRATORIOS
- 1era EXAMINADOS ###
- 1era POSITIVOS ###
- 1era NEGATIVOS ###

- 2nda EXAMINADOS ###
- 2nda POSITIVOS ###
- 2nda NEGATIVOS ###

BACILOSCOPIAS DE CONTROL
- EXAMINADOS ###
- POSITIVOS ###
- NEGATIVOS ###

CULTIVOS
- REALIZADOS ###
- POSITIVOS ###

La Planilla Diaria para Informe Trimestral, TB-2, se elabora para cada UPS, con los datos de producción que se indica. Cerciorese que tiene los datos de todas las UPS para todo el período (trimestre) antes de comenzar la entrada de tados.

PLANILLA DIARIA PARA INFORME TRIMESTRAL (TB-2)

UPS ##### REGISTRO _____

==========

Atenciones a mayores de 15 a ######

No. Sintomaticos Respiratorios ######
No. Baciloscopias #####
Casos Bac. Positivos #####

No. Diagnosticos por Rayos X #####

Bacilosc. Control #####

No. Convivientes #####
Convivientes Examinados #####
Conviv. Positivos #####

El Informe Trimestral de Casos Nuevos, Recaidas y Muertes también se elabora con datos de las UPS. Cerciorese que tiene los datos de todas las UPS para todo el período (trimestre) antes de comenzar la entrada de tados.

INFORME TRIMESTRAL DE CASOS NUEVOS DE TB Y RECAIDAS

UPS ##### REGISTRO _____

==========

NO. VIH REALIZADOS ####
NO. VIH POSITIVOS ####

NUEVOS MASC ####
NUEVOS FEMI ####

RECAIDA MASC ###
RECAIDA FEMI ###

BACIL NEG MAS ###
BACIL NEG FEM ###

EX PULM MASC ###
EX PULM FEMI ###

MUERTES MASC ##
MUERTES FEMI ##

Se tiene que ingresar la información acerca de casos nuevos y muertes, desglozada por sexo y edad. En el formulario del PNT, estos datos se registran en cuadros como el siguiente:

0-4			5-14			15-24			25-34			35-44			45-54			55-64			>65			IGNORADA			TOTAL		
M	F	T	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T

En el SIT, se ingresa esta información en pantallas secundarias como las que se muestran a continuación, una para cada grupo de edad en el formulario. Las pantallas aparecen automaticamente cuando se ingresa un número positivo en la casilla de casos nuevos o muertes (masculino o feminino).

DESGLOSE DE ^ CASOS NUEVOS^ POR GRUPO DE EDAD

REGISTRO _____

==========

GRUPO DE EDAD _____

MASCULINO #####

FEMININO #####

DESGLOSE DE ^ MUERTES^ POR GRUPO DE EDAD

REGISTRO _____

==========

GRUPO DE EDAD _____

MASCULINO #####

FEMININO #####

Por ejemplo, si en el cuadro del formulario se tiene 2 nuevos casos masculinos en el grupo de edad 25-34, se registraría el dato en una pantalla secundaria como sigue: Recuerde que, al no tener casos nuevos femininos, se debe ingresar cero (0) en el espacio correspondiente.

El GRUPO DE EDAD está predeterminada en el sistema y las opciones pueden visualizarse cuando el cursor este en el campo y se oprime la tecla <F9> (opciones). Se sube o baja el cursor con las flechas arriba y abajo hasta resaltar el grupo de edad que desea y se acepta con <ENTER>.

```
DESGLOSE DE ^ CASOS NUEVOS
POR GRUPO DE EDAD

REGISTRO _3/00/991_
==========================

GRUPO DE EDAD _25-34

MASCULINO  2

FEMININO  0
```

Para el caso del Informe Trimestral de Resultados de Tratamientos, cada UPS reporta el cohorte que comenzó su tratamiento hace un año, registrando en el encabezado el trimestre y año correspondiente. Luego, se registra el número total de baciloscopias positivas entre masculinos y femininos (7.1 y 7.2) y estos se dividen por grupo de tratamiento entre casos nuevos (8.1 y 8.2) o reingresos (9.4 y 9.5). A su vez, los reingresos se desglozan entre recaidas (9.1), abandonos recuperados (9.2) y fracasos (9.3). Es decir, el total de recaidas, abandonos recuperados y fracasos debe ser igual al total de reingresos masculinos y femininos. El total de reingresos masculinos y nuevos masculinos debe ser igual a baciloscopias positivas masculinas; igual procede para los casos femininos.

```
INFORME TRIMESTRAL DE RESULTADOS DE TRATAMIENTOS

UPS #####    REGISTRO _________

6. PACIENTES REGISTRADOS DURANTE TRIMESTRE _ DEL ANNO __
=======================================================

7.1 BACIL POS MASC     ####
7.2 BACIL POS FEMI     ####

8.1 NUEVOS MASC        ####
8.2 NUEVOS FEMI        ####

9.4 REINGR MASC        ###
9.5 REINGR FEMI        ###

9.1 RECAIDAS           ###

9.2 ABANDOS RECUPERADOS ###

9.3 FRACASOS           ###
```


2-71

En el formulario del PNT, los resultados de tratamiento en cada grupo de tratamiento se desglozan en las casillas a la derecha del grupo en las columnas numeradas de 10 a 18. En el SIT, se ingresan estos datos en pantallas secundarias como la que sigue. Se abre una pantalla secundaria cada vez que se registran baciloscopias positivas o casos nuevos o reingresos. Los resultados de tratamiento pueden ser: curado (11), terminado (el tratamiento sin baciloscopia confirmatoria - 12), muerte (13), fracaso (14), abandono (15) y traslado (sin información - 16). El SIT no requiere el total del formulario (17), ya que lo calculará automaticamente. Finalmente, se registra el número de casos en el grupo de tratamiento cuya prueba de VIH resultara positiva (columna 18).

DESGLOSE DE RESULTADOS DE TRATAMIENTOS

REGISTRO _____

==========

10. ESQUEMA ____

11. CURADOS ###

12. TERMINADOS ###

13. MUERTES ###

14. FRACASOS ###

15. ABANDONOS ###

16. TRASLADO ##

18. VIH POSITIVO ###

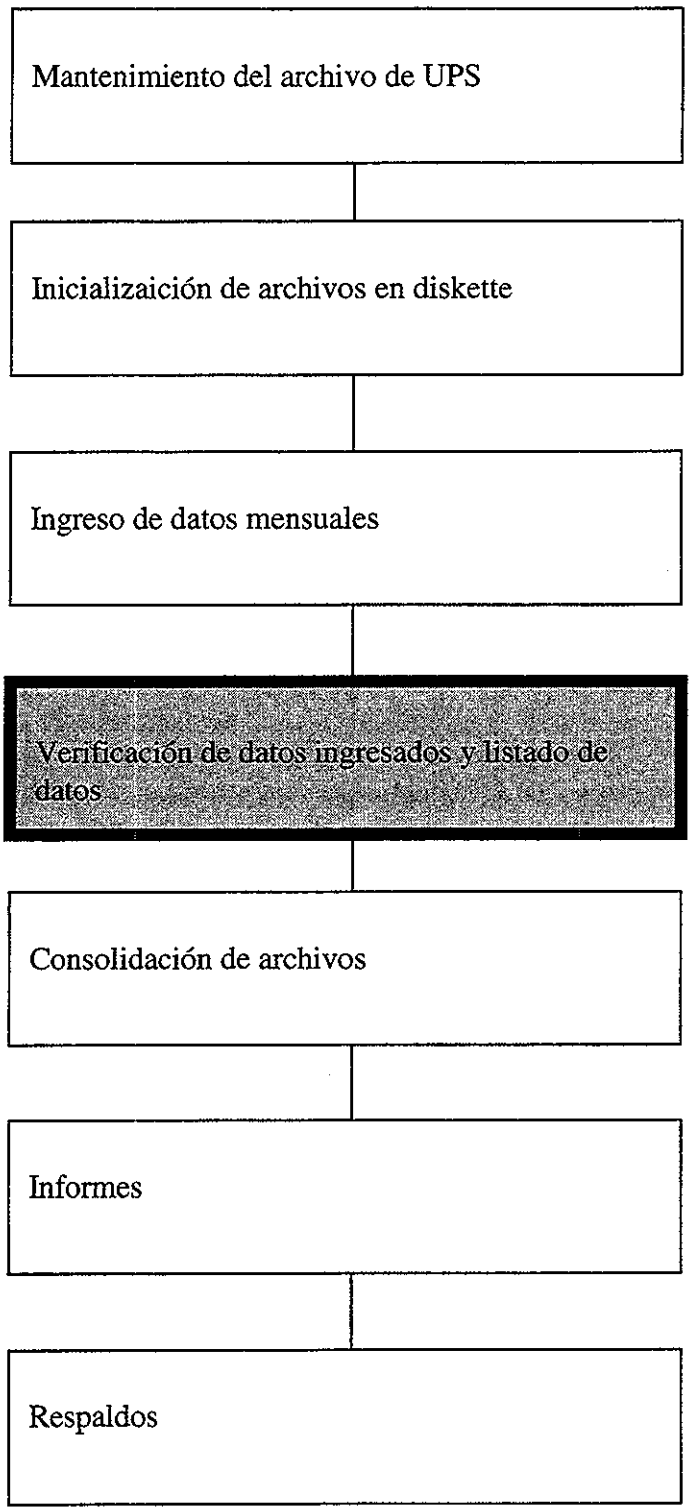
Se digita **un** formulario de Movimientos Trimestrales y Solicitud de Medicamentos Antifímicos para los medicamentos que se encuentran en las bodegas de la Región y hospital regional.

MOVIMIENTOS TRIMESTRALES Y SOLICITUD DE MEDICAMENTOS ANTIFIMICOS

AREA ## REGISTRO _____

==========

	EXIST INIC	ENTRADAS SECR	ENTRADAS OTROS	TOTAL DISP	CONSUMO	EXIST FINAL	CANTID SOLICIT
TRIPLE	#####	#####	#####	#####	#####	#####	#####
DOBLE	#####	#####	#####	#####	#####	#####	#####
ETAMBUTOL	#####	#####	#####	#####	#####	#####	#####
PIRAZINAMIDA	#####	#####	#####	#####	#####	#####	#####
ESTREPTOMICINA	#####	#####	#####	#####	#####	#####	#####
ISONIACIDA	#####	#####	#####	#####	#####	#####	#####
RIFAMP.SUSP	#####	#####	#####	#####	#####	#####	#####
KANIMICINA	#####	#####	#####	#####	#####	#####	#####


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

273

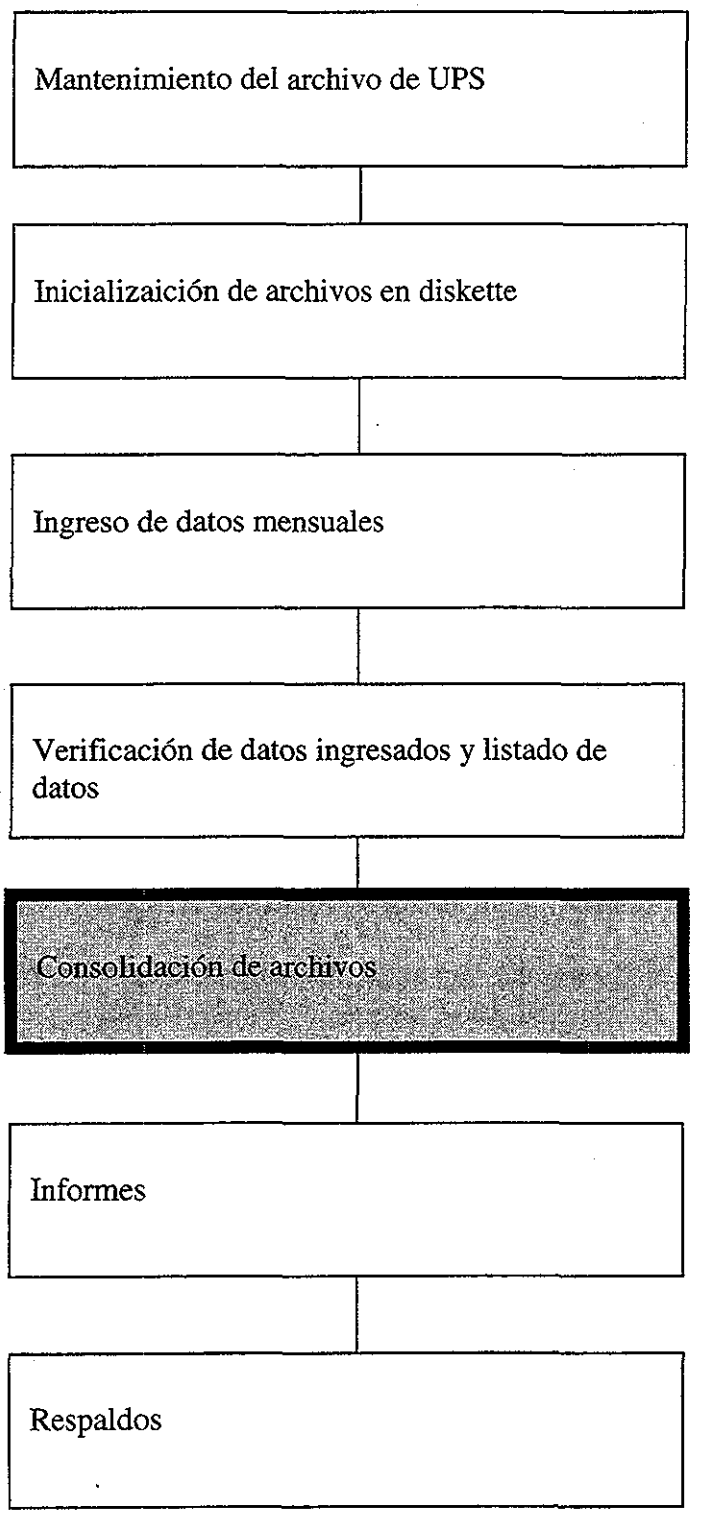
Verificación de Datos Ingresados y Listado de Datos

Una vez que se termine de ingresar todos los datos de la Región (o Area), se procede a la verificación de éstos para determinar si se ha registrado datos de todas las UPS en el Area o Región.

Del menú de Tuberculosis, escoja la opción Verificación de Datos Ingresados y se presentará un submenú de opciones relacionadas con cada archivo de datos. Al escoger cualquier de estas, se preguntará por el código de Región y Area a verificar. Estos se ingresan **con un espacio** entre los dos códigos (ej. 7 2) y se acepta con <ENTER>. A continuación, se presenta una lista de archivos del tipo que se quier verificar. Generalmente, habrá uno solo con el trimestre y año de interes, el que quedará resaltado. Se solicta la selección y confirmación del archivo a verificar y enseguida, se presenta una lista de todas las UPS en la región y se señala aquellas que no tienen datos registrados mediante un punto (.) al lado del nombre de la unidad.

A continuación se puede realizar un listado de los datos ingresados, tanto en pantalla como en la impresora, a fin de llevar a cabo una revisión y depuración de los datos registrados. Se escoge la opción Listar Datos Ingresados del menú principal y se presenta un submenú con los cinco archivos principales que se pueden listar. Luego de escoger uno, los detalles se presentan en pantalla y, a su vez, quedan grabados en un archivo (LISTA1.TXT) que se puede imprimir en la impresora al oprimir la tecla <F5>.

Como resultado de los dos procesos anteriores, se habrá detectado datos erroneos o faltantes. Habrá que recabar los datos perdidos para completar la información y volver al Ingreso de Datos del Período para ingresar los nuevos o corregir los erroneos.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

275

Consolidación de Archivos

Cuando se haya terminado la verificación de los archivos y completado los datos que pueden haber faltado, se procede a consolidar los datos contenidos en el diskette, pasandolos a los archivos maestros en el disco duro de la computadora. De esta manera, se contará con un archivo donde residen todos los datos de la región (o Area o país) durante todos los períodos de operación. Es sobre estos archivos maestros que se realizan los análisis y reportes.

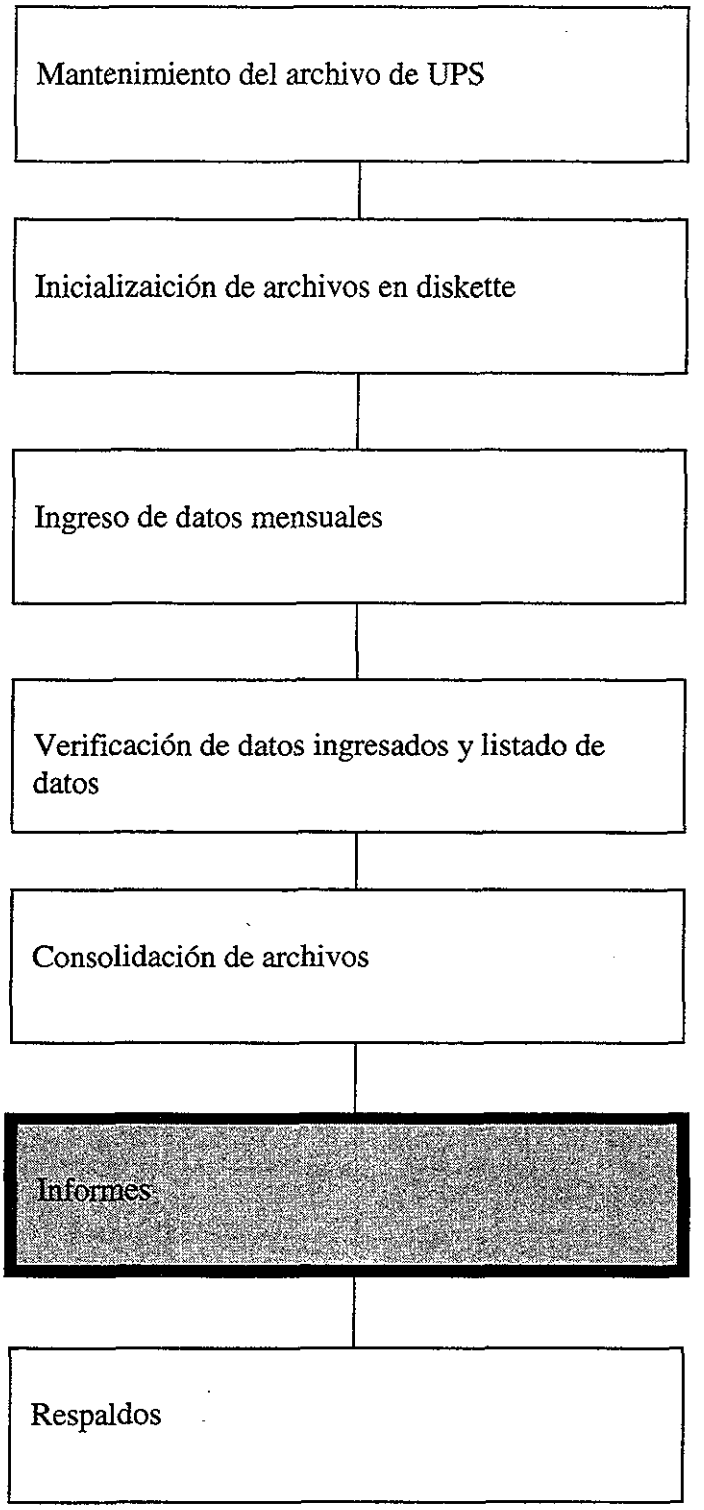
Hay una consideración importante para que el procedimiento de consolidación resulte exitoso. Hay que **respaldar** los archivos maestros antes de realizar la consolidación. Esto permitirá que, en caso de falla (error, perdida de energía, etc.) se pueda volver el sistema a la condición inicial, antes de comenzar la consolidación.

Por esta razón, al escoger la opcion Consolidación de Archivos del menú de Tuberculosis, aparecerá un submenú cuya primera opción es Respaldar Archivos a Diskette. Se debe insertar un diskette en blanco al lector antes de aceptar esta opción. Se copiarán todos los archivos MAES del disco duro al diskette y aparecerá un mensaje que indica que se puede proceder a la consolidación con la tercera opción.

La consolidación comienza verificando que el diskette con el REGISTRO de control conformado por TRIMESTRE/AÑO/UPS no haya sido consolidado anteriormente. Si fuera así, aparecería el mensaje "Ud ya realizó una consolidación con esos parametros" y permitirá abortar el proceso si fuera una consolidación repetida por error (aceptar CANCEL en la ventanita). Sin embargo, existe la posibilidad que se haya ingresado datos con el mismo REGISTRO en dos o mas ocasiones (por ejemplo, cuando se ha tenido que mandar datos incompletos al nivel central y se ingresan los faltantes en un momento posterior). En tal caso, se acepta OK en la ventanita.

La consolidación continua al trasladar todos los datos de los archivos en diskette al disco duro y grabar el REGISTRO en el archivo de control. Cuando el proceso termina, volverá el menú principal.

Si fuere necesario revertir el proceso de consolidación, en el submenú de Consolidar Datos, la segunda opción es de restaurar los archivos en diskette al disco duro. En efecto, este proceso pone al sistema en su condición inicial, antes de comenzar la consolidación y así permite reiniciar el proceso o volver a operaciones anteriores como es el ingreso de datos.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

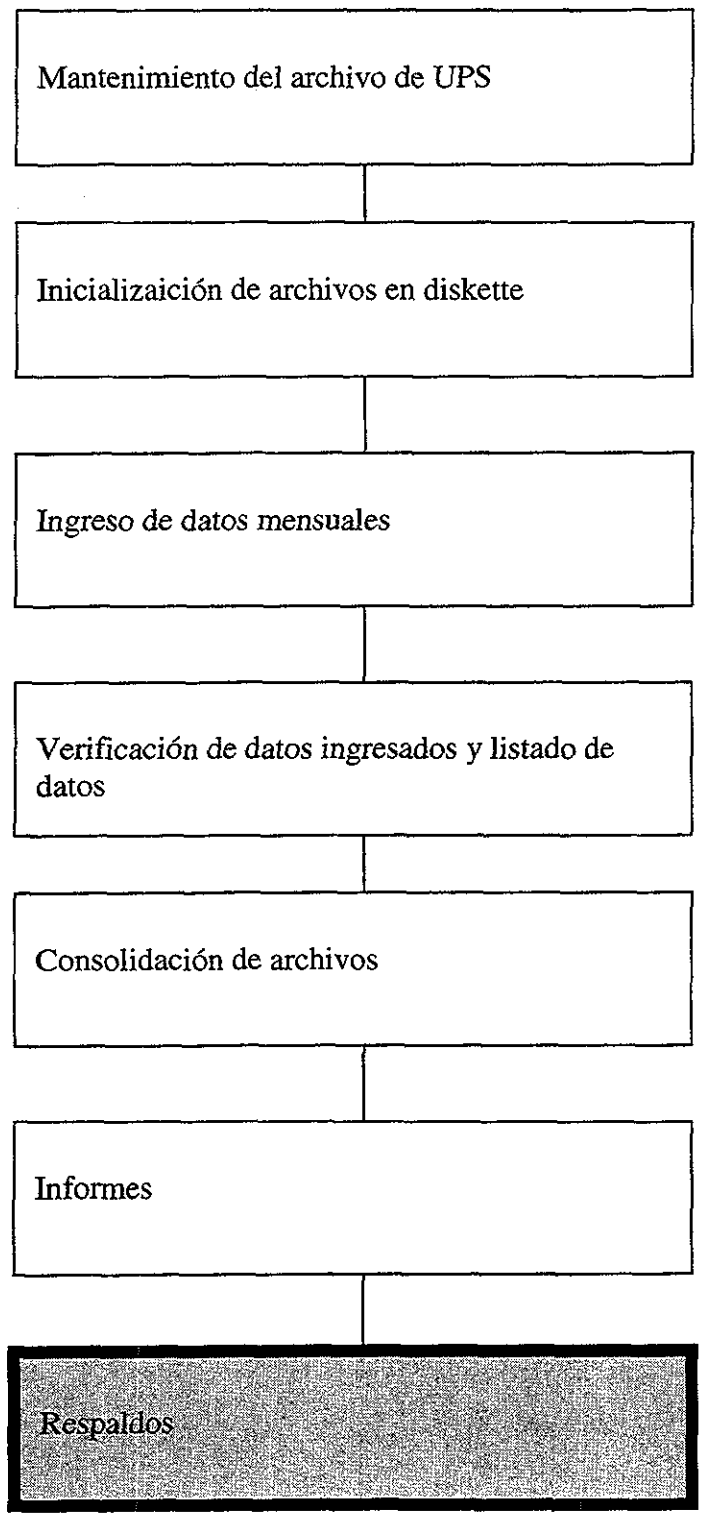
Informes

La opción de Informes procesa los datos de los archivos maestros para dar información basada en indicadores definidas por el PNT, tales como:

- Número de casos baciloscopía positivas por 1000 sintomáticos respiratorios
- Número de baciloscopías por caso baciloscopía positiva
- Tasa de positividad

y otros que se encuentran elaborados en el Manual de Normas del PNT. Se producen los informes a partir de cada uno de los archivos ya mencionados:

- Laboratorio
- Producción. Los informes para TB-2 incluyen: Gráficas de barras, Resumen de datos mensuales e Indicadores
- Cohortes
- Casos Nuevos y Recaidas
- Medicamentos.


Mantenimiento del archivo de UPS
Inicializaición de archivos en diskette
Ingreso de datos mensuales
Verificación de datos ingresados y listado de datos
Consolidación de archivos
Informes
Respaldos

279

Respaldos

Hay un dicho al que nadie presta atención hasta cuando sea tarde: "La cuestión no es 'si pederá sus datos,' sino 'cuando perderá sus datos.'" En algun momento, Ud perderá sus datos, sin lugar a duda. Además, perderá tiempo. Su lamentación será, "si tan solo hubiera hecho un respaldo."

La última opción en el menú de Tuberculosis permite pasar todos los archivos del SIT (no solo los MAES) del disco duro a un diskette. Este procedimiento debe realizarse cada vez que cierra una etapa del proceso. Puede ser a final de cada día o semana o una vez terminado todo el proceso mensual o trimestral. La frecuencia con que se hacen los respaldos determinará cuanto tiempo Ud pierda al repetir el trabajo no respaldado.

El diskette de respaldo debe guardarse en un lugar seguro para evitar su perdida en caso que sufra daños o desastres las oficinas o los equipos (robo, incendio, inundación, falla de disco duro).

Si fuere necesario restaurar los archivos originales desde diskette, en el submenú de Respaldo, la tercera opción es de **restaurar** los archivos en diskette al disco duro. En efecto, este proceso pone al sistema en su condición al momento de realizar el respaldo. A partir de ese punto, se puede volver a realizar las operaciones perdidas después del respaldo.

Consideraciones Adicionales

1. Cómo funciona EPI-INFO
2. Importancia de respaldos para recuperar errores y fallas
3. Importancia de los datos – completos y consistentes
4. Cómo ingresar datos por partes
5. AYUDA en linea
6. Cómo usar la información que produce el SIT
7. Estructura de archivos – base relacional con pantallas diferentes, como funcionan las sumas de control
8. Consideraciones sobre la Verificación de datos

Hungary

Acronyms

ACE	angiotensin-converting enzyme
ATC	Anatomical Therapeutic Classification
DDD	defined daily dose
DRG	Disease-Related Group (Project)
DUR	drug utilization review
Ft	forint
GP	general practitioner
HSMTC	Health Service Management Training Centre of the Semmelweis University of Medicine
HUF	Hungarian Forint (currency)
NHIF	National Health Insurance Fund
OEP	National Health Insurance Fund Administration (acronym in Hungarian)
RPM	Rational Pharmaceutical Management (Project)
USAID	U.S. Agency for International Development

Project Overview

Background

In the fall of 1997, the U.S. Agency for International Development (USAID) Mission in Hungary requested that the Rational Pharmaceutical Management (RPM) Project develop and carry out a limited country program on pharmaceutical management in Hungary before the close of the Mission's activities in Hungary in July 1999. In October 1997, RPM Director Anthony Savelli visited Hungary to gain local perspectives on problems in the pharmaceutical sector and identify appropriate areas for interventions.

Through discussions with the Mission and Hungarian health officials and experts, RPM identified major problems and concerns in the pharmaceutical sector as follows:

- The number of drug products registered in Hungary increased dramatically following the market liberalization and was still increasing. Drug costs were becoming increasingly burdensome to the public health care system.

- Anecdotal information suggested irrational prescribing and use of drugs. Physicians did not consider drug costs in the course of prescribing. Also, they did not have adequate training in clinical pharmacology needed for rational selection and prescribing.

- The list of drugs that was fully subsidized by the government through the National Health Insurance Fund (NHIF) might contain drugs that were not safe or effective.

On the basis of these findings, RPM and the USAID Mission in Hungary explored the probable focus of RPM activities in Hungary as follows:

- RPM would conduct an analysis, with recommendations, on the list of fully subsidized drugs by the government looking at drug costs, safety, effectiveness, duplication, and clinical necessity.

- RPM would work to improve prescribing practices by general practitioners (GP). This group is responsible for the bulk of drug prescription in Hungary. RPM would give serious consideration to working through one of the associations in its work in this technical area.

- RPM would work to improve pharmaceutical services provided at the Vac Hospital. This would support the USAID-funded Hospital Partnership Project and the Disease-Related Group (DRG) Project. (The exact technical activities were to be identified depending on the assessment and discussion with the hospital officials.)

Technical Areas and Activities

RPM and the Mission agreed on the following three technical areas for RPM activities in Hungary.

1. Assessment of the Subsidized Drug List of the National Health Insurance Fund

   - Objective—Help local counterparts improve appropriateness and sustainability of the drug subsidy system

   - Activities—
     - Conducted desktop analysis of fully subsidized drug database and recommended a number of deletions of duplicative drug products from the subsidized drug list and promotion of generic and therapeutic drug substitution

     - Provided OEP officials with hands-on training in the analysis of drug utilization database

     - Recommended steps to improve the use of drug database for monitoring and improving the prescribing decisions by physicians and options for improving drug procurement practices

2. Survey on General Practitioners' Prescribing Patterns for Antihypertensive Drugs

   - Objective—Provide objective information about prescribing patterns by general practitioners (GPs) in management of hypertension
     - Conducted a survey of prescribing records of GPs

     - Presented recommendations on how to promote rational use of antihypertensives by GPs

3. Assessment of Utilization of Hospital Drug Formulary Systems in Hungary

   - Objective—Improve pharmaceutical management at hospitals through promotion of drug formulary systems
     - Conducted a mail survey targeting all 150 hospitals in Hungary to determine the current status of drug formulary systems

     - Presented key findings and recommendations to policy makers through individual meetings and the USAID conference

(Note: After an RPM visit to the Vac Hospital site and several sessions of discussion with hospital officials, a gap existed between what RPM recommended for feasible and necessary technical assistance and what the hospital officials recognized as their needs. The Mission and RPM agreed to drop this line of activity from the work plan.)

RPM Hungary Program Implementation

Assessment of the Subsidized Drug List of the National Health Insurance Fund

Background

With the liberalization of the Hungarian pharmaceutical market in the 1990s, the number of drugs in the country dramatically increased: It was reported that about 300-400 new drug products were introduced each year in Hungary. As a result, the number of registered drug products increased fourfold between 1990 and 1997, including many "me-too" products and expensive imported drugs whose cheaper equivalents already existed.

Against this background, there were growing concerns among health officials about appropriateness of the selection criteria for drugs subsidized by the NHIF. The Hungarian list of subsidized drugs covered a large number of products (3,428 drug products in the 1996 list), and there were concerns that the list might include too many, too expensive, or unsafe drugs with financial and public health implications for the national health care system.

The USAID Mission in Hungary and RPM agreed that the latter would conduct an initial assessment of the subsidized drug list by focusing on 1,095 fully subsidized drug products (Phase 1). During the first phase in the spring of 1998, however, RPM experienced difficulties in obtaining full cooperation of the NHIF Administration (OEP, the acronym in Hungarian) and gaining access to necessary information to conduct the assessment.

In the summer of 1998, there were major changes in the Cabinet and the Government of Hungary as a result of the parliamentary election. This dramatic change in the political scenery in the country created a favorable environment for RPM's collaboration with the OEP. New leadership at the OEP not only supported the further assessment of the subsidized drug list by RPM but also requested additional technical assistance from RPM in exploring ways to rationalize the pharmaceutical benefit scheme (Phase 2).

Objectives of the RPM Activity

- Evaluate products for potential lack of therapeutic efficacy and possible toxicity risk
- Identify duplication of products within generic drug grouping and within therapeutic classes
- Suggest ways to reduce the duplication on the list

Mode of Implementation

Phase 1—Desktop Analysis of Subsidized Drug Database for Rational Selection

Between February and March 1998, RPM consultant Edward P. Armstrong and RPM Senior Program Associate Tomoko Fujisaki conducted a desktop analysis of the 1996 subsidized drug list database obtained from the OEP. Results and recommendations were presented to the USAID Mission in Hungary and key officials at the OEP during the second RPM visit in April and May 1998. At these meetings, Armstrong and Fujisaki proposed joint activities by the OEP and RPM in further therapeutic and financial analysis of the subsidized drug policy. However, the Administration officials did not respond to the proposal.

Phase 2—Direct Technical Assistance to OEP

RPM Director Tony Savelli and Fujisaki visited Hungary in February 1999 to determine the area of collaboration with the OEP during the remaining project period. RPM presented to the USAID Mission in Hungary and the executive officials at the OEP key observations from RPM activities in all three technical areas (i.e., subsidized drug list, prescribing survey, and hospital formulary system) and made recommendations that rationalizing the drug selection and pricing system should be the priority for the Fund Administration. RPM also suggested that the Fund might wish to consider conducting a pilot implementation of a hospital drug formulary system at selected hospitals, using the RPM manual on hospital drug formulary system development, as the first step in the introduction of such a system at a larger scale.

In responding to the subsequent proposal from the Director-General of OEP, Armstrong visited Hungary again in May 1999 to provide direct technical assistance to officials at the Administration in analyzing the drug benefit scheme. Armstrong found that although a rich database of drug use at a national level existed, which could be sorted by patient and by physician, there were no routine reports created to assess and monitor medication use within the OEP. Building upon the findings from the first phase of the assessment by RPM, Armstrong conducted a detailed analysis of drug utilization patterns together with the OEP officials. The recommendations for possible strategies to address most critical issues were presented to the Director-General and his advisors; some of the recommendations were used by the Fund Administration in its reports to the Committee of the Pharmaceutical Benefit Scheme—a technical committee reporting to the Prime Minister on health reform.

The activity also provided the Fund Administration officials with a hands-on training opportunity in analyzing the drug use patterns and designing the reporting system. RPM also provided a number of standard reference materials to the OEP. In addition, RPM prepared and submitted a technical paper on the Reference Drug Pricing Systems for consideration as an option for rationalizing the procurement and pricing of drug products through the Fund.

Key Findings and Recommendations

Phase 1—Desktop Analysis of Subsidized Drug Database for Rational Selection

The first phase of the assessment of 1,095 fully subsidized drug products revealed that—

- The number of drug products on the list could be reduced by up to 40 percent. The vast majority of the recommended deletions were for different brand names for the same generic entity. Under the current system of reimbursement, this type of reduction results in inventory savings. (Under a system of reference pricing, the market determines which brand of a particular drug a pharmacy stocks.)

- A number of recommended deletions were made for drugs known to be ineffective (e.g., papaverine, pentoxifylin) or unsafe (e.g., metamizol, aminophenazon).

- There were very few products with dubious efficacy among items listed for full subsidy.

- The greatest number of fully subsidized products, as well as the greatest number of recommendations for possible deletion from the list, was found in four therapeutic categories according to the Anatomical Therapeutic Classification (ATC) main groups—

    1. Alimentary tract and metabolism
    2. Cardiovascular system
    3. Nervous system
    4. Respiratory system

- These suggested deletions represent 33 percent of all fully subsidized drug products. Table 1 presents the summary of fully subsidized drug products by therapeutic classes.

Table 1. Summary of Fully Subsidized Drug Products by Therapeutic Classes

ATC Main Group	Group	Number of Unique Chemical Entities (N=347)	Number of Products in the Class (N=1,095)	% of Total Number of Products	Number of Suggested Deletions (N=442)	% of Suggested Deletions (Mean = 40.4%)
A	**Alimentary Tract and Metabolism**	**53**	**177**	**16.2**	**107**	**60.5**
B	Blood and Blood Forming Organs	13	24	2.2	3	12.5
C	**Cardiovascular System**	**45**	**160**	**14.6**	**81**	**50.6**
D	Dermatologicals	27	45	4.1	4	8.9
G	Genitourinary System and Sex Hormones	18	33	3.0	1	3.0
H	Systematic Hormonal Preparations, excl. Sec. Hormones	14	53	4.8	23	43.4
J	General Antiinfectives for Systematic Use	15	44	4.0	11	25.0
L	Antineoplastic and Immunomodulating Agents	28	76	6.9	11	14.5
M	Musculoskeletal System	18	51	4.7	21	41.2
N	**Nervous System**	**62**	**220**	**20.1**	**116**	**52.7**
P	Antiparasitic Products, Insecticides, and Repellents	5	5	0.5	1	20.0
R	**Respiratory System**	**26**	**82**	**7.5**	**58**	**70.7**
S	Sensory Organs	23	32	2.9	5	15.6
V	Various	N/A	93	8.5	N/A	N/A

RPM recommended that—

- Further analysis should be conducted to determine the current patterns of product choice and proportion of drug costs spent by the NHIF for each group of drugs and individual products. For this, data on frequency of use is necessary.
- Introduction of generic and therapeutic substitution should be considered in selection, procurement, and use of drug products in Hungary.
- Establishment of a Reference Pricing System should be considered as an option for drug reimbursement by the NHIF.

Phase 2—Technical Assistance for Improving Drug Selection, Procurement, and Prescribing

At the second phase of the drug subsidy system analysis, detailed information became available to RPM including national level drug utilization data by individual drug products and by prescribers. A summary of key findings and recommendations by RPM are presented below.

Drug Utilization Patterns

Drug utilization patterns and potential financial savings by promoting rational drug prescribing and consumption were examined by reviewing the data of the largest expenditure items. Major observations are listed below (see Appendix A for detailed results).

- The largest single item in terms of reimbursement costs for the NHIF was vinpocetine (Cavinton). This is a product in the "psychostimulant" category. This product has not been shown to be effective in the treatment of dementia or stroke. Potentially huge cost savings (more than $9 million annually) could be achieved by eliminating the product from the subsidy list.

- Similarly, piracetam (Nootropil 2000) was another psychostimulant with unproven efficacy that should no longer be covered by the NHIF drug benefit scheme.

- It was estimated that substantial savings could be made when generic or therapeutic class substitutions were promoted. For example, generic substitutions for major items such as captopril, fluoxetine, and ranitidine could result in 10 billion Hungarian forints (HUF) per year (more than $41,000,000).

As an illustrative example of using the existing OEP drug database for monitoring prescribing patterns of physicians, Armstrong demonstrated to OEP officials an analysis of antibiotic use by physicians. The data indicated that—

- Most of the 39 antibiotics with more than 100,000,000 HUF (approximately $435,000) of annual reimbursement levels were costly penicillin combinations, macrolides, cephalosporins, and quinolones.

- A relatively small number of physicians, especially general practitioners, had costly antibiotic prescriptions that were much higher than those of their peers. For example, 290 out of 3,457 (8.4%) general practitioners accounted for more than $664,889 (22.4%) of a total of $2,968,429 per month costs for antibiotics in Hungary.

Modifying prescribing practices is critical to ensure rational and cost-effective pharmaceutical care. Armstrong recommended that the Fund Administration officials—

- Collect additional data from research in disease management, outcome research, and pharmacoeconomics, which should provide scientific basis for OEP to stop OEP payment for products without documented efficacy.

- Expand standard treatment guidelines development and encourage dissemination of treatment algorithms.

- Develop drug monitoring reports from OEP database (discussed more below).

- Create a physician "report card" for feedback regarding medication use to provide to individual physicians. OEP should provide education outreach consultation with providers when opportunities to improve patient care are identified.

- Consider implementation of a "prior authorization" procedure for selected medications or procedures when problems in use have been identified.

- Encourage development of patient information leaflets to improve patient knowledge about their medications.

- Encourage development of a research and education foundation by strengthening affiliations with universities, nongovernmental organizations, Ministry of Health, Ministry of Finance, and industry organizations to encourage research in disease management, health care outcomes, pharmacoeconomics, and database research.

Drug Information System

RPM encouraged OEP to use the existing database for more active assessment and monitoring of health care delivery, especially focusing on the following:

- OEP should consolidate pieces of the database that exist in different parts of the organization and create routine (e.g., quarterly) reports to more accurately monitor changes in disease management, health care trends, and medication use.

- Initiate monitoring of medication use at the individual physician level to identify practice variations and help OEP.

- The current data elements should be used in disease modeling and pharmacoeconomic assessments of treatment options.

Table 2 shows the types of routine reports recommended to the Fund Administration. All reports should be produced by therapeutic class (e.g., ATC group), brand name, and generic name of drug products.

After experience is gained from these basic reports, it is suggested that they will be modified into exception reports based on key parameters.

Table 2. Recommended Reports

Type of Report	Objective	Necessary Information
1. Rank of drugs, by HUF spent	Determine NHIF spending patterns	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment
2. Rank of drugs, by the number of prescriptions	Determine prescribing patterns of physicians	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment
3. Changes (%) in monetary value spent (HUF) compared with the previous quarter and year	Determine recent changes in NHIF spending patterns	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment % HUF spent in last quarter % HUF spent in last year
4. Changes (%) in the number of prescriptions from the previous quarter and year	Determine recent changes in prescribing patterns by physicians	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment % HUF spent in last quarter % HUF spent in last year

291

Table 2. Recommended Reports (cont'd.)

Type of Report	Objective	Necessary Information
5. Amount of patient copayment	Determine the financial costs to patients	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment
6. Drugs, by volume of HUF by physician	Determine high- and low-cost prescribing physicians	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment Physician's name Physician's specialty
7. Number of prescriptions by physician	Determine prescribing patterns of physicians	Rank of drug product ATC group Brand name Generic name Total HUF spent HUF paid by NHIF Patient copayment Physician's name Physician's specialty

Improve Drug Procurement Practices

Under the current health insurance system, drug prices were negotiated between OEP and individual manufactures for each individual drug product (product-by-product pricing). Products include innovator (brand-name) products as well as generic products. Under this model, factors considered in pricing decisions typically include—

- Cost of manufacturing, plus a "reasonable" margin for profit
- Cost-effectiveness compared with existing drugs of choice
- Additional therapeutic benefits over existing products
- Price of comparable products

This system of pricing is time-consuming and labor-intensive, and objective data may be difficult to obtain. In addition, in the absence of active generic and therapeutic substitution practices and incentives among physicians and patients to select lower-priced but therapeutically equivalent products, product-by-product pricing tends to push up the drug costs, as RPM observed in Hungary. The same situation was observed from drug procurement practices by the OEP (which reimburses drug costs for outpatient care) as well as hospitals that were paid by the OEP based on the DRG system including drug costs.

To improve drug procurement practices, RPM recommended that OEP—

- Evaluate the feasibility of introducing alternative procurement mechanisms, such as bidding/tendering and a reference pricing system, through which OEP can strengthen its negotiating power as a purchaser of pharmaceutical products.

- Revise the subsidized drug list with reduced numbers of products and make it a restrictive drug formulary for the OEP's coverage for drug treatment.

- Encourage hospitals to improve their procurement practices, including the development of a hospital drug formulary system and pooled procurement of drugs with other hospitals and the introduction of a transparent tendering system.

RPM developed a technical paper on the reference pricing system and provided it to the OEP officials for their reference.

Outcomes

Training

OEP officials who worked with RPM and were familiarized with pharmaceutical management are now teaching modules in pharmaceutical reimbursement, regulation, purchasing, and the like as part of a new curriculum at health service management schools in Hungary.

Selection

Findings and recommendations from the RPM assessment of the subsidized drug list were used in a report prepared by OEP officials and submitted to the Committee of the Pharmaceutical Benefit Scheme of the Government of Hungary.

Procurement

OEP developed a plan to centralize drug procurement for hospitals using tenders with explicit selection criteria developed.

OEP is planning to make it compulsory for hospitals to develop a drug formulary. A proposal was submitted to the Ministry of Health and Ministry of Finance to develop a national guideline on how to develop a hospital-based drug formulary. An RPM formulary development manual was included in the proposal as the basis of such a guideline.

Outputs

Documents Developed

The following documents were developed during the project.

- Assessment of Fully Subsidized Hungarian Medication List
- RPM Hungary Drug Reference Pricing: Models and Issues
- RPM Hungary Trip Report, November 5, 1997
- RPM Hungary Trip Report, April 18–May 9, 1998
- RPM Hungary Trip Report, May 15–22, 1999

References Provided to the National Health Insurance Fund Administration

- *American Hospital Formulary System Drug Information*, American Society of Health-System Pharmacists, 1999
- *Drug Information Handbook*, Lexi-Comp Inc. and the American Pharmaceutical Association, 4th edition, 1996
- *Medication Formulary*, Cigna Health Care of Arizona, Spring 1988
- *RPM Manual for the Development and Maintenance of Hospital Drug Formularies* (Hungarian translation)

- *RPM Guidelines for Implementing Drug Utilization Review Programs in Hospitals* (Hungarian translation)
- RPM Assessment of Fully Subsidized Hungarian Medication List (completed April 20, 1998)
- ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems, *Practice Standards of ASHP 1997–1998,* American Society of Health-System Pharmacists, Inc., Deffengaugh JH, ed., Bethesda, MD, 1998
- "Professional Relations," Chapter 66, *Handbook of Institutional Pharmacy Practice*, 2nd edition, Brown TR, Smith MC, eds., Williams and Wilkins, Baltimore, MD, 1986
- "Managing Procurement," Chapter 13, *Managing Drug Supply, The Selection, Procurement, Distribution, and Use of Pharmaceuticals, 2nd edition,* Management Sciences for Health, Kumarian Press

Survey on General Practitioners' Prescribing Patterns for Antihypertensive Drugs

Background

While a number of key personnel interviewed by RPM expressed concerns regarding the problematic prescribing patterns among health care providers, documentation of evidence to support the concern was generally limited. The survey would help determine the extent and the common types of prescribing problems among general practitioners who are at the front line of the Hungarian health care system.

Treatment of hypertension was selected as the focus of this survey because—

- It is a major cause of morbidity and mortality among the Hungarian population.
- Most of drugs for hypertension control are covered by the drug subsidy policy.
- Proposed treatment guidelines for hypertension had been created by the (then) Ministry of Welfare.

Objectives of the RPM Activity

The survey was conducted to—

- Identify common forms and the magnitude of prescribing problems among general practitioners in Hungary in treating patients with hypertension

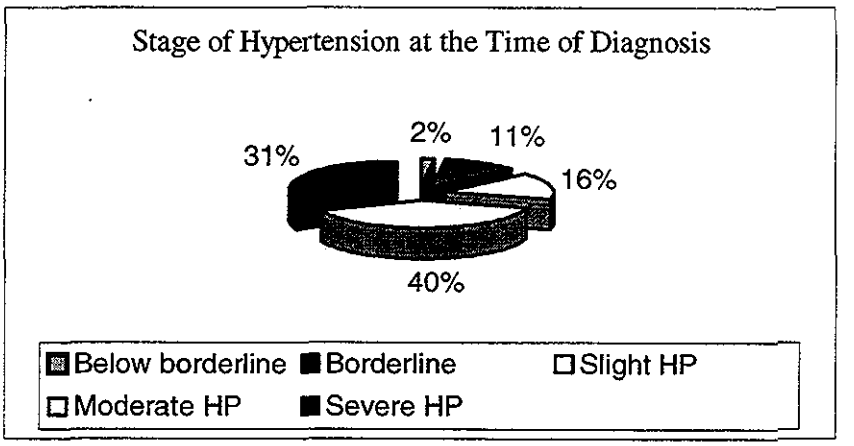
- Recommend possible forms of interventions to improve prescribing practices

Mode of Implementation

RPM entered into a subcontract agreement with Green Cross, a Hungarian association for private physicians. Green Cross collected data on patient background, blood pressure and other laboratory tests, and drugs prescribed from 800 case records with diagnosis of hypertension, using a standardized questionnaire developed by RPM. Data were collected from 40 general practitioners' offices in Budapest and 4 other randomly selected counties. RPM compared prescribing patterns with the treatment guidelines for hypertension proposed by the Ministry of Welfare (1996) and the 6th Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure by the U.S. National Institutes of Health (1997).

Key Findings

1. The majority of cases were not detected at an early stage: 40 percent of cases were first diagnosed with moderate hypertension and another 31percent with severe hypertension.



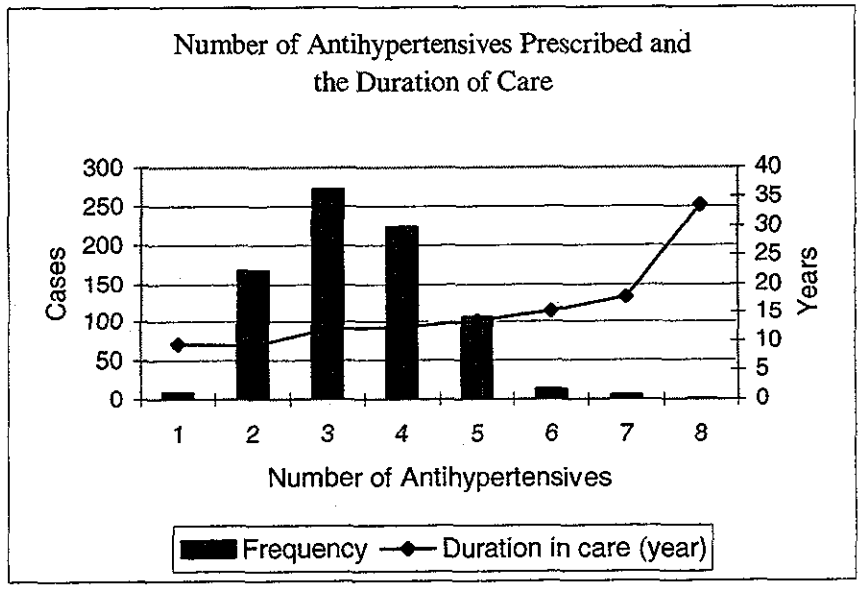
2. There are a great number of therapeutic choices for drug treatment of hypertension, as shown in the right two columns in the table below. The most frequently prescribed classes of drugs were angiotensin-converting enzyme (ACE) inhibitors, calcium channel blockers, and beta-blockers. Six products[1] accounted for nearly half (47%) of all drugs prescribed among the surveyed 800 cases.

[1] They are Betaloc (metoprolol), Ednyt (enalapril), Retinec (enalapril), Amilorid (hydrochlorothiazid + amilorid), Corinfar (nifedipin), and Tensiomin (captopril).

Table 3. Classes of Drugs and Therapeutic Choices for Treatment of Hypertension

Class of Antihypertensives	Frequency Prescribed (% of total 1,921 drugs prescribed)		Number of Items Mentioned in the Survey (in chemical entity)	(in product)
ACE inhibitor	576	30.0%	7	13
Calcium channel blocker	382	20.0%	10	17
Beta-blocker				
Cardio-selective	316	17.0%	5	7
Non-cardio-selective	35	2.0%	4	6
Diuretic				
Thiazides	100	5.0%	3	3
Loop diuretics	92	5.0%	2	2
Potassium-sparing agent	3	0.2%	2	2
Thiazide + potassium-sparing agent	116	6.0%	1	1
Other				
Psychostimulant (vinpocetine)	101	5.0%	1	1
Alpha-2 stimulant	100	5.0%	3	3
Alpha-1 inhibitor	75	4.0%	2	2
Beta-blocker (nonselective) + diuretic	12	0.6%	1	1
Vasodilator	9	0.5%	3	3
ACE inhibitor + diuretic	4	0.2%	1	1

3. The majority of cases (78%) were prescribed multiple antihypertensive drugs at a time.



4. Treatment guidelines proposed by the Ministry of Welfare (1996) for the initial treatment of hypertension leave practitioners with a wide range of choices that include the use of diuretics, beta-blockers, calcium channel blockers, ACE inhibitors, alpha-1 inhibitors, alpha-2 stimulants, and vasodilators.

5. Cost analysis suggests potential drug cost savings through the use of a reference pricing system for the subsidized drugs or the use of generic and therapeutic drug substitutions. Tables 4 and 5 present comparative costs of the most frequently prescribed drug products against the least expensive drug product of the same chemical entity using the defined daily dose (DDD). Potential size of drug cost savings could not be assessed in the absence of patient volume data.

Table 4. Most Frequently Prescribed ACE Inhibitors

Generic Name	Product Name	Frequency Prescribed	Daily Therapeutic Cost (HUF)	Monthly Therapeutic Cost (HUF)	Relative Drug Cost Compared with the Least Expensive Equivalent Product
Enalapril (DDD 10 mg)	Ednyt, 10 mg tab	57	23.7	711	108%
	Ednyt, 5 mg tab	58	32.0	960	146%
	Renitec, 10 mg tab	58	24.8	744	113%
	Renitec, 5 mg tab	32	33.8	1014	154%
Captopril (DDD 50 mg)	Tensiomin, 25 mg tab	48	16.8	504	100%
	Tensiomin, 12.5 mg tab	33	20.2	606	120%
	Tensiomin, 25 mg tab	30	22.3	669	133%
Perindopril (DDD 4 mg)	Coverex, 4 mg tab	54	39.0	1170	—

Table 5. Most Frequently Prescribed Beta-Blockers

Generic Name	Product Name	Frequency Prescribed	Daily Therapeutic Cost (HUF)	Monthly Therapeutic Cost (HUF)	Relative Drug Cost Compared with the Least Expensive Equivalent Product
Metprolol (DDD 200 mg)	Betaloc, 50 mg tab	110	14.0	420	132%
	Betaloc ZOK, 100 mg tab	96	29.6	888	279%
Atenolol (DDD 75 mg)	Atenolol Pharmavit, 50 mg filmtab	15	10.6	318	141%

Recommendations

1. There is a need to strengthen the regular blood pressure monitoring at the ambulatory settings so that more cases will be detected at an early stage of hypertension.

2. A study should be conducted to identify potential cost savings of using the more cost-effective drug within therapeutic categories based on the patient volume data.

3. Recommendations from the study for the most cost-effective treatment of hypertension should be disseminated to health care providers through various means including the treatment guidelines and the continuing education of physicians.

4. When there are too many duplications of therapeutic choices, elimination of less cost-effective drugs from the subsidized drug list should be considered.

Outputs

- RPM report on the Survey on General Practitioners' Prescribing Patterns for Antihypertensive Drugs

Assessment of Utilization of the Hospital Drug Formulary Systems

Background

Hospital expenditures for drugs typically make up a significant portion of any health system's overall budget. Without a system for controlling the number of drugs purchased by the hospital, stocks inevitably swell to contain an unmanageable number of duplicate or unnecessary products. Additionally, some products on the market in many countries are unsafe or ineffective. Finally, it is well known that irrational prescribing and use routinely occur in health care settings in which drug use is not regularly monitored and evaluated. These important financial and clinical issues are typically addressed though the use of drug formulary systems,[2] implemented and maintained by drug and therapeutics committees.

It was known that formulary systems were used at some Hungarian hospitals, although the extent of its application was not known. Furthermore, little was known regarding the effectiveness of the systems, or what implementation or ongoing problems are being encountered by hospital managers and clinicians. It was reported anecdotally that hospitals routinely stock and use large numbers of products.

Objectives of the RPM Activity

RPM and the Semmelweis University of Medicine Health Service Management Training Centre (HSMTC) conducted a mail survey to obtain the information on—

[2] Drug Formulary System activities include (1) maintaining and enforcing the list of drugs approved for procurement and use, (2) provision of unbiased, summary drug information, usually in the form of a manual, (3) monitoring and evaluating drugs use, (4) adverse drug reaction monitoring, (5) development and dissemination of newsletters, and (6) educational programs.

- The degree to which elements of a formulary system were in use in Hungary
- How widely the concept of hospital formulary systems was known to hospital managers and pharmacists
- Patterns that might exist among various types of hospitals in Hungary about the way in which the drug formulary system is implemented
- Challenges that were experienced and areas that need additional supports in developing and maintaining formulary systems

Mode of Implementation

During the second visit by RPM to Hungary in April 1998, RPM identified HSMTC as the local partner in this technical area based on its unique position as one of few academic and research institutions in Hungary focusing on health care management and its past history in working with projects supported by USAID and other European donor agencies. RPM Hungary Country Program Manager Fujisaki presented the staff assigned to this project basic concepts of a hospital-based drug formulary system and its significance in an overall management at hospitals.

RPM and the HSMTC developed a survey instrument to collect information on hospital-based drug formulary activities in Hungary. The survey questionnaire was mailed to 150 hospitals, of which 102 hospitals (68%) responded to the survey. The data was collated and analyzed by the HSMTC in consultation with RPM.

The findings were reported to key policy makers and professionals in the Hungarian health sector at the USAID-DHHS All Health Transition Conference on June 3, 1999. Key findings and RPM's recommendations were also presented to the Director-General of the OEP and his advisors.

Key Findings

All hospitals in Hungary (150) received the questionnaire, and the response rate was 68 percent (102). The survey data indicated the following:

1. Basic concepts of drug formulary list development were well known in Hungary, even in those hospitals that had not been involved. It was less clear whether the idea of a comprehensive formulary system—including drug utilization review (DUR) and provision of information and education—were known. The substantial citing of financial need and improvement of quality of care indicated understanding of the rationale for formulary systems. The fact that 17 respondents did not feel that formulary systems were useful suggested the need for additional advocacy activities.

2. Sixty-five responding facilities (43% of all hospitals) had developed formulary lists, distributed as shown in tables 6 and 7.

Table 6. Distribution by Hospital Size

Bed Size	Facilities with Formulary Lists
200–400	19
400–600	9
600–800	10
800–1000	4
>1000	14
Total	65

Table 7. Distribution by Hospital Type

Type	Facilities with Formulary Lists
County	13
Municipal	27
Budapest	5
National Institute	7
University	5
Others	8
Total	65

3. Seventy-three facilities reported having programs to monitor and evaluate drug use.

4. Challenges to the implementation of formulary systems included—

   - Formulary products are most commonly listed by brand name only (60%). This practice can bias thinking toward particular manufacturers and discourages generic substitution.

   - There is a lack of unbiased drug information, critical for making formulary decisions, developing treatment guidelines, and developing drug use evaluation criteria. Discussion of evidence-based medicine approaches may be useful.

   - While it is impossible to arrive at a "correct" number of drugs for a particular type or size of hospital to use, it appears that additional deletions can be made in some hospitals (71% of respondents with formularies have greater than 400 drug products).

   - There is an overreliance on education/information dissemination interventions (58%) to correct problems identified through drug utilization review as compared with managerial and policy change interventions (42%).

Recommendations

Based on survey findings and RPM knowledge of the current situation in hospital-based pharmaceutical management, RPM recommended the following to the USAID Mission in Hungary and to senior officials at the OEP and the Ministry of Health.

1. A national strategy for formulary system implementation should be developed. (What levels of the health care system should have formularies? Where should selection decisions be made?) A Policy Options Workshop might be a useful venue for this purpose.

2. Additional advocacy for formulary development may be necessary to arrive at a "critical mass," as evidenced by the number of respondents who did not feel that formularies were useful.

3. A model site for formulary systems could be developed at one of the many hospitals that have already gone through the process. Trained staff from the model site(s) could be used for further training and roll-out efforts, as well as staff of the Semmelweis University of Medicine HSMTC.

4. Regardless of the strategy and approach chosen, training in formulary systems implementation and maintenance should be conducted. RPM had already developed a standard manual for this purpose in Hungarian. In addition to the operational aspects of the formulary system, clinical pharmacology education and pharmacoeconomic evaluation should be included in training efforts.

5. Readily available and unbiased sources of drug information are needed in Hungary, including textbooks, international medical and pharmacy refereed journals, and the Internet. Evidence-based medicine concepts should be further promoted.

6. Selection and prescribing of drugs by generic name only should be promoted by law.

7. Formulary activities should be closely coordinated with changes in DRG policies and reimbursement rates.

Outcomes

As described in the section for Technical Area 1 (Assessment of Subsidized Drug List of the National Health Insurance Fund), OEP is planning to make it compulsory for hospitals to develop a drug formulary. A proposal was submitted to the Ministry of Health and Ministry of Finance to develop a national guideline on how to develop a hospital-based drug formulary. The RPM formulary development manual was included in the proposal as the basis of such a guideline.

Outputs

The following documents were developed during the project.

- RPM Manual for Developing and Maintaining Hospital Drug Formulary System (translated into Hungarian)
- RPM Manual for Drug Utilization Review at Hospitals (translated into Hungarian)
- Report on the Hungarian Hospital Survey for Use of Formulary System

Likely Needs after the End of the Project

Drug Subsidy System under the National Health Insurance

Additional technical assistance to the OEP and the MOH in the following areas will be beneficial in supporting initiatives for the drug subsidy system reforms.

- Assist with model development to compare costs of drug subsidies under various reform options, such as reference pricing, spending caps, and simply revising the current subsidized drug list. Such an analysis will guide the policy dialogue and decisions regarding the reform.
- Help OEP and MOH organize a policy options meeting on reforming the subsidized drug system to promote policy dialogue between key stakeholders based on objective information.
- Based on the decisions at the above policy options meeting, technical assistance can be provided to develop and implement a reformed drug subsidy system. This could include revising the list of drugs for subsidy, establishing reference prices, or deciding on the maximum drug spending or the utilization level.

Technical expertise in health economics and financing, pharmaceutical management, and clinical pharmacology would be necessary to support these activities.

Rational Prescribing for Treatment of Hypertension by General Practitioners

Next steps in these technical areas include the following:

- Identifying the most cost-effective treatment of various stages and types of hypertension
- Developing continuing education modules for treatment of hypertension by GPs

- Training for GPs on treatment of hypertension management
- Evaluating impacts of educational interventions to improve prescribing of antihypertensives by GPs

These activities should involve all key stakeholders among policy makers (e.g., MOH and OEP), medical schools, and professional organizations (e.g., Hungarian Chamber of Physicians, Association of General Practitioners, Green Cross).

Hospital Drug Formulary System

Given the potential leadership by OEP in this area, the future technical assistance should be focused on the following:

- Provide technical assistance to one or more health facilities in formulary system implementation.
- Facilitate a policy options meeting on expanding and strengthening hospital drug formulary systems.
- Help organize a workshop on developing and maintaining the hospital drug formulary systems.

The above activities will take place at the policy level as well as at the facility level. It may be useful to plan the activities in the order listed above so that understanding and support for introduction of a drug formulary system can be built based on the experience at model facilities.

Lessons Learned

- The concept of drug management as a cycle of components consisting of selection, procurement, distribution, and use, and supported by a legal and policy framework proved to be very useful in understanding and communicating major issues in the pharmaceutical sector in Hungary. Underneath various problems identified at the health system level, hospital level, and practitioners' level, there were a few common factors in the current system: prevalent use of brand names instead of generic names in identifying drugs, lack of cost-consciousness in selecting drugs, need for systematic approach in disease management, and monitoring current practices. By using the drug management cycle in addressing the three technical areas of activities in Hungary, RPM was able to identify the linkage between seemingly isolated observations from different parts of the pharmaceutical sector and point out areas for effective interventions for addressing the problems.

- Political changes in early 1998 resulted in a breakthrough for RPM in establishing a cooperative working relationship with OEP. Although the shift came at a relatively late stage of the project life in Hungary, the reform-minded leadership at the OEP took full advantage of technical supports provided by RPM and was able to use information and skills gained in advancing its reform agenda.

- Subcontracting activities to the Semmelweis University of Medicine Health Service Management Training Centre and to Green Cross helped RPM conduct multiple activity components within a short period of time without extensive local presence. Initially, however, RPM encountered difficulties in identifying capable subcontractors outside the government system due to the fact that Hungary was still in transition from a centrally managed socialist system to the privatized system. The role played by the local coordinator (supported by the DHHS) was also significant in the environment where rapid changes were taking place politically.

Appendix A. Summary of Sample Analysis of OEP Drug Database

ATC group	Generic Name	Brand Name	Price of One Box	Unit Price (Ft/mg)	DDD (mg)	Cost of DoT	Reimburse-ment Rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings
N06BX18	Vinpocetine	Cavinton	387	1.5	15	23.2	90	10	2,126,777,495 Ft	delete	2,126,777,495 Ft
N06BX18	Vinpocetine	Cavinton VR	669	1.5	15	22.3	90	10		delete	
C01DA02	Nitroglycerine	Nitromint R 2,6mg	568	3.6	5.2	18.9	90	10	2,013,856,715 Ft	switch to Isosorbide	426,213,061 Ft
C09AA04	Perindopril	Coverex 4 mg	1720	14.3	4	57.3	90	10	1,752,722,752 Ft	switch to captopril	1,156,858,193 Ft
N06AB04	Citalopram	Seropram	5400	9.6	20	192.9	100	0	1,666,427,135 Ft	switch to fluoxetine	549,303,759 Ft
N06AB05	Paroxetin	Seroxat	5810	9.7	20	193.7	100	0	1,444,819,345 Ft	switch to fluoxetine	544,604,882 Ft
L02AE03	Goserelin	Zoladex depot	38000	10555.6	0.128	1351.1	100	0	1,394,360,784 Ft	guideline	
C09AA02	Enalapril	Ednyt 10 mg x28	970	3.5	10	34.6	fix	10	1,244,484,623 Ft	switch to captopril	529,445,481 Ft
C09AA02	Enalapril	Ednyt 10 mg x100	2970	3.0	10	29.7	90	10			
C08CA01	Amlodipin	Norvasc 5 mg	2870	19.1	5	95.7	70	30	1,218,007,680 Ft	switch to nifedepine R	727,409,464 Ft
N06AB06	Sertralin	Zoloft	4970	3.6	50	177.5	100	0	1,159,077,214 Ft	switch to fluoxetine	314,839,887 Ft
A02BA02	Ranitidin	Ulceran 150	1850	0.2	300	61.7	fix		1,140,830,820 Ft	switch to gen ranitidine	295,999,347 Ft
L03AA04	interferon alpha 2b	Intron A 10 millió	16900	16900.0	287300.0	287300.0	100	0	1,117,766,000 Ft		
C09AA02	Enalapril	Renitec 10 mg	970	3.5	10	34.6	fix		1,108,429,994 Ft	switch to captopril	476,624,897 Ft
A02BA03	Famotidin	Quamatel 20 mg 28	939	1.7	40	67.1	100	0	1,033,791,486 Ft	switch to generic	330,196,086 Ft
J01CR02	amoxicillin +	Augmentin 625 mg	2640	0.2	1000	201.1	70	30	1,014,369,257 Ft		
A10BB01	Glibenclamid	Gilemal	305	2.0	10	20.3	90	10	1,002,237,128 Ft	maintain	
C09AA02	Enalapril	Ednyt 20,0 mg	1450	2.6	10	25.9	fix		974,219,378 Ft		
B01AC05	Ticlopidin	Ticlid 250 mg	2850	0.6	500	285.0	70	30	934,634,925 Ft	guideline	
J01CR02	amoxicillin +	Augmentin-Biogal 375 mg	1860	0.2	1000	236.2	70	30	893,717,515 Ft		
A11CC03	Alfacalcidol	Alpha D3 0,25 mcg	1940	129333.3	1000	129333333.3	100	0	867,603,432 Ft	guideline	

306

Appendix A. Summary of Sample Analysis of OEP Drug Database (cont'd.)

ATC group	Generic Name	Brand Name	Price of One Box	Unit Price (Ft/mg)	DDD (mg)	Cost of DoT	Reimburse-ment Rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings
M01AB05	Diclofenac	Diclofenac Duo Pharmavit 75 mg	946	0.4	40	16.8	90	10	847,377,413 Ft	switch to generic	
A02BA03	Famotidin	Quamatel 40 mg	939	1.7	40	67.1	100	0	834,093,278 Ft		
C09AA02	Enalapril	Renitec 20 mg	1450	2.6	40	103.6	fix		829,613,983 Ft		
R06AX13	Loratidin	Claritine	1350	6.8	10	67.5	90	10	791,404,380 Ft		
R06AE07	Cetirizin	Zyrtec	1270	6.4	10	63.5	90	10	789,103,962 Ft		
C09AA02	Enalapril	Ednyt 5,0	686	4.9	10	49.0	fix		749,343,808 Ft		
C01DA02	Nitroglycerine	Nitroderm TTS-5 tapasz	2320	3.1	5	15.5	70	30	737,280,270 Ft		
C05BX01	calcium dobesilat	Doxium	466	0.1		0.0	70	30	697,445,398 Ft		
L02BB01	Flutamid	Fugerel	21700	0.9	750	651.0	100		687,644,550 Ft		
N06BX03	Piracetam	Nootropil 1200	1940	0.0	2400	64.7	90/ fix	10	670,156,396 Ft	delete	670,156,396 Ft
N06AB03	Fluoxetin	Prozac 20 mg	4870	8.7	20	173.9	100	0	629,619,764 Ft	switch to generic	161,606,715 Ft
C04AD03	Pentoxifyllin	Trental 400 drg	1220	0.0	1000	30.5	fix		623,221,550 Ft	delete	623,221,550 Ft
A10AB01	human insulin	Humulin M3	1290	0.9	40	34.4	100	0	609,745,288 Ft		
C07AB02	Metoprolol	Betaloc 100 mg	367	0.2	150	27.5	90	10	598,666,591 Ft		
M05BA04	alendronic acid	Fosamax 10 mg	7660	27.4	10	273.6	90	10	591,236,334 Ft		
H05BA01 (nincs 200)	Calcitonin	Miacalcic 200	8070	1.4	200	288.2	90	10	579,363,861 Ft		
C04AD03	Pentoxifyllin	Chinotal drg.	1140	0.0	1000	28.5	fix		579,198,445 Ft	delete	579,198,445 Ft
A06AB06	senna glycosidok	Tisasen A + B drg.	225	0.8		0.0	90	10	566,727,623 Ft	delete	
A12BA01	kalium chlorid	Kalium-R	299	10.0	3000	29900.0	90	10	565,247,604 Ft		
C08CA05	Nifedipin	Corinfar drg.	378	0.4	30	11.3	fix		554,508,479 Ft		
C07AB02	Metoprolol	Betaloc 50 mg	252	0.2	150	25.2	Fix		552,837,240 Ft		

Appendix A. Summary of Sample Analysis of OEP Drug Database (cont'd.)

ATC group	Generic Name	Brand Name	Price of One Box	Unit Price (Ft/mg)	DDD (mg)	Cost of DoT	Reimburse-ment Rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings
J01FA10	Azithromycin	Sumamed 250	3610	2.4	300	722.0	70	30	527,706,719 Ft	guideline	
M05BA02	natrium clodronat	Lodronat	44000	0.9	1500	1375.0	100	0	522,775,667 Ft		
C09AA02	Enalapril	Renitec 5,0 mg	686	4.9	10	49.0	fix		504,221,343 Ft		
A02BA02	Ranitidin	Zantac 150 mg	1850	0.2	300	61.7	fix		497,181,268 Ft		
L02AE04	Triptorelin	Decapeptyl	35700	9520.0	0.134	1275.7	100	0	486,422,200 Ft	guideline	
C07CA03	pindolol +	Viskaldix	637	3.2		0.0	90	10	486,132,461 Ft		
M01AB05	diclofenac K	Cataflam 50 mg	685	1.4	100	137.0	50	50	486,063,618 Ft		
A10BA03	Buformin	Adebit	230	0.1	200	23.0	90	10	485,017,773 Ft		
C03EA01	hydrochlorothiazid +	Amilorid comp. Pharmavit	411	0.3		0.0	90	10	482,332,842 Ft		
C10AA01	Simvastatin	Zocor 10 mg	3660	13.1	15	196.1	70	30	481,050,170 Ft	switch to cheapest	
										Total	9,512,455,658 Ft

308

Moldova

Acronyms

DI	dispensing information
DOTS	Directly Observed Treatment, Short-course
DRUGS	RPM-Moldova's main local counterpart
ENI	USAID Bureau for Europe and the New Independent States
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
NIP	National Institute of Pharmacy
NIS	Newly Independent States
RMC	regional medical center
RPM	Rational Pharmaceutical Management [Project]
STG	standard treatment guideline
TA	technical assistance
TB	tuberculosis
USAID	U.S. Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Project Overview

Introduction

In August 1998, the U.S. Agency for International Development (USAID) Bureau for Europe and the New Independent States (ENI) requested that the Management Sciences for Health (MSH) Rational Pharmaceutical Management (RPM) Project carry out a limited program of assistance in Moldova. To assess local needs, inform USAID and interested parties of the types of RPM assistance available, and plan next steps, Moldova Country Program Manager Diana Callender and MSH Senior Program Associate Olya Duzey visited Moldova in October 1998. The most significant finding from this visit was that a high level of interest in formulary development existed in Moldova. The Ministry of Health (MOH) had attempted to implement a national formulary system, but this attempt had not succeeded and had been met with resistance from key health care professionals who had not been involved in the decision-making process.

Systems did not exist at the health facility level for rationally selecting drugs for procurement and use. Funds for drug procurement were extremely limited, cost-effectiveness was not considered when selecting drugs, and some drugs were of unproven quality or efficacy. There had been a marked increase in the number of drug products available on the market, but key decision makers did not have access to sources of unbiased drug information on which to base rational drug selections. Physicians and pharmacists did not have adequate training in clinical pharmacology to make appropriate selection decisions.

Because of Moldova's expressed interest, the problems described above, and the RPM Project's extensive experience in Russia, RPM offered to assist in formulary system development.

Initial Steps

To reach a consensus on how to implement a formulary system in Moldova, RPM's initial activity was to hold a national Policy Options Workshop in January 1999. Three demonstration sites—City Hospital No. 1 in Chisinau, the Regional Medical Center (RMC) in Stefan-Voda, and the RMC in Comrat, Gaugauzia—were selected in January 1999.

Demonstration sites were selected based on the interest expressed by key decision makers in the development of a hospital formulary list and on the fact that these sites represented the capital, Chisinau, as well as rural areas of Moldova.

Challenges Facing RPM-Moldova

RPM planned to help develop formulary lists at the demonstration sites that complemented the MOH's plans for formulary system implementation at the national level. During this process, RPM-Moldova had to respond to several challenges:

Lack of Agreement on the Best Method of Implementing a Formulary System

There was a lack of a consensus on whether formulary system implementation should start at the MOH level, i.e., "top down," or at the facility level, i.e., "bottom up." The MOH had experienced resistance from some health professionals at the facility level who felt that the MOH should have invited wider consultation before deciding to implement a national formulary system. This constraint was overcome by RPM-Moldova conducting a Policy Options Workshop in January 1999 to determine the best method of formulary system implementation. During that workshop RPM, the nongovernmental organization DRUGS [RPM-Moldova's main local counterpart], the MOH, and key health professionals built necessary consensus and decided to further develop the national drug formulary system with RPM assistance.

Lack of Managerial Skills and Know-How

The centralized drug supply system of the former Soviet Union required few managerial skills of Moldovan health officials because key decisions were made in Moscow. With the dissolution of the Soviet Union, Moldovan health officials at the ministry and district level faced the challenge of managerial responsibilities and decision making for which they had never been trained.

Economic Situation

During the project implementation period, Moldova was going through a severe economic crisis. Lack of funds led to nonpayment of health professionals and, in some cases, inability to buy key drugs, such as insulin and antituberculosis drugs. Nonetheless, as a result of RPM training, the demonstration sites reported saving funds by not procuring nonessential drugs. The funds were used to buy vital or essential drugs.

Concurrent Health Care Reform Initiatives

During the RPM project implementation period, Moldova was undergoing significant health care reforms, including decentralization of the health care budgeting process and of drug procurement, reorganization of health care districts, changes in the status of some hospitals from tertiary to secondary or primary care, cost-recovery initiatives in state pharmacies, and the introduction of family physicians. At the same time, the MOH introduced a national insurance program and mandated the development of minimal levels of care for all Moldovans.
These rapidly occurring changes were disturbing to health care professionals, who feared that they might lose their jobs due to downsizing of the health sector or be given different responsibilities, possibly with less authority.

Implementation Strategy

The RPM-Moldova implementation strategy was developed based on the findings of the reconnaissance visit and the local challenges and situations described above. The following strategy was used in developing formulary lists and the beginning of formulary system implementation at RPM demonstration sites:

1. Creation of stakeholders
2. Creation of demonstration sites
3. Training of Moldovan counterparts
4. Using RPM-trained Russian experts
5. Disseminating RPM tools and information
6. Collaborating with USAID-funded organizations
7. Disseminating RPM information
8. Conducting additional activities

The key activities of RPM-Moldova are listed by modes of implementation in Annex 1.

Moldova Project Implementation

Creation of Stakeholders

RPM-Moldova strengthened its relationship with the drug information center, DRUGS, a nongovernmental organization (NGO) that was identified as RPM's main counterpart during the initial visit. Relationships were also developed with the MOH, the National Institute of Pharmacy (NIP), and the Medical University. Stakeholders were created by—

1. Involving Moldovan health care professionals as facilitators at workshops

2. Having representatives of DRUGS, the MOH, the NIP, and the Medical University present data at workshops on the situation in the pharmaceutical sector in Moldova and on their accomplishments in developing a national formulary system

3. Working closely with health care professionals at the three demonstration sites to identify their particular needs

4. Having members of the formulary committees from the demonstration sites present formulary lists, which RPM helped them develop and analyze, at the Formulary Systems Implementation Workshop, demonstrating that the RPM methodology could be applied to facilities in Moldova

Creation of Demonstration Sites

The duration of the RPM-Moldova program was only a year so it was important to choose demonstration sites early in the program. By the end of project each of these facilities had developed a formulary list.

City Hospital No. 1

This 600-bed multidisciplinary hospital developed a formulary list of 80 drugs based initially on the morbidity patterns at the hospital and broken down into pharmacotherapeutic groups. ABC/VEN analysis led to the removal of 10 nonessential drugs from the list. The Medical Council of Moldova adopted the formulary list. After the list was published in the national medical newspaper, it then became official, and the medical staff were required to adhere to it. The Formulary Committee developed minimal treatment patterns for the main diseases seen at the hospital.

Stefan-Voda

The Formulary Committee of this 500-bed multidisciplinary RMC in Stefan-Voda created its formulary list based on information and materials from RPM during the January Policy Options Workshop and direct technical assistance (TA). Thirty-eight drugs were removed from the list of drugs procured in 1998 for reasons including lack of efficacy, expensive drugs of questionable efficacy, expensive nonessential drugs, and seldom-used preparations. Eight drugs were added to the list because of high efficacy or high cost-effectiveness ratio. The list required further evaluation because ABC/VEN analysis showed that nonessential drugs were still on the formulary list (see Annex IV). The final formulary list consists of 80 drugs.

Comrat

The Formulary Committee of the 600-bed RMC in Comrat (capital of the Autonomous Republic of Gaugauzia) developed a formulary list with RPM assistance. Seventy-seven drugs were removed from the list of drugs procured in 1998 because of duplication, high cost, or the fact that they were not needed given the pattern of diseases treated at the hospital. The formulary list consists of 90 drugs based on the morbidity patterns at the hospital (see Annex VI). ABC/VEN analysis of the list is in progress.

Training of Moldovan Counterparts

Training was an important part of the RPM-Moldova implementation strategy. Many concepts, such as cost-effective drug selection and the development of formulary lists, manuals, and systems, were not easily understood by some officials and health care professionals.

On-Site Training by Visiting Experts

Formulary list development was facilitated at the demonstration sites through direct TA by RPM experts. The direct TA was combined with ad hoc lectures to hospital staff on formulary development. The lectures created stakeholders among hospital staff who were not participants at the RPM workshops.

Workshops

Formal training consisted of two workshops that covered topics including—

- Options in formulary system development
- Cost-effective drug selection/formulary development
- Rational drug use
- Drug use review and drug use evaluation
- Formulary manual development
- Role of unbiased drug information in formulary development

Additional Specialized Training

Many Moldovan physicians and pharmacists lacked training in clinical pharmacology. Therefore, in addition to the workshops, pharmacology lectures were held for 25 participants from throughout Moldova. In addition, the topics "Criteria for Antibiotic Selection" and "Selection of Cardiovascular Drugs for the Formulary" were covered during the Formulary Systems Implementation Workshop.

Russian RPM-Trained Experts as TA Providers

RPM-Russia had established a team of Russian experts capable of providing training in rational drug use issues to other countries in the region interested in implementing pharmaceutical sector reforms. RPM-trained expert Marina Semenchenko, a professor of pharmacology at the Ryazan State Medical University in Russia, made presentations at both the Policy Options Workshop and the Formulary Systems Implementation Workshop. Many Moldovan health professionals were impressed by the work done in Ryazan in formulary implementation, especially since that oblast had a health care system and economic problems similar to those in Moldova. RPM-trained expert Oleg Karpov, a clinical pharmacologist from the St. Petersburg Medical University, made clinical pharmacology presentations at the Formulary Systems Implementation Workshop, and his facilitation of the sessions on formulary development at the United States Pharmacopeia (USP) and DRUGS drug information conference in June 1999 were also very well received. Thus RPM-Russia trained experts were a cost-effective way of providing TA to Moldova.

RPM Tools and Materials Disseminated

During the course of the project, a number of RPM and MSH tools were disseminated. RPM was able to adapt for use in Moldova tools that had been developed for use in Russia, i.e., the *Manual for the Development and Maintenance of Hospital Drug Formularies* and *Guidelines for Implementing Drug Utilization Review in Hospitals*. See Annex III for a list of key RPM materials disseminated in Moldova.

To further assist with formulary list development and promote rational drug use, USP and MSH provided sets of five Russian-language volumes of USP dispensing information (DI) to representatives of hospitals in rural Moldova that participated in the Formulary Systems Implementation Workshop. Copies of USP DI were also given to hospitals in Chisinau; to representatives of the MOH, the NIP, and the Medical University; and to the DRUGS association. In all, 40 sets of five volumes of USP DI were distributed to these institutions.

Russian-language translations of articles from *The Medical Letter* on choice of antibacterials, antibiotic prophylaxis, and surgery and management of tuberculosis (TB) were distributed to participants at the workshops and pharmacology lectures. These were extremely well received as there is a marked lack of current information on pharmaceutical agents in Moldova, largely because the cost of medical journals and textbooks is prohibitive. Copies of WHO's *Essential Drugs List* were also widely distributed.

Collaboration with USAID-Funded Organizations

MSH collaborated with USP on two activities in Moldova. USP made a presentation on the use of unbiased information in formulary development during the Formulary Systems Implementation Workshop in April 1999. MSH facilitated the sessions on formulary development in a drug information conference held by USP and DRUGS in June 1999.

USP also assisted RPM-Moldova by partially funding the 200 Russian language volumes of USP DI that were disseminated in Moldova.

RPM Information Dissemination

Moldova is a small country and information is spread easily by television and radio. RPM-Moldova reached a wide audience through television interviews in October 1998 and January 1999 and through radio interviews in October 1998, January 1999, and April 1999.

Additional Activities

RPM met with members of the National Formulary Committee in April 1999, including Deputy Ministers of Health Dr. Vladimir Hotineanu, Dr. Valentina Buliga, Dr. Boris Parii, Dr. Alexandru Voloc, and Dr. Nicolae Frunze. Topics discussed included—

- The National Formulary as it relates to the regional and hospital formularies
- Need for assistance in publishing a National Formulary Manual
- Need for technical assistance in developing standard treatment guidelines (STGs), as required by the government

(See Annex XI for a list of the members of the National Formulary Committee and Annex XII for a list of district formulary committee chairmen.)

Several members of the National Formulary Committee were representatives of the Ministry of Health, and other issues of interest to the MOH discussed during the meeting were—

- MOH need for technical assistance in developing a system of hospital accreditation
- New MOH order for state pharmacies that will allow cost recovery through the sale of pharmaceuticals for profit
- Continuing increase in the number of cases of TB, the lack of anti-TB drugs, and the lack of funds to implement the national TB program
- High infant mortality rate in Moldova

Accomplishments

The accomplishments of MSH/RPM-Moldova include the following:

1. RPM initiated policy options dialogue that facilitated the acceptance of the national formulary system that the MOH was trying to implement by health care officials from facilities throughout Moldova. This acceptance was accomplished through the Policy Options Workshop that allowed health care workers who were not initially involved in decision making to take ownership in the formulary system implementation process.

2. RPM and hospital counterparts developed formulary lists, based on local morbidity and the cost-effectiveness of the drugs, at three demonstration sites. Drugs of questionable efficacy and duplicate drugs were removed from use.

3. Funds previously spent on nonessential drugs, or drugs of no or questionable efficacy, were reallocated to buy vital and essential drugs.

    - Comrat RMC projected a cost savings of approximately US$70,000 on drugs procured in 1999 compared with the cost of drugs procured in 1998.

- Stefan-Voda RMC estimated a savings of 31 percent of drugs allocated for procurement by eliminating nonessential drugs from the list of drugs procured.

4. The City Hospital No. 1 formulary list, developed with RPM assistance, was accepted by the Medical Council of Moldova and will become the official hospital formulary list.

5. The Formulary Committee of City Hospital No. 1 used RPM materials to develop STGs for a minimal level of care at the hospital.

Lessons Learned

- A forum for policy decisions, such as the Policy Options Workshop and the Formulary Systems Implementation Workshop, that brings government officials and health care professionals together and facilitates cooperation at the central and district level by creating stakeholders at those levels was useful in Moldova.

- The use of regional experts was a cost-effective way of promoting rational pharmaceutical management and formulary system development. The regional experts related well with counterparts due to similarities in their health care systems and in their economic constraints.

- The lack of availability of drugs is a problem in Moldova because the government is unable to provide facilities with the funds budgeted for pharmaceuticals. Hospitals are only purchasing a few pharmaceuticals, so the implementation of drug management systems appears futile to many health professionals.

- Despite economic constraints, development of formulary lists allows the most effective use of scarce resources by enabling decision makers to reallocate resources slated to buy nonessential drugs to the purchase of vital and essential drugs.

- Access to reliable sources of unbiased drug information is essential to drug interventions. Working with partners such as USP facilitates information dissemination and acceptance of changes in methods of drug management.

- Additional training in drug selection and procurement at the district and national levels is needed.

- The MOH realizes that it does not have the resources to combat TB and drug-resistant TB and it is actively looking for assistance from international donors to implement modern methods of diagnosis and treatment. The National TB Program is in keeping with USAID's strategic objective to slow the emergence of infectious diseases.

Likely Needs after the End of the Project

National-Level Needs

The lack of availability of drugs remains a problem because the government is unable to provide facilities with the funds budgeted for pharmaceuticals. Hospitals are only purchasing a few pharmaceuticals so the implementation of drug management systems appears futile to many health professionals. Future technical assistance, however, could be focused on the further training of health professionals in clinical pharmacology and in principles of rational drug use, training in quantification and procurement of pharmaceuticals for national programs such as oncology and diabetes, assistance with development of standard treatment guidelines, and the training of community pharmacists in the management of private pharmacies.

District-Level Needs

Given the restructuring and decentralization of the health sector, the need for training in drug management at the district level will increase. Technical assistance will be needed in the following areas:

- Development of local formulary lists or harmonization of formulary lists with modern treatment standards
- Further utilization of ABC/VEN analysis as a tool for prioritizing drug selection
- Training in quantification and procurement at the district level
- Training in drug use evaluation and adverse drug reaction monitoring
- Development of standard treatment guidelines

Current Situation with TB

The MOH identified TB as a major public health problem and implemented a national TB control program in 1999. MOH statistics show that the incidence of TB increased 47.3 percent between 1990 and 1998. In 1998 the incidence of TB in Moldova was 75.9/10,000 population compared with an average incidence in Europe of 34.6/10,000. The incidence of TB in prisons is 48 times greater than that of the general population, with 14.9 percent of cases in 1998 and 9 percent of cases in 1999, diagnosed in prisons. In 1999, 12.6 percent of patients were assessed as having multidrug-resistant TB.

The Institute of Pulmonology, a governmental organization, is responsible for implementing the national TB program. The objectives of this institute include—

- Development of standard guidelines for short courses of treatment of TB
- Improved detection, diagnosis, and treatment of patients with TB
- Early detection of TB
- Use of the Directly Observed Treatment, Short-course (DOTS)
- Improved training of doctors in the diagnosis and treatment of TB

The goals of the national TB program are to—

- Successfully treat at least 85 percent of new cases of pulmonary TB positive on microscopic examination of sputum during 1999–2000
- Improve early diagnosis of TB patients using microscopic examination of sputum
- Introduce and implement the WHO DOTS strategy at the national level
- Improve the system of monitoring and evaluating the national TB program

Planned activities include—

- Training medical staff at the national, regional, and hospital level in the diagnosis and treatment of TB
- Improving laboratory services so microscopy and culture of sputum samples can be performed
- Training laboratory personnel to test organisms for sensitivity to anti-TB drugs
- Upgrading radiology apparatus needed to monitor TB patients and screen individuals at risk

The estimated cost of the 1999 MOH program is 30,000,000 Lei (US$3,000,000). However, only US$1,448,300 is available from the government of Moldova for this project. The MOH is therefore seeking financial assistance from international donor agencies in order to implement this program. The Moldova national TB program is a comprehensive program that includes internationally accepted methods of diagnosis and treatment of TB. Successful implementation of the program should decrease the incidence of TB and drug-resistant TB, and the program could serve as a model for other Newly Independent States.

A major component of this program is drug treatment. The MOH would therefore benefit from future assistance in the selection, quantification, procurement, and use of anti-TB drugs.

Annex I. Key Activities of RPM-Moldova, by Mode of Implementation

A. Reconnaissance Visit

October 24–28, 1998: A reconnaissance visit was made to Moldova to provide information to USAID and other interested parties on the types of assistance that could be provided through the RPM Project and to allow RPM to get local perspectives on pharmaceutical sector problems. The drug information center DRUGS was chosen as RPM-Moldova's main local counterpart.

B. Policy Options Workshop

January 18–20, 1999: A Policy Options Workshop was held in Chisinau, Moldova, for 36 officials and specialists from throughout Moldova. This resulted in consensus among the MOH, DRUGS, the National Institute of Pharmacy, and health professionals that the MOH would continue with implementing a National Formulary System in Moldova.

C. Formulary Systems Implementation Workshop

April 28–30, 1999: A Formulary Systems Implementation Workshop was held in Chisinau for 40 officials and specialists from throughout Moldova.

D. Direct Technical Assistance

January 1999: RPM provided direct TA to City Hospital No.1 in Chisinau, the RMC in Stefan-Voda, and the RMC in Comrat. As a result, City Hospital No. 1 and RMC Stefan-Voda developed formulary lists.

April 1999: RPM provided direct TA to City Hospital No. 1 and RMC Stefan-Voda to assist with ABC/VEN analysis of their formulary lists. As a result, their formulary lists were further revised. Comrat RMC has since completed its formulary list and ABC/VEN analysis is in progress.

E. Pharmacology Lectures

January 1999: RPM arranged lectures in clinical pharmacology for 24 participants from Chisinau and the rural areas of Moldova. Other topics covered were Drug Use Evaluation, Pharmaco-economics and the Application of Decision Analysis Techniques, Current Treatment of Tuberculosis, and Curriculum Changes Made at Ryazan University to teach medicine and pharmacy students about formulary systems.

Annex II. Documents Obtained

The following is a list of the main documents obtained by RPM while implementing the project in Moldova:

1. Copy of the National Formulary List
2. Copy of the National Drug Policy, 1997
3. Copy of the Law on Drugs, 1997
4. Law on Pharmaceutical Activity, 1993
5. List of Drugs Registered in Moldova, 1998
6. Copy of the National TB Program
7. Copy of the Order allowing state pharmacies to sell drugs at a profit
8. Common Country Assessment for the Republic of Moldova, WHO, 1997
9. *Perinatology Bulletin*, 1998 (published with the aid of UNICEF)
10. *Bulletin of Obstetrics*, Gynaecology and Pediatrics, 1998 (published with the aid of UNICEF)
11. Publications of the Information Pharmacological.Association DRUGS
    - *Drug Use in the NIS: Why and How Drugs Should Be Used Rationally*
    - *Special Issue: Presentation of the Drug Information Center DRUGS*
    - *Who Can Solve the Problem of Adverse Drug Reaction Reporting?*

Annex III. RPM-Related Publications and Key Materials Disseminated in Moldova

Callender, D. *The Diagnosis and Treatment of Tuberculosis in Five Russian Hospitals.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1998.

Management Sciences for Health. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.* Boston, MA: MSH, 1997.

Moore, T. M, A. Bykov, A. V. Savelli, and A. Zagorski. *Guidelines for Implementing Drug Utilization Review in Hospitals.* Arlington, VA: Rational Pharmaceutical Management Project/ Management Sciences for Health, 1997.

Savelli, A. V., H. O. Schwartz, A. Zagorski, and A. Bykov. *Manual for the Development and Maintenance of Hospital Drug Formulary Systems.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, February, 1997.

Zagorski, A. *Availability and Procurement Methods of First-Line Tuberculosis Drugs in Novgorod, Pskov, Ryazan, and Yaroslav Oblasts.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1998.

Annex IV. Formulary List of Stefan-Voda Regional Medical Center, May 1999

Number	Classification (VEN)	Preparation	Presentation
1	V	Adrenaline, 0.1%	Ampoule
2	V	Albumin, 10%, 100 ml	Vial
3	N	Natrium Albucide, 30%	Vial
4	N	Alvesin, 500 ml	Vial
5	N	Aminasin, 2.5%	Ampoule
6	V	Aminocaproic Acid, 5%	Vial
7	V	Ampicillin, 0.5 g	Vial
8	E	Analgin, 50%	Ampoule
9	E	Aspirin, 0.5%	Tablets
10	V	Atrpine, 0.01% solution	Ampoule
11	E	Baralgin, 5 ml	Ampoule
12	N	Validol, 0.06g	Tablets
13	V	Verapamil, 1 ml	Ampoule
14	N	Hemodes, 400 ml	Vial
15	V	Gentamicin, 80 mg	Ampoule
16	V	Heparin, 5 ml	Ampoule
17	E	Glucose, 40%	Ampoule
18	N	Hordoks, 100,000 units	Ampoule
19	V	Dexamethasone, 4 mg	Ampoule
20	V	Diazepam, 0.5%	Ampoule
21	N	Diabazol, 1%	Ampoule
22	N	Digistin	Tablets
23	V	Digoxin, 1 ml	Ampoule
24	N	Dimedrol, 1%	Ampoule
25	V	Ditilin, 2%	Ampoule
26	V	Droperidol, 5 ml	Ampoule
27	V	Insulin	Ampoule
28	V	Insulin	Ampoule
29	V	Insulin	Ampoule
30	V	Calipsol, 10 ml	Vial
31	E	Potassium Chloride, 4%	Ampoule
32	E	Calcium Gluconate, 10%	Ampoule
33	E	Calcium Chloride, 10%	Ampoule
34	N	Captopril	Tablets
35	N	Clofelin	Tablets
36	V	Corglucone	Ampoule
37	E	Lasix, 1%	Ampoule
38	N	Lidocaine, 2%	Ampoule
39	V	Lincomycin, 30%	Ampoule
40	N	Magnesium Sulphate 25%	Ampoule
41	V	Mesaton, 1%	Ampoule
42	E	Metrogil, 100 ml	Vial
43	V	Morphine, 1%	Ampoule
44	E	Natrium Hydrocarbonate	Vial

Annex IV. Formulary List of Stefan-Voda Regional Medical Center (cont'd.)

Number	Classification (VEN)	Preparation	Presentation
45	E	Natrium Oxybuterat, 20%	Ampoule
46	N	Nifidilin	Tablets
47	N	Novocaine, 0.5%	Ampoule
48	N	No-Spa, 2 ml	Ampoule
49	V	Oxytocin, 1 ml	Ampoule
50	E	Panangin, 10 ml	Ampoule
51	N	Papaverine, 2%	Ampoule
52	N	Paracetamol	Tablets
53	V	Penicillin, 1 ml units	Vial
54	V	Pentazacyl, 1 ml	Ampoule
55	E	Pentamine, 5%	Ampoule
56	N	Hydrogen Peroxide, 3%	Vial
57	E	Platifillin, 0.2%	Ampoule
58	V	Polyglucine, 400 ml	Vial
59	V	Prednisolone, 30 mg	Ampoule
60	E	Proserin, 0.05%	Ampoule
61	V	Promedol, 2%	Ampoule
62	N	Iodium Solution, 5%	Vial
63	V	Reopolyglugin, 400 ml	Vial
64	N	Riboxine, 2%	Ampoule
65	E	Sinestrol, 1 ml	Ampoule
66	N	Spirinlactone	Tablets
67	N	Ethyl Alcohol, 96%	
68	V	Strofantin-K	Ampoule
69	E	Antibotulinic serum kit	
70	E	Antigangrenouse serum kit	
71	V	Tetanus serum, kit	
72	V	Tetracycline	Tablets
73	V	Thiopental, 0.5 g	Vial
74	N	Trental, 5 ml	Ampoule
75	V	Phentanil, 10 ml	Ampoule
76	E	Finlepsin, 0.2 g	Tablets
77	E	Furosemide	Tablets
78	N	Ednit	Tablets
79	V	Etamsilat, 12.5%	Ampoule
80	V	Euphillin, 2.4%	Ampoule

Annex V. Results of ABC/VEN Analysis of Formulary List from Stefan-Voda

Presented at Formulary Systems Implementation Workshop, April 1999

Group A Drugs

VEN	Drug	Cost/ # Units/(Lei)	# Units/ Month	Cost/Year ($US)	Percentage	Cumulative Percentage
V	Insulin lente	60	200	1200	19.89%	20%
V	Finplepsin	62	100	620	10.28%	30%
V	Insulin	45	100	450	7.46%	38%
N	Nootropill	9	400	360	5.97%	44%
V	Penicillin	1.5	2000	300	4.97%	49%
V	Heparin	13	200	260	4.31%	53%
V	Albumin	200	10	200	3.32%	56%
N	96% alcohol	10	200	200	3.32%	60%
V	Ampicillin, 500mg	3	500	150	2.49%	62%
V	Calipsol	15	100	150	2.49%	65%
N	Hemodes	13	100	130	2.16%	67%
V	Gentamicin	1.2	1000	120	1.99%	69%
V	Polyglucine	22	50	110	1.82%	71 %
V	Morphine	5	200	100	1.66%	72%
V	Reopoly-glucine	20	50	100	1.66%	74%
E	Ca Chloride	2	500	100	1.66%	76%
V	Lincomycin	1.8	500	90	1.49%	77%
V	Amino-caproic acid	7.5	100	75	1.24%	78%
N	Novocaine	0.7	1000	70	1.16%	79%
N	Mg Sulphate	1.3	500	65	1.08%	81%

Annex VI. Formulary List of Comrat Regional Medical Center, May 1999

No.	Preparation	Dosage	Presentation
1	Cordaron	0.2	Tablets
2	Lidocaine	2.0	Ampoule
3	Verapamil	0.04	Tablets
4	Nifedipine	0.1	Tablets
5	Nitroglycerine	0.0005	Tablets
6	Nitrosorbide	0.1	Tablets
7	Propranolol	0.04	Tablets
8	Cavinton	0.05% -2.0	Ampoule
9	Tsinarisin	0.025	Tablets
10	Captopril	0.25	Tablets
11	Dibasol	0.5-1.0%	Ampoule
12	Pentamin	1.0	Ampoule
13	Papaverine	2%-2.0	Ampoule
14	No-Spa	2.0	Ampoule
15	Euphyllin	2.4%-5.0	Ampoule
16	Diroxin	0.00024%-1.0	Ampoule
17	Strofantin	0.0005%-1.0	Ampoule
18	Furosemide	1 %-2.0	Ampoule
19	Furosemide		Tablets
20	Triampur		Tablets
21	Morphine Hydrochloride	1%-1.0	Ampoule
22	Promedol	2%-1.0	Ampoule
23	Pentanil	0.005%-10.0 #50	Ampoule
24	Analgin	50%- 1.0	Ampoule
25	Baralgin	0.25	Tablets
26	Diclofenac	3.0	Ampoule
27	Methoclorpramid	2.0	Ampoule
28	Indomethacin	0.25	Tablets
29	Nystatin	0.5	Tablets
30	Diphenin		Tablets
31	Finlepsin	0.2	Tablets
32	Phenobarbital	0.1	Tablets
33	Cordiamin	0.25%-2.0	Ampoule
34	Diazepam	0.5%-2.0	Ampoule
35	Aminazin	0.025%-1.0	Ampoule
36	Droperidol	0.25%-2.0	Ampoule
37	Calipsol	0.002%-5.0	Ampoule
38	Natrium Thiopental	0.001	Vial
39	Novocaine	0.001	Ampoule
40	Pyrocetam	10.0	Ampoule
41	Dimedrol	20 % -5.0	Ampoule
42	Tavegil	2%-1.0	Ampoule
43	Pentoxiphilli	2%-5.0	Ampoule
44	Acetylsalicylic acid	0.5	Tablets

Annex VI. Formulary List of Comrat Regional Medical Center (cont'd.)

No.	Preparation	Dosage	Presentation
45	Heparin	5000 units	Vial
46	Phenillin	0.03	Tablets
47	Allohol		Tablets
48	Mukaltin	0.05	Tablets
49	Atropine	0.1 %-1.0	Ampoule
50	Proserin	0.05%-1.0	Ampoule
51	Gumisel	2.0	Ampoule
52	Aloe extraction	1.0	Ampoule
53	Pancreatine	0.25	Tablets
54	Contrical	10,000 units	Vial
55	Thiamin Chloride	2.5%-1.0	Ampoule
56	Pyridoxine	5%-1.0	Ampoule
57	Tocoferol Acetate	1.0	Ampoule
58	Cocarboxilase	50 mg	Ampoule
59	Nicotinic acid	1.0	Ampoule
60	Lipoid acid	0.5%-2.0	Ampoule
61	Ascorbic acid	5%-2.0	Ampoule
62	Vicasol	1 %-1.0	Ampoule
63	Natrium Etamsinate	12.5 %-2.0	Ampoule
64	Protamine Sulfate	1 %-5.0	Vial
65	Calcium Chloride	10%-5.0	Ampoule
66	Aminocaproic acid	100.0	Vial
67	Reopolyglucine	400.0	Vial
68	Gemodes	400.0	Vial
69	Albumin	200.0	Vial
70	Natrium Chloride	Kg	Powder
71	Potassium Chloride	Kg	Powder
72	Natrium Bicarbonate	Kg	Powder
73	Furacillin	Kg	Powder
74	Benzyl penicillin	1.0	Vial
75	Gentamicin	4%-2.0	Ampoule
76	Doxacilline Hydrochloride	0.11	Pellet
77	Cefazolin	1.0	Vial
78	Metrogyl	100.0	Vial
79	Streptomycin	1.0	Vial
80	Bactrim	480.0	Tablets
81	Furazolidon	0.1	Tablets
82	Nitroxolin	0.05	Tablets
83	Metronidazole	0.25	Tablets
84	Dexamethasone	0.004	Ampoule
85	Prednisolone	0.025	Ampoule
86	Oxytocin	1.0	Ampoule
87	Pituitrin	1.0	Ampoule
88	Insulin actrapid		Vial
89	Insulin monotard.		Vial
90	Adrenaline Hydrochloride	0.1%-1.0	Ampoule

Annex VII. Policy Options Workshop, Agenda

Day 1	January 18	Time
	Opening Ceremony: D. Callender (MSH), Dr. V. Hotineanu, (Deputy MOH, Chairman, National Formulary Committee) Objectives of Workshop, D. Callender	10:00-10:45
	Options in Formulary Systems Implementation, D. Callender	10:45-11:15
	Coffee Break	11:15-11:30
	The Current Situation in the Health Sector in Moldova, Dr. V. Hotineanu	*11:30-11:45*
	Morbidity Patterns in Children in Moldova, Professor P. Moganianu (Medical University)	11:45-12:15
	The Role of the Pharmacist in Formulary System Development, Professor Procopischin (Medical University)	12:15-13:00
	Lunch	13:00-14:00
	Drug Selection/Formulary Development, D. Callender	14:00-15:00
	Coffee Break	15:00-15:15
	Drug Use Evaluation, E. Armstrong (MSH)	15:15-16:15
Day 2	**January 19**	**Time**
	Rational Drug Use, E. Armstrong	10:00-10:45
	The Ryazan Experience in Formulary System Implementation: Curriculum Changes Made at Ryazan State University, M. Semenchenko (MSH)	10:45-11:30
	Coffee Break	11:30-12:45
	The Role of the Drug Information in Formulary System Development in Moldova, N. Cebotarenco (DRUGS)	12:45-13:00
	Lunch	13:00-16:00
	Work Group Sessions: Participants Discussion of Options for Formulary Development: Writing of Work Plans, D. Callender, E. Armstrong, N. Cebotarenco	14:00-16:00
Day 3	**January 20**	**Time**
	Presentation of Work Plans by Technical Areas: Technical Group Leaders. Moderator, D. Callender	10:00-10:45
	Coffee Break	10:45-11:15
	Closing Ceremonies, Presentation of Certificates: D. Callender, E. Armstrong, N. Cebotarenco	11:15-11:30

Annex VIII. Policy Options Workshop, Participants

	Name	Occupation
1	Talmazan Eugenia	National Institute of Pharmacy
2	Mogoreanu Petru	Medical University
3	Russu Oleg	Chief Republican Hospital
4	Neaga Maria	BIC
5	Russu Galina	BIC
6	Cetulean Maria Ilie	DF
7	Buzdugan Larisa	Chief Republican Hospital
8	Draguta Nelea	Medical University, Chisinau
9	Laticevski Valentina	COSMC
10	Beregoi Gheorghe	City Hospital #1
11	Lica Constantin	City Hospital #1
12	Razborsky Ludmila	Pharmacy, Speranta
13	Gherghelas Nadejda	City Hospital #3
14	Ciobanu Irina	Medical University, Chisinau
15	Bradu Liliana	Pharmacy #204
16	Morari Galina	Medical University, Chisinau
17	Merjan Vladimir	Department of Health, Comrat
18	Gheorghiev Ion	Department of Health Comrat
19	Damascanu Tatiana	Recional Medical Center, Comrat
20	Rusu Nicolai	Regional Medical Center, Singerei
21	Rosca Viorica	Regional Medical Center, Singerei
22	Scurchin Sergiu N.	Regional Medical Center, Stefan-Voda
23	Malache Mihail	Regional Medical Center, Stefan-Voda
24	Zadir Victor	Department of Health, Tiraspol
25	Litvinova Tatiana	Department of Health, Tiraspol
26	Popovici Vera	Regional Medical Center, Anenii-Noi
27	Vrabie Viorica	Regional Medical Center, Anenii-Noi
28	Marinov Ion	MOH, Basarabeasca
29	Hilitov Nicolai	DF Bender
30	Popa Mihai	Regional Medical Center, Glodeni
31	Cebotarenco Natalia	DRUGS
32	Peev Tatiana	DRUGS
33	Cebotarenco Sergiu	DRUGS
34	Postolaki Michail	DRUGS
35	Salaur Marina	DRUGS
36	Craciuc Iurii	Regional Medical Center Ungheni

Annex IX. Formulary Systems Implementation Workshop, Agenda

Day 1	April 28	Time
	Opening Remarks: D. Callender (MSH), N. Cebotarenco (DRUGS), K. Burimski (USP)	9:00-9:30
	Objectives of the Workshop, D. Callender	9:30-9:45
	Drug Formularies: A Step-by-Step Approach, C. Olson (MSH)	9:45-11:15
	Coffee Break	11:15-11:30
	ABC/VEN Analysis, M. Semenchenko (MSH)	11:30-13:00
	Lunch	13:00-14:00
	Presentation and discussion of ABC/VEN analyses of formulary lists from City Hospital #1 and Stefan-Voda, M. Semenchenko, D. Callender, Hospital staff Stefan-Voda and City Hospital No.1	14:00-15:45
Day 2	**April 29**	**Time**
	Formulary System—MOH Perspective, V. Buliga (MOH)	9:00-9:30
	Criteria for Selecting Cardiovascular Drugs for the Formulary, O. Karpov (MSH)	9:30-11:15
	Coffee Break	11:15-11:30
	Drug Use Review & Drug Use Evaluation, D. Callender	11:30-12:00
	Adverse Drug Reactions, C. Olson	12:00-12:30
	Criteria for Selecting Antibiotics for Formulary, O. Karpov	12:30-13:30
	Lunch	13:30-14:30
	Drug Information, K. Burimski, (USP)	14:30-15:30
	The Role of DICs in Formulary System Implementation in Moldova Small Group Activity, N. Cebotarenco	15:30-16:30
Day 3	**April 30**	**Time**
	Rational Drug Use, D. Callender	9:00-9:45
	Report of Procurement Workshop Kazakhstan, R. Siecas (Procurement Officer, MOH)	9:30-9:45
	Report on the Training of Clinical Pharmacists in Moldova, Professor V. Procopishin (Medical University)	9:45-10:15
	Drug Formulary Manual Development, M. Semenchenko	10:15-11:15
	Coffee Break	11:15-11:30
	Discussion Groups: Progress Made and Next Steps of Hospitals Represented at April Workshop Since January Policy Options Workshop, C. Olson, D. Callender, M. Semenchenko	11:30-13:30
	Closing Comments and Presentation of Certificates, D. Callender, C. Olson, N. Cebotarenco	13:00-14:00

Annex X. Formulary Systems Implementation Workshop, Participants

Name	Affiliation
Hotineanu Vladimir	MOH
Rita Seicas	MOH
Buliga Valentina	MOH
Foca Natalia	MOH
Vatamanu Eleonora	MOH
Matcovschi Constantin	National Institute of Pharmacy
Dubcenco Valeriu	National Institute of Pharmacy
Safta Vladimir	National Institute of Pharmacy
Valica Vladimir	National Institute of Pharmacy
Chetrari Tamara	National Institute of Pharmacy
Chiperi, Angela	National Institute of Pharmacy
Russu, Oleg	SCRC
Neaga Maria	BIC
Russsu Galina	BIC
Lica Constantin	SCM #1
Razborsky, Ludmila	Farmacie Speranta
Laticevski. Valentina	Comrat Regional Medical Center
Malanco, Sergiu	ComratRegional MedicalCenter
Cirlig Sergiu	IO
Gheorghiev Ilia	Departmentof Health, Comrat
Damascanu Tatiana	Denartment of Health Comrat
Mazurenco Tatiana	Department of Health, Comrat
Rusu Nicolai	Regional Medical Center, Singerei
Rosca Viorica	Regional Medical Center, Singerei
Calalb Ilie	Regional Medical Center, Stefan-Voda
Scurchin Sergiu N.	Regional Medical Center, Stefan-Voda
Dereza Anatol	Regional Medical Center, Stefan-Voda
Popovici Vera	Regional Medical Center, Anenii-Noi
Vrabie Viorica	Regional Medical Center, Anenii-Noi
Marinov Ion	Regional Medical Center, Basarabeasca
Procopisin Vasilii	Medical University, Chisinau
Botnaru Victor	Medical University, Chisinau
Mogoreanu Petru	Medical University, Chisinau
Draguta Nelea	Medical University, Chisinau
Adauji Stela	Medical University, Chisinau
Buruiana Raisa	Medical University, Chisinau
Rosca Ludrnila	Medical University, Chisinau
Gaiduchevici Natalia	Medical University, Chisinau
Lupascu Ghenadii	Medical University, Chisinau
Sutula Elena	SMPU, Chisinau
Peev Tatiana	DRUGS
Postolaki Michail	DRUGS
Cebotarenco Sergiu	DRUGS

Annex XI. Members of the National Formulary Committee of Moldova

	Name	Position
1	Bivol, Grigore	Chief Therapist, MOH; Chair of Family Doctors; Assistant Professor Medical University
2	Boris, Parii	Director, National Institute of Pharmacology
3	Botnaru, Victor	Head, Chair of Internal Diseases, Medical University
4	Brumarei, Mihai	Assistant Professor, Chair of Organization and Economics and Pharmacology, Medical University
5	Buliga, Valentina	Head, Directorate for Pharmaceuticals and Medical Equipment, MOH
6	Fripu, Valentin	Chief Obstetrician, MOH; Doctor of Medicine
7	Frunze, Nicolae	Head, Chief Directorate for Medical Assistance, Technology, and Standards, MOH
8	Garmas, Vladimir	
9	Gherec, Valeriu	Chief Reanimatologist, MOH; Chair, Anesthesiology and Reanimatology, Medical University
10	Ghicavi, Victor	Chair of Pharmacology, Medical University; Vice-Chairman, Formulary Committee
11	Hotineanu, Vladimir	Vice-Minister, Chairman, Formulary Committee
12	Maloman, Eugen	Chief Surgeon, MOH, Professor
13	Safta, Vladimir	
14	Seicas, Rita	Chief Procurement Officer, MOH; Secretary, Formulary Committee
15	Vatamanu, Eleonara	Cardiologist, Doctor of Medicine, Head of Clinic of Cardiac Deficiencies
16	Voloc, Alexandru	Chief Pediatrician, MOH

Annex XII. List of Chairmen of District Formulary Committees

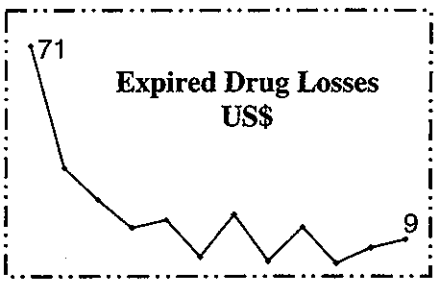
	District	Chairman
1	Balt	Cugal, G.
2	Briceni	Moldovan, B.
3	Cahul	Spinu, B.
4	Cainari	Cubja, P.
5	Calaras	Lupu, N.
6	Cornrat	Railean, N.
7	Criuleni	Clius, A.
8	Cuaseni	Bucuci, T.
9	Donduseni	Goria, V.
10	Edinet	Antoci, V.
11	Falesti	Munteanu E.
12	Glodeni	Surduleac, V.
13	Hincesti	Vasilu, St.
14	Nisporen	Gladun, V.
15	Rascini	Tabarti, V.
16	Rezina	Florea, M.
17	Singerei	Rusu, N.
18	Soroca	Buzurniuc, S.
19	Stefan-Voda	Malaelei, M.
20	Straseni	Topor, J.
21	Telenesti	Bulat, G.
22	Ungheni	Crasiuc, Y.

Mozambique

Executive Summary

This is the closing report for the U.S. Agency for International Development (USAID)-funded program in Mozambique, the global Rational Pharmaceutical Management (RPM) Project ending June 30, 2000. This report shows results of the various program activities, which evolved from an initial pharmaceutical sector assessment in 1993, when poor drug management skills of health professionals at central and provincial levels were identified as an important limiting factor for improving the drug-supply system.

Strengthening capacity in the districts of Mozambique's provinces was a major area of focus for the RPM program and has led to significant improvement in drug management. For example, since RPM began its technical and financial support of district medical and pharmacy directors in 1998, the value of drug losses due to expiration dating has fallen an average of 87% (from US$71to US$9) in reporting districts. In fact, 39% of the 57 district facilities recently reporting showed *zero* loss of drugs due to expiration. Pharmacy managers are understanding that monitoring a drug's expiration date and comparing it with average monthly consumption data will allow the redistribution of unneeded quantities of drugs to health facilities that need them and can use them before they expire.



At the end of the project RPM has fully implemented drug management activities in six of Mozambique's ten provinces, with partial implementation in two other provinces. By the time RPM support ends, a total of 118 districts and 137 health facilities throughout the country will have developed drug management programs and ongoing supervision.

As part of program support, RPM provided financial assistance for drug management activities using a decentralized approach. Funds were provided directly to provincial medical and pharmacy directors who managed funds, filed expense reports with RPM, and gained valuable financial management experience in the health system's decentralizing environment.

Program activities actually began with collaboration with the Mozambique Ministry of Health (MOH) Pharmacy Department in 1995. RPM developed training materials, adapted them to Mozambique policy, and with a core of local experts trained 162 medical and pharmacy personnel through a series of national, regional, and provincial training courses from 1995 to 1997. Course participants became leaders of the CPS (capacity building, planning, supervision) strategy later employed for capacitating staffs of the districts.

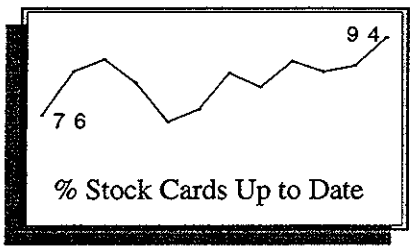
BASIC AREAS
Stock Management
Inventory Control
Drug Distribution
Information System
Rational Drug Use

In 1998, RPM conducted a study to test the original 162 participants in five basic areas of drug management. With an average score of 79% (ranging from 73% to

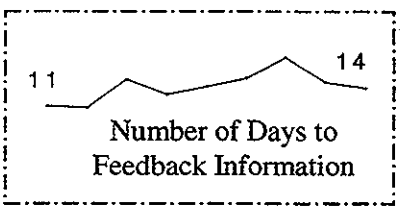
88%) for all five areas combined, course participants demonstrated retention of a working knowledge of basic procedures, whether they took the courses in 1995, 1996, or 1997.

Using provincial directors trained in RPM courses as facilitators, CPS implementation at the district level began in July 1998, and led district facility staffs in eight provinces to adopt management tools for improving their work. The supervisory component of CPS provides key indicators to supervisors for pointing out weak management areas. Armed with this information, supervisors are able to target continuing education for local managers.

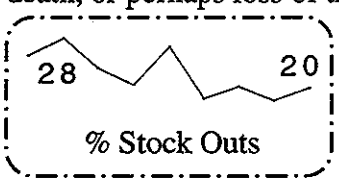
One of the drug management indicators, *% of Stock Cards Up to Date*, shows improvement from an average of 76%, when facilities began to monitor this indicator, to the most recent 94%. Generally it is accepted best practice to manage drugs through the use of individual stock cards, to record movement of drugs into and out of the health facility. Now that more personnel are using the cards, this is a good indicator they are also better controlling inventories.



Having a management information system that allows feedback of drug use data in a timely manner is a must for a health system to accurately quantify drug and supplies needs. The drug management indicator, *Elapsed Days to Send Consumption Data*, measures how frequently facility managers are complying with health system feedback time lines. According to policy, data should be sent by the 10th of the next month. As seen in the graph, reporting facilities are not complying with this requirement and in fact have worsened, with an increase to 14 days for feeding back consumption data to the warehouse compared with 11 days when first measured. Supervisors must monitor this activity much more closely and take measures to ensure that pharmacy directors comply with the procedure.



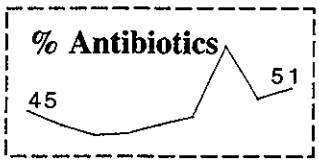
The indicator *% Stock Outs* measures a health facility's ability to have drugs and supplies available when ordered by the prescriber. Even when drugs are selected, ordered, and stored appropriately, if the correct ones are not available when the patient needs them, the pharmaceutical supply system has failed. The consequences of nontreatment because of unavailability of drugs could include any of the following: a worsening health condition, possible death, or perhaps loss of trust in the health system by the patient. In Mozambique, drugs are purchased centrally and distributed to provinces and subsequently to district facilities by a push system. This means that the central agency decides *which* and *how many* drugs and supplies ultimately reach health clinics. The push system makes efforts to improve drug availability by individual health centers more difficult. Even so, of the district health facilities reporting this indicator, there has been some improvement in the area of stock outs, which decreased from 28%, when the first measurement was taken, to 20% more recently.



Rational drug *use* (RDU) is one of the primary components of drug management and encompasses *use* by the prescriber when he or she prescribes a drug, *use* by the dispenser when

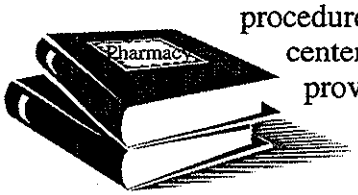
he or she dispenses the drug to the patient, and lastly, *use* by the patient. In Mozambique, the district health director, also a prescriber, must authorize drug requisitions. From the beginning, the RPM drug management strategy included the practice of joining the two professionals (prescriber and dispenser) in all activities. This approach has been well received and provides a forum to resolve drug supply issues.

One of the rational drug use indicators is the *% of Patients Prescribed Antibiotics*. This indicator draws attention to unecessary prescribing of antibiotics, which directly contributes to excessive cost, but could also contribute to development of antibiotic resistance, depending on how the antibiotics are prescribed. Initially there was an overall favorable decline in the districts in antibiotic prescribing practices, but later results show an increase to 51% from the original figure of 45%. The local medical directors in respective provinces must investigate the cause of the increases to see if they are justified. Mozambique has recently gone through periods of cholera epidemic, typhoons, and flooding, thus related health conditions and water-borne infections may justify the increased antibiotic prescribing.



Other indicators are being calculated by district facilities, both during supervisory visits and on demand, often monthly, by provincial supervisors. When RPM support is no longer available, it is expected that supervision will continue through monitoring of indicators. It is hoped that on-site supervisory visits will continue as well, but the poor financial situation of local governments may make this a big challenge. RPM has estimated that US$63,200 the first year and US$31,600 the second and subsequent years will be required to continue site visits.

Another significant activity took place in 1998 when RPM provided technical assistance to the MOH Pharmacy Department in drafting a *manual of pharmacy operations*. The draft manual contains logistics policies and procedures and various control forms to track the movement of drugs and supplies from central warehouse → provincial warehouse → health center or hospital → health post. In 1999, the procedures manual evolved into the *Normalized System of Drug Management*, and the MOH established procedures specific to four health facility types: health posts, health centers, hospitals, and provincial warehouses. The MOH trained provincial directors on the new system in 1999 and planned to expand training to district staffs in 2000, after which the Pharmacy Department expected to implement the new procedures.



To round out support in the various areas of the pharmaceutical sector, RPM collaborated with the Institute of Health Sciences in Maputo and the Eduardo Mondlane Medical School's research department, and conducted a study of the private pharmacy sector to assist the MOH in planning for health finance reform.

Drug management training materials used in RPM activities were adapted and included in the pharmacy technician curriculum at the Institute of Health Sciences. In 1999 the RPM program supported internships for 15 pharmacy technician students who needed the practicums for

graduation. The interns received hands-on experience in hospitals, health centers, and provincial warehouses, and completed joint projects on various topics of rational drug use.

At the Medical School's research department, RPM established a small grant in 1998–1999 to promote rational drug use. Approximately 80 students were trained in research methodology, prepared study proposals, collected and analyzed data, and presented findings and recommendations at a final conference. Students followed up their recommendations by meeting with respective departments of the Ministry of Health. One such recommendation was to improve the prescriber's skills in writing prescriptions, which resulted in a workshop sponsored by the Medical School and attended by various Ministry of Health physicians and other prescribers.

A private pharmacy study was conducted at the request of the MOH to show how much money actually flows through the private sector. Twelve pharmacies were surveyed and data including average monthly expenses on drug purchases, monthly operating costs, number of client visits, and drug spending by clients during one pharmacy visit were collected. Using these data, RPM calculated that private pharmacies make an average annual profit of 28%, which is similar to the gross profit figures of U.S. pharmacies (26% to 30%) as reported by the National Community Pharmacists Association. The MOH is reviewing the information provided by RPM along with health expenditure studies of the public and private sectors from other sources.

The United States Pharmacopoeia (USP) has a separate cooperative agreement under the RPM Project, and Management Sciences for Health (MSH) collaborated with USP in the area of drug information availability in Mozambique. USP provided drug monographs in the Portuguese language to participants of the provincial training courses mentioned above. During USP drug information seminars held in the country, MSH introduced national and provincial participants to hospital drug formulary and drug use review systems.

Pharmaceutical sector donors in Mozambique formed the "pooling" concept in 1998 to allow the MOH and provincial directorates of health to build management experience in purchasing pharmaceuticals for the entire health system with donated funds. The pooling committee established measurable targets to meet objectives of the MOH strategic plan in 1999. MSH began sharing results of RPM drug management activities with the donor committee at that time.

RPM/MSH encountered various challenges during program implementation in the provinces relative to the gradual decentralization policy established by the government. In essence, there was no formal decentralization plan, and provincial staffs often lacked skills, finances, and clear authority to make significant changes.

Drug management in Mozambique's health facilities has been strengthened by the capacity-building efforts described above. To sustain and improve the knowledge and skills learned during the program, RPM recommends that national and provincial health directors support ongoing continuing education with regular supervision and monitoring for pharmacy and medical directors in all districts.

Part of the drug management–strengthening program has been to teach facility managers how to quantify drugs and supplies needed for their facilities. RPM recommends that the Pharmacy Department begin to use these data to quantify drug needs for the whole country, since consumption data calculated in a systematic way are more reliable than distribution data, which is currently used to purchase drugs for Mozambique.

Finally, to kick off the use of consumption data for quantification, RPM suggests that a one-time national drug estimation activity be conducted in representative health facilities throughout the country, taking morbidity data and drug stock-out data into account to establish a baseline of needs.

Annex 1 contains a list of reference documents produced by RPM/MSH during the Mozambique program.

Acknowledgments

RPM would like to acknowledge the following persons for their support of the Mozambique activities, and to thank the many others who have contributed to the program. Although they are not listed by name, without the support of the medical and pharmacy directors of the following provinces, the RPM program would not have been successful.

Provinces

Cabo Delgado
Gaza
Inhambane
Maputo Province and City
Nampula
Niassa
Tete
Zambezia

Ministry of Health

Joaquim Durão	Director of Pharmacy Department
Chonguiça M. Chonguiça	Former Director of Pharmacy Department
Rathod K. Bachubai	Director of Essential Drugs
Benedito Chaque	Pharmacy Department
Isaura Possolo	Pharmacy Department
Clara Ferrão	Training Department

School of Medicine

Leopoldo da Costa	Research Department-FAIACS
Esperança Sevene	Staff
Alda Mariano	Staff

Maputo Central Hospital

Sam Patel	Director of Medical Department
Bachira Rugnate	Staff

Institute of Health Science in Maputo

Júlio Langa	Pedagogical Director
Sharadchandra C. Unewal	Former Director of Pharmacy Curriculum

UNICEF

Jonas Chambule	Health Coordinator
Valigy I. Valigy	Medical Consultant
Gertrudes J. Mehatine	Medical Consultant

USAID

Okey Nwanyanwu	Mozambique
Aurelio Gomes	Mozambique
Laura Slobey	Formerly Mozambique
Armand Utshudi	Formerly Mozambique
Anthony Boni	Cognizant Technical Officer-Washington
Susan Bacheller	Washington

DONORS

Isabel Soares	Swiss Cooperation
Joris Jurriens	Dutch Embassy
Ana Helena Azedo	Norwegian Embassy

MSH

Anthony Savelli	Director of global MSH/RPM project-Washington
Douglas Keene	Deputy Dir. of global MSH/RPM project-Washington
Elvira Beracochea	Former Dep. Dir. of MSH/RPM project-Washington
Jean Pierre N. Kasongo	Technical Advisor-Nampula Province
Sharadchandra C. Unewal	Technical consultant-Maputo
Juan P. Guevara	Medical/Pharmaceutical Consultant-Peru
Maria Miralles	Sr. Program Associate-Washington
Jean Pierre Sallet	Sr. Program Associate-South Africa
Guttorm Folkedal	Pharmaceutical Consultant-Norway
Jorge Tojais	Field office coordinator-Maputo
Mehreen Butt	Sr. Program Assistant-Washington

USP

Keith Johnson	Director of global USP/RPM project-Washington
Nancy Blum	Former manager of Mozambique Program-Washington
Lloyd Vetter	Manager of Mozambique Program-Washington

Acronyms

CPS	capacity building, planning, and supervision
FAIACS	Foundation for Applied Research, Medical Faculty, Maputo
ICSM	Health Sciences Institute in Maputo
INRUD	International Network of the Rational Use of Drugs
MOH	Ministry of Health
MSH	Management Sciences for Health
PO	Program Objective
RDU	rational drug use
RPM	Rational Pharmaceutical Management
SO	Strategic Objective
SWAP	sectorwide approach
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USP	United States Pharmacopoeia

Program Overview

At the request of the USAID Mission in Mozambique, RPM conducted a pharmaceutical sector assessment in 1993. Based on the findings, the Pharmaceutical Department of the MOH asked for assistance in strengthening capacity of pharmacy and medical staffs, both at the national and provincial levels, in the areas of drug management and rational drug use. Capacity in these areas had ebbed due to brain drain when Mozambique gained its independence from Portugal, followed by a 16-year civil war. USAID began funding the RPM program in Mozambique in 1995, with field support.

In collaboration with the MOH, RPM developed training materials and practical exercises in logistics management, and rational drug use, which incorporated MOH drug policy and procedures. RPM capacitated a group of national facilitators who began the training activities. By 1997, through collaborative financial support of RPM, UNICEF, and the Swiss Cooperation, 162 pharmacy and medical personnel were trained at central and provincial levels. RPM estimates that approximately $50,000 was leveraged from the donors for these training activities.

In 1998, using RPM's CPS tool, district staffs began implementation of basic drug management procedures. The tool includes monitoring indicators for ongoing supervision. By the end of the project, RPM had technically supported implementation of the CPS strategy in 8 of the country's 10 provinces, including approximately 118 districts and 137 health facilities.

As part of program support, RPM provided financial assistance for the capacity-building drug management activities using a decentralized approach. Funds were provided directly to provincial medical and pharmacy directors who managed funds, filed expense reports with RPM, and gained valuable financial management experience in the health system's decentralized environment.

Objectives

The RPM activities supported USAID's Strategic Objective (SO) 3: *increased use of key child health and nutrition interventions* and the Mozambique Mission's Program Objectives (PO) 3.1.3: *more health facilities with trained staff* and PO 3.3: *strengthened provincial management of MCH/FP service delivery.* The basic RPM program objectives were to—

- Capacitate a core of national trainers in drug logistics management and rational drug use
- Provide technical assistance to the MOH Pharmacy Department to harmonize pharmacy procedures nationwide
- Capacitate provincial pharmacy and medical directors in basic drug management techniques and to function as supervisors of district health facility staffs

- Support capacity building of district facility staffs, using RPM drug management CPS strategies
- Support supervisory visits by provincial supervisors to district health facilities
- Evaluate the new harmonized pharmacy procedures once implemented in the country

Implementation Strategy and Major Activities

RPM strategy for the Mozambique program included the following:

- Develop drug management and rational drug use training materials with adaptation to the Mozambique situation
- Capacitate a group of trainers
- Conduct training workshops for national and provincial staffs
- Adapt the CPS tool, originally developed by RPM in Ecuador, to the Mozambique situation
- Provide technical assistance to provincial directors for implementing the CPS drug management tool
- Provide financial support for training and supervision

Major activities included the following:

- One national drug management course
- Three regional drug management courses in northern, central, and southern geographical zones
- Two provincial drug management courses
- Technical assistance to harmonize national pharmacy procedures
- Technical assistance to implement the CPS drug management tool in eight provinces
- Financial assistance to support CPS supervision activities in eight provinces

Challenges Facing RPM Mozambique Implementation

As RPM was beginning to field-test the CPS tool for Mozambique in 1997, the pharmaceutical sector entered an independent audit, funded by sector donors. The audit was conducted to document the extent of drug diversion and graft that had permeated the entire MOH system. As a result, RPM was asked to delay all planned activities from October 1997 to February 1998. A new MOH Pharmacy Department director was appointed to clean up the drug diversion problem in September 1997. Other demands on this new counterpart caused further delay, but in May of 1998, RPM conducted the field test of the CPS tool in Gaza province.

From January to March 2000, Mozambique was inundated with heavy rains and cyclones. Approximately 1 million citizens were displaced from their homes, including health workers. Many health facilities were destroyed, and overland transportation routes were knocked out. The standing water caused an increase in the mosquito population, which worsened malaria, already endemic in the country. Unaffected health workers were mobilized to help with the disaster. Thus many of the directors and health workers involved in RPM activities had to divert their attention to these matters. RPM therefore was not able to fully implement the CPS drug management strategies in all 10 provinces of the country. By the end of the project, RPM had implemented CPS in eight provinces, partially in two of the provinces, but with no activity in two others.

Also because of the floods, the MOH could not implement the procedures outlined in the new *Normalized System of Drug Management* in the provinces and districts. For this reason RPM was unable to carry out an evaluation of the new procedures as planned.

Chronological Activity Timeline

RPM activities in Mozambique began in 1993 with a pharmaceutical sector assessment and ended in May 2000 with support of supervisory visits by provincial directors.

Table 1. Activity Timeline

Date		Activity
Dec	1993	Pharmaceutical Sector Assessment
Jun	1995	National drug management course in Maputo
Oct	1995	Central region drug management course in Chimoio
Jun	1996	Southern region drug management course in Namaacha
Sep	1996	Northern region drug management course in Chokas Mar
May	1997	Provincial drug management course in Gaza province
Sep	1997	Provincial drug management course in Zambezia province
May	1998	CPS drug management tool field tested in Gaza province
Sep	1998	CPS drug management strategy implemented in Niassa and Nampula provinces
Nov	1998	CPS drug management strategy implemented in Tete and Inhambane provinces
Dec	1998	Supervisory activities implemented in Niassa, Nampula, Tete, Inhambane
Jan	1999	Study of private pharmacy sector
Feb	1999	Study measuring course participant knowledge of basic drug management practices
Mar	1999	CPS drug management strategy implemented in Cabo Delgado province

Table 1. Activity Time Line (cont'd.)

Date		Activity
May	1999	Supervisory activities implemented in Cabo Delgado province
Sep	1999	CPS drug management strategy implemented in Maputo province and city
Oct	1999	CPS drug management strategy implemented in Gaza province
Nov	1999	CPS drug management strategy implemented in Zambezia province
Dec	1999	Supervisory activities implemented in Maputo province and city
Jan	2000	Questionnaires developed for evaluating new harmonized pharmacy procedures
Mar	2000	Supervisory activities implemented in Zambezia province
Jun	2000	Project closed

Program Accomplishments

Pharmaceutical Sector Assessment

The assessment was led by a team of five persons, two RPM international consultants and three local economists, and took place during the last quarter of 1993. Health facilities surveyed were located in the capital, Maputo, and in five provinces, representing northern, central, and southern regions of the country.

Although details of the assessment can be found in RPM's publication, *Ministry of Health of Mozambique, Mozambique Pharmaceutical Sector Assessment Final Report,* several important findings are mentioned here. (See Annex 1 for a listing of this and other documents produced during the RPM Mozambique program.)

Procurement capabilities of local staffs at the monopolistic MEDIMOC parastatal company were considered to be adequate. For example, only drugs listed on the National Formulary were purchased and the provincial medical stores obtained their drugs and supplies from the central stores. In addition, competitive tender was used for 91% of the purchases, and MEDIMOC was able to obtain prices equal to or better than the average international price 76% of the time.

However, inventory record-keeping practices were found to be problematic. The warehouse stock cards indicated that items in stock were on average 129% of the actual count. The records kept in the administrative offices, from which order quantities are calculated, were found to be on average 159% of the actual count.

A list of 21 tracer drugs, selected for study as essential drugs for health care delivery, were found to be available 67% of the time in central stores, 80% in provincial stores, and 59% in health centers and hospitals surveyed.

When comparing these and other drug use data with those of countries studied by the International Network for Rational Use of Drugs (INRUD), findings on drug utilization in Mozambique were mixed. For example, 52% of patients in Mozambique are prescribed antibiotics compared with 43% for INRUD countries studied. The average dispensing time of 13

seconds was much less in Mozambique than the average 59 seconds of countries included in the INRUD study. Patient knowledge of correct use of dispensed drugs was 53% in Mozambique compared with 64% in INRUD countries. On the other hand, Mozambique showed more favorable results than INRUD averages: for the percentage of patients receiving injectables (18% in Mozambique versus 25% for the INRUD average) and drugs prescribed by generic name (99% in Mozambique versus 67% for the INRUD average).

In light of the findings, and because of poorly trained personnel throughout the pharmacy sector, the MOH in Mozambique believed that RPM could best contribute to the country's objectives by providing training in drug logistics, from the top down. This led to the establishment of a national coordinating team composed of RPM, pharmacy personnel at the MOH and Institute of Health Sciences, and medical personnel at the School of Medicine. The team developed a strategy to train national, provincial, and district personnel in basic drug logistics management.

Drug Management

Training

The RPM and Ministry of Health coordinating team outlined a plan for training target personnel and developing the training materials. The team selected the *Managing Drug Supply Training Series* as the basis for the training materials. The materials were adapted to local policy and translated into the Portuguese language. The 16 drug management topics covered were—

- National Drug Policy
- Strategies of Drug Supply
- Managing Storerooms and Warehouses
- Inventory Concepts
- Stock Control
- Managing Inventory for Drug Acquisition
- Management Information System for Drug Supply Systems
- Distribution Strategies
- Drug Kit Distribution System
- Financing Drug Supply Systems
- Systematic Reduction in Drug Costs
- Rational Use of Drugs
- Problems with Irrational Drug Use
- How to Learn about Drug Use Problems
- Role of the Pharmacist in Promoting Rational Drug Use
- Strategies to Improve Use of Drugs

The program plan included a national course to build training capacity at the central level and three regional courses to build training capacity in the provinces. The national course was held in June 1995 in Maputo. The regional courses were held in central, southern, and northern

geographical zones: Chimoio in October 1995, Namaacha in June 1996, and Chokas Mar in September 1996, respectively.

The same training materials were used for two provincial courses to test their suitability for the health-facility level. The provincial courses were held in Xai-Xai, Gaza province, in May 1997, and Quelimane, Zambezia province, in September 1997. Due to lessons learned from the provincial courses, the formal course approach was discontinued because on-site practical training was thought to be more appropriate for applying basic management techniques to daily work activities for health facility personnel in the districts.

RPM conducted a study to measure knowledge of basic practices in drug management and rational drug use for the 162 participants of the six training courses mentioned above. The study questionnaire contained 22 questions in five skill areas: stock management, inventory control, distribution, management information system, and rational drug use. After local testing, the questionnaires were distributed to all 162 participants who work throughout the 10 provinces of the country. The questionnaires contained a cover page explaining the purpose of the study and instructions for completing the self-test questionnaire. Participants were not monitored and no restrictions were made concerning the use of reference materials while answering the questions. Responses were kept confidential by not requiring participant names on the questionnaires.

The study was conducted during the first quarter of 1999. Combining results of both prescribers and pharmacy personnel, average scores for the five areas studied were: 79% for stock management, 79% for inventory control, 88% for drug distribution, 78% for management information system, and 73% for rational drug use.

Table 2. Drug Management Course Participant Study

Participant Personnel	Stock Manage-ment	Inventory Control	Distribution	MIS	RDU	Average
	% Correct					
All (N=47)	79	79	88	78	73	79
Prescriber (N=10)	68	77	78	85	70	75
Pharmacy (N=37)	82	79	91	76	74	80

The average overall score of 79% (range 73% to 88%) demonstrated that course participants still have a working knowledge of drug management and rational use procedures regardless of when they participated in the courses.

Strengthening Capacity in the Districts

To build upon the expertise gained from the drug management courses, RPM chose to use the CPS strategy, first applied in Ecuador by the RPM Project. In collaboration with the MOH,

RPM adapted the tool and expanded it for the Mozambique environment to train district personnel in sound drug management techniques for the decentralized health-care setting. Personnel who had been trained in the national, regional, and provincial drug management courses learned the CPS techniques from RPM and actually put the CPS strategy into practice. The strategy involves setting up a supervisory team of pharmacy and medical administrators who use the CPS tool to prepare and conduct one-day drug management sessions for pharmacy and medical directors of warehouses, health centers, and hospitals. In Mozambique, teams were set up at the provincial level. The practical CPS tool consists of a manual with specific drug management information, instruction, checklists, reference tables, and indicators. See the Tools Development section of this report for further information.

Using CPS, pharmacy and medical staffs analyze their facility's problems, improve their problem-solving skills, and plan activities to implement identified solutions. The Mozambique CPS tool encompasses five modules that can be implemented in one or multiple sessions, depending on the local situation. The five drug management sessions are—

- Evaluating Your Storeroom
- Procurement of Drugs and Supplies
- How to Order Drugs and Supplies; Distribution Systems for Health Facilities
- Receiving Drugs and Supplies, Using Information Systems, and Comprehending Costs
- Rational Use of Drugs

As sessions are completed, pharmacy and warehouse managers plan their individual activities for the following month. Supervisors review plan implementation during follow-on site visits.

The CPS strategy emphasizes self-monitoring using indicators, but it is recommended that a member of a supervisory team visit the facilities at least monthly at the start of CPS implementation. This allows supervisors to continue capacity-building exercises, document improvements in drug management, and review problems in the facilities. As part of the strategy, a series of drug management tools permits local pharmacy personnel and warehouse managers to identify and analyze their operational problems.

The drug management and rational use indicators developed for Mozambique are—

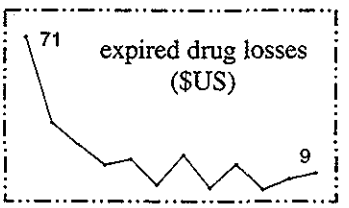
- The value of expired drugs and supplies during the last month
- Percentage of stock cards up to date
- Percentage of items that were out of stock at least once during the last month
- Elapsed time since drug order was placed and items were received
- Number of days elapsed before consumption data were sent to the warehouse
- Average number of drugs prescribed per patient visit
- Percentage of patients who were prescribed antibiotics
- Percentage of patients who were prescribed injectables
- Percentage of drugs prescribed with the drug code from the National Formulary

Since the indicators are designed to serve as a monitoring tool and be a simple activity that can be accomplished by local staffs, the sample size is small. For the first five indicators above,

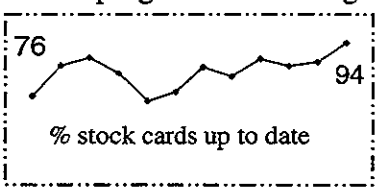
managers randomly choose 10 drugs that were received or dispensed in the last month. For the last four indicators, which are rational drug indicators, 30 prescriptions are chosen at random from the most recent ones filled in dispensing pharmacies.

RPM periodically collected data from provinces where CPS was being implemented. For the five drug management indicators the following results were obtained.

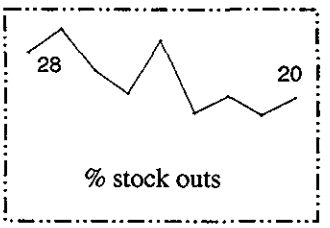
- The indicator, *value of losses due to drug expiration,* is important to monitor because of poor drug management habits of MOH personnel, a difficult economic crisis in the country, and donor insistence that the government share a larger cost of supplying drugs. Each monitoring period, staffs calculate the value of expired drugs in their health facilities for the past month. RPM periodically collected the data and averaged them to create this graph. Overall the loss has declined 87%, from ($US71 to $US9). Although the values are not great when measured in US$, they were considered significant in local currency at the district level.



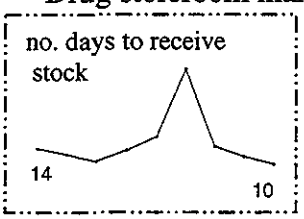
- Keeping individual drug stock cards up to date coupled with an inspection of in-stock drugs and supplies is a very basic way to monitor inventories, to ensure there are enough drugs and supplies, that they are not expired, and that they are protected from heat, light, and pests. In Mozambique, district health facilities have consistently improved their record-keeping practices.



- The *% stock outs* indicator measures the percentage of items that were out of stock the month before the monitoring activity took place. Obviously, without drugs available when the patient needs them, the supply system has failed. Notice that health facilities in Mozambique on average have decreased the percentage of out-of-stock drugs since 1998 when the CPS activities first began. This is quite likely due to improved record keeping and monitoring of lead time to receive drugs at the health facilities, and possibly due to improved levels of stock in the provincial warehouses.

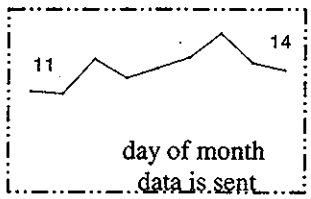


- Drug storeroom managers should know the amount of time it takes to receive drugs and supplies once they have placed an order. This indicator measures the number of days that have elapsed since an order was placed to the warehouse until it is received by the health facility. Since monitoring began, the average number of days needed to receive an order has declined 29% (14 > 10 days). Armed with these data and the average monthly consumption quantity for each item, managers can better maintain their inventories to avoid stock outs.



351

- Health facilities must prepare drug consumption data and send it to higher levels so procurement of the correct quantities of drugs and supplies can take place. The requirement in Mozambique is to send the data by the 10th of the next month. On average, facilities are not complying with this procedure, and steps must be taken to have drug managers comply as soon as possible. At present the procurement department uses quantities distributed to health facilities by the provincial warehouses for procurement, when they should be using consumption data supplied by health facilities. RPM expects this will begin once the provincial warehouses are computerized by the MOH, which could happen within a year.



RPM has found that in Mozambique, the CPS strategy provides a mechanism for long-term professional empowerment and hands-on practical implementation, and therefore will likely sustain itself long after the project has ended.

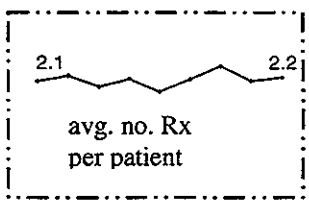
Rational Drug Use

At the beginning of the project, rational drug use was chosen as one of the key areas of focus, since the MOH had seen from early discussions with RPM the necessity of doing so. In fact, the MOH national drug policy drafted about that time included wording also supporting RDU.

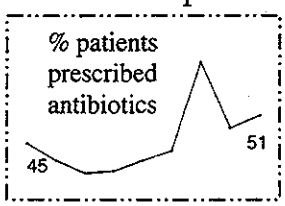
Thus, the initial drug management course training materials include several modules on RDU. The CPS tool that followed devotes one of the five practical sessions entirely to rational drug use. (See lists of course topics and CPS session topics in the section above.)

The rational drug use component of the CPS tool provides four RDU indicators for self- and supervisory monitoring. Since 1998 when CPS began, the RDU indicators demonstrated the following:

- The average number of drugs prescribed per patient has remained relatively stable since measurement began. The graph shows that prescribers are not practicing polypharmacy (overprescribing), which can potentially expose patients to unexpected side reactions and add unnecessary costs to drug treatment.



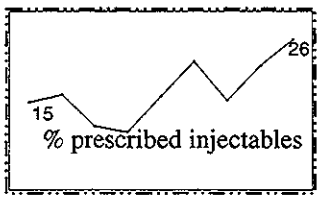
- Antibiotic prescribing has increased in Mozambique, possibly due to natural causes, since the country has experienced cholera and malaria epidemics and excessive flooding and cyclones during the last year. While there is no "standard" percentage of antibiotic usage for a health system, monitoring the percentage of antibiotics prescribed allows a health director to determine whether unprecedented rises in antibiotic use are justified. Otherwise,



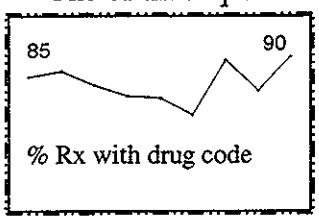
356

continuing education or other interventions could be employed to change the unwanted prescribing behavior.

- Like antibiotics, injectable drugs are overprescribed in many countries. In Mozambique, in spite of monitoring by supervisors, the percentage of patients prescribed injectables increased. This is quite likely because of the natural disasters described above. While there is also no "standard" percentage of injectables usage for a health system, monitoring this practice allows a health director to analyze whether unprecedented rises in injectable use are justified. Otherwise, continuing education or other interventions could be employed to change the unwanted prescribing behavior.



- One of the requirements of the National Health Service in Mozambique is to have prescribers write the drug code listed in the National Formulary on the prescription order. The code identifies the drug, drug strength, daily dose, and the type of health worker who is authorized to prescribe the drug. The code also allows the dispenser to verify the drug to be dispensed and to give proper instructions to the patient. Since implementation of CPS, there has been an increase in compliance with this procedure from 85% to 90%, contributing to rational drug use.



Student Training Support

To round out support of the pharmaceutical sector in Mozambique, RPM established programs with the Eduardo Mondlane Medical School and the Institute of Health Sciences in Maputo in 1998 and 1999, respectively. The programs introduced medical students to RDU study methodology and provided practice in developing proposals, collecting and analyzing data, and preparing a report of findings. Pharmacy technicians at the Institute of Health Sciences received support from RPM in the form of internships in health centers, hospitals, and warehouses, where students conducted studies and presented findings at the end of their internships.

Private Pharmacy Study

In 1997 the government of Mozambique passed a new drug law allowing the development of private pharmacies. Prior to that, "private" pharmacies consisted mainly of quasi-government pharmacies managed by the FARMAC association. The MOH is reviewing its options for reforming health finance, and it asked RPM to assess how much money actually flows through the young private sector.

Of the 80 private pharmacies in the country, RPM randomly selected 12 pharmacies, 6 privately owned and 6 FARMAC, and interviewed owners and clients using prepared questionnaires. Managers reported average monthly expenses on drug purchases of US$3,084, average monthly

operational costs of US$1,220, and average number of client visits of 1,300 per month. Clients reported spending an average of US$4.61 per visit. Using these data RPM calculated that private pharmacies make an average annual profit of 28%. The profit appears similar to the gross profit figures of U.S. pharmacies (26% to 30%) as reported by the National Community Pharmacists Association in 1997.

A total of 353 of the clients studied were prescribed drugs and 20% responded that they were unable to buy them for the following reasons: unavailable for purchase (49%), couldn't afford the price (36%), or decided not to buy for other reasons (15%). Of prescribers who consulted the clients, 91% work in government facilities and 68% are physicians.

Drug selling prices varied wildly from pharmacy to pharmacy, and it appears that the government is not monitoring pricing schemes very well. For example, the data collected for 13 commonly prescribed drugs showed selling price differences of 25% to 7511%.

RPM suggested that any health reform program should consider that visiting private pharmacies to purchase drugs is a burden for many clients. Also, RPM suggested several follow-on studies to broaden MOH understanding of private pharmacy sector forces. Suggested study topics are a comparison of urban and rural private pharmacies, demand for private pharmacy services, licensure requirements, financial benefit to the government from private pharmacies, and patient education of private market forces.

Tools Development

While RPM was adapting the CPS strategy for Mozambique, it became clear that district facility managers needed a basic tool in simple language that could easily guide them in their daily work. Thus, starting with the manuals used in the original drug management training courses, RPM extracted the main points, simplified the text, and combined the topics into five sessions. The five sessions are combined into a manual, which is designed for either self-instruction or instruction by a supervisor. Each session contains the following:

- A one- to three-page simple discussion of the drug management topic, using graphics for ease of understanding
- Checklists to identify problem areas in the pharmacy and storeroom
- A planning tool to record problems, establish solutions for each problem, and state who will carry out the plan and when
- One or more indicators with brief instructions of how to collect data, calculate the indicator, and frequency for sending the information to supervisors

In the districts where CPS was implemented, each drug manager and medical director received one day of instruction on use of the tool, following which individual drug management activities began. Impact of this work can be seen in the CPS indicator sections of the report.

Donor Collaboration

An estimated 90% of drugs and supplies needs of the government health system are donated. In concert with the sectorwide approach (SWAP) to health development under way in Mozambique, the donors established a committee and initiated the pooling of resources concept in 1998 to reduce the number of restrictions placed on these funds by a particular donor. In pooling, the donor funds are transferred directly to the MOH or provincial Directorate of Health and the money is managed solely by the agency for the purposes agreed upon by the donor committee. The pooling arrangement is monitored using measurable objectives set by the committee and based on the MOH strategic plan. The objectives were first drafted in 1999. The MSH/RPM program of activities includes indicators connected to the MOH strategic plan, and MSH began sharing results of activities with the donors at that time.

Collaboration with the United States Pharmacopeia

The RPM project is composed of separate cooperative agreements for MSH and USP. As in other RPM countries, MSH collaborated with USP in the area of drug information in Mozambique. Materials used in the drug management courses conducted in the country included drug monographs prepared by USP in the Portuguese language. Other activities included MSH's presentations on use of hospital formulary and drug use review systems for hospitals and health centers during USP drug information seminars held in Maputo in 1998 and 1999 and in Beira in 1999.

Sustainability

Sustainability has always been a goal of RPM's work in Mozambique. By continuing to support the drug management supervisory activities in the country, RPM hoped that supervision would eventually become an integral part of normal MOH drug management functions, which it has. Although on-site supervision may not continue on a regular basis, remote supervision using indicator monitoring will, as long as provincial administrators continue to support it.

As evidenced by the new *Normalized System of Drug Management*, instituted by the MOH in 1999–2000, much of the RPM technical work done with the central level MOH staff in 1998 has been incorporated into system procedures. The technical work involved harmonizing storeroom and warehouse practices for all provinces, culminating in the development of standardized control forms and procedures.

The MOH adapted the standardized control procedures into four manuals for each of the four types of health facilities (health posts, health centers, hospitals, and warehouses). The procedures are being implemented by the MOH using CPS, RPM's training methodology.

RPM believes that MOH drug management capacity will continue to be reinforced through the new *Normalized System of Drug Management*, and it hopes that funds will be identified to provide continued support of the on-site supervisory component.

Activities Not Completed

RPM was able to fully implement the CPS drug management strategy in six provinces and partially in two others. Because of other MOH program commitments by district staffs throughout the project, and because of heavy rains and cyclones in the country between January and March 2000, the two remaining provinces received no RPM support.

Also because of the floods, the MOH Pharmacy Department could not implement the new *Normalized System of Drug Management* procedures in the provinces and districts. Therefore, RPM could not carry out the planned evaluation of the new system.

Likely Needs at End of Project

To improve the drug supply system in Mozambique, RPM recommends the following after the project has ended.

1. Financial and technical support for provincial health directors is needed for ongoing continuing education to district staffs in basic drug management and rational use procedures. The support should include technical and financial assistance for regular supervision and monitoring of pharmacy and medical directors in all districts, and the use of drug management indicator data to identify problems and monitor improvements in drug delivery.

2. Technical and financial assistance will be needed by the MOH Department of Pharmacy to quantify national drug and supplies needs. The MOH currently uses data from previous drug distributions, which does not take stock outs and expired drug quantities into account. Thus, stock outs of drugs continue to occur. The output would be a list of national drug and supplies needs from a quantification study of consumption and morbidity data.

3. Building on the national quantification described in the paragraph above, the MOH needs to promote the use of consumption data from districts and provinces. Consumption data use will allow the MOH to more accurately quantify future national drug needs. To accomplish this, the MOH will need financial and technical support for a combined manual/computerized information system for provincial warehouses. Data from this system will be fed to the national procurement center for more accurate purchasing of drug and supplies needs.

4. The MOH Department of Pharmacy requested an evaluation of the *Normalized System of Drug Management* procedures. The new procedures were established in 2000 and some training has been provided to health facility managers. Further training and publishing and dissemination of the procedures are needed. Once the system is fully implemented,

an evaluation should be conducted to point out both weaknesses in the procedures and suggestions for improvement.

5. In concert with planned health sector reforms, technical assistance to improve the drug and supplies cost-recovery scheme used in government health facilities is needed. Specific activities would need to be coordinated with the MOH planning commission.

6. In 1999, Mozambique established a plan to gradually implement the Integrated Management of Childhood Illness (IMCI) scheme. Technical assistance will be needed for the drug management component of IMCI.

7. Mozambique is integrating several of its vertical health programs for diseases such as tuberculosis and malaria. Technical assistance for selection, procurement, and proper use of drugs will be needed to comply with WHO treatment regimens and to prevent the use of drugs that have developed resistance to these diseases.

8. The donor community working in the pharmaceutical sector of the MOH has organized a committee to better manage donor activities within the country. Many of the members have health experience but no real drug management expertise. Technical assistance is needed to better focus and coordinate donor support and to set meaningful objectives for the pharmacy sector.

9. After many years a new National Drug Formulary was published by the MOH in December 1999. Because the MOH did not conduct a comprehensive technical review, drugs in certain disease categories, like HIV/AIDS, are missing as are fixed-dose combination drugs for tuberculosis. Technical and financial support is needed to upgrade the formulary and to establish a scheme for dissemination of the formulary throughout the country.

10. Drug registration in Mozambique is nonexistent at this time, but the MOH has hired a person to work in this area. Technical assistance is needed to establish a comprehensive policy and service for registering new and currently used drugs. With the new drug law in 1998, private importers and pharmacies are now allowed to open for business, making the need for drug registration even more urgent.

Lessons Learned

1. Drug management systems *can* be improved with short-term technical assistance.

   RPM technical assistance in Mozambique was threefold: development of local pharmacy advisors, working with an MOH team to harmonize national pharmacy procedures, and development of provincial pharmacy teams to supervise drug management of district facility staffs.

Improvements resulting from the technical assistance are as follows: the pharmacy advisors are serving as local experts for logistics management and rational drug use; national pharmacy procedures evolved into the *Normalized System of Drug Management* to document and control drug supply; and provincial pharmacy supervisors are using indicators to monitor drug management activities in the provinces. Since RPM technical activities began in the districts in 1998, indicators show that average drug loss due to expiration has decreased 87%, and average drug availability has improved 29% for the country.

2. If *sustainable improvement* is a goal, an enabling environment and proper incentives must support capacity-building efforts.

   Because Mozambique is decentralizing its health system and the MOH needed assistance in capacitating local staffs, RPM trained provincial pharmacy teams to monitor drug management activities in the districts of each province. As part of the capacity-building efforts, RPM also established a financial system to fund the provincial and district activities, whereby provincial pharmacy teams received funds for discrete activities and filed expense reports to RPM.

   Now that the project is near its close, many of the procedures have become a natural part of daily activities. One thing that is lacking, however, is financial support to continue supervisory visits to district facilities. The MOH maintains that enough funding is provided to provincial directorates to spend on health activities. However, provincial directorates insist that the funding is not nearly enough to provide all the goods and services demanded by the MOH. Coupled with this, provincial directorates have had to work in a decentralizing environment without written procedures to follow.

   Therefore, RPM does not see the Mozambique environment as an entirely enabling one, until the poor financial situation and the promise of health-care-for-all-citizens conflict is reconciled.

3. The CPS district drug management strategy worked to build capacity.

   A combination of wars, natural disasters, and poor economic conditions have made the provision of quality health care in Mozambique problematic. Personnel responsible for drug management were poorly skilled and lacked tools to manage drug activities, such as ordering, receiving, inventory control, storeroom management, distribution, and rational drug use. The CPS district drug management strategy provided practical tools to provincial supervisors who needed them to capacitate health facility staff and to monitor their activities.

4. The drug management indicator data proved valuable as a monitoring tool.

   Monitoring of drug management activities in the provinces and districts was minimal to nonexistent before implementation of RPM activities. Provincial directors had no systematic way to supervise drug management in health facilities.

The drug management and rational drug use indicators introduced by the CPS strategy provided a graphic way for supervisors to understand problems in the drug sector of their province. With this data, supervisors can plan and implement suitable interventions.

5. Decentralization requires planning and should provide written procedures for local staff to understand and follow.

   The government of Mozambique developed a policy of gradual decentralization to take place over several years. With this policy, provincial directors are confused about their real authority and responsibility at times, and lack human and financial resources to make necessary changes. This affected steady implementation of RPM activities, and partly contributed to work being limited to only 8 of the country's 10 provinces.

6. The USAID cooperative agreement mechanism provided flexibility for RPM to meet USAID's goals in the arena of drug management.

   The Mozambique program evolved over time, partly because USAID wanted to see how a program such as RPM's could fit into the policies of a developing country that had emerged from a long civil war. Using results of the pharmaceutical sector assessment, the MOH indicated the type of assistance it would like from RPM, and USAID provided enough funding for development of drug management training materials and a national training course in 1995. Seeing the results of the first course, the MOH asked for additional courses in the three regions of the country. Using funds provided by USAID and leveraging donor funds, RPM completed this work in 1995–1996.

   At this point USAID began regular funding of the project for RPM to focus on capacitating drug management personnel in the provinces and districts. Without the flexible cooperative agreement mechanism, RPM would not have been able to quickly adapt to the wants and needs of the MOH and establish USAID as one of the leaders in the drug management arena.

Annex 1. Reference Documents Produced during the RPM Mozambique Program

1. *Basic Techniques for Managing Drugs and Supplies: A Five-Session Tool for Capacity Building, Planning, and Supervision,* Management Sciences for Health, March 1999 (Portuguese and English).

2. *Drug Management Courses in Mozambique,* Management Sciences for Health, November 1999 (Portuguese and English).

3. *RPM Support of Drug Use Studies in Mozambique,* Management Sciences for Health, October 1999 (English).

4. *RPM Complements Preparation of New Pharmacy Technicians in Mozambique,* Management Sciences for Health, January 2000 (English).

5. *Financial Burden of Supervising Government Pharmaceutical Services in Mozambique,* Management Sciences for Health, February 2000 (English).

6. *Gestão do Aprovisionamento e Uso Racional de Medicamentos: Guia de Sessão* (drug management course participant's manual), Management Sciences for Health, January 1999 (Portuguese).

7. *Gestão do Aprovisionamento e Uso Racional de Medicamentos: Guia do Formador* (drug management course trainer's manual), Management Sciences for Health, January 1999 (Portuguese).

8. *Mozambique Pharmaceutical Sector Assessment Final Report,* Management Sciences for Health, January 1994 (Portuguese and English).

9. *Study of Private Pharmacy Sector*, Management Sciences for Health, February 1999 (Portuguese and English).

10. *Estimate of Total Throughput in Private Pharmacies,* Management Sciences for Health, May 1999.

Nepal

Executive Summary

The Rational Pharmaceutical Management (RPM) Project began working in Nepal in 1993, with technical work concentrated on assisting the Ministry of Health (MOH) Logistics Management Division (LMD) to develop a computerized system for tracking drug inventory at the national level and to develop a drug information network. RPM also collaborated with UNICEF and the MOH to study cost-recovery programs in Nepal to provide quantitative and qualitative information that would facilitate the development and implementation of cost-sharing programs for essential drugs.

The USAID Mission in Nepal, in collaboration with His Majesty's Government (HMG) MOH, implemented the Program for the Prevention and Control of Selected Infectious Diseases in Nepal in 1998. RPM was responsible for coordinating the antimicrobial resistance (AMR) component of the Infectious Disease (ID) Program, working with the United States Pharmacopeia (USP) and the partner organization, the International Centre for Diarrheal Disease Research, Bangladesh/Centre for Health and Population Research.

When the USAID/Infectious Disease Program was implemented in 1998, RPM shifted the technical focus of the country program to provide assistance in AMR activities at the national and district level. At the national level, RPM began work to establish a national advisory committee to link AMR surveillance data to national AMR policy development. In spring 1999, the National AMR Technical Advisory Committee (NATAC) was appointed. Shortly thereafter, the USP convened a broad range of interested organizations to review an antibiotic policy drafted by the Drug Information Network of Nepal and Alliance for the Prudent Use of Antibiotics/Nepal. At this meeting, consensus was reached to broaden the membership of a national advisory group. RPM, together with the World Health Organization (WHO), conducted a preliminary meeting with a broad range of interested organizations to introduce the WHO Global Strategy and identify priority AMR issues, and met with officials at the MOH to discuss how to proceed with the advisory committee. A new committee, called the National Antibiotic Coordinating Committee (NACC), was proposed by the MOH. The Special Secretary of Health consented to chair this group, elevating the level of discussion. It was suggested that the previously formed NATAC become a subcommittee of NACC with specific technical functions, and that the NACC be the umbrella committee to address policy issues.

Through a separate initiative, RPM was involved in the development of the WHO Global Strategy for the Containment of Antimicrobial Resistance. When that strategy is finalized, it is anticipated that country level the implementation activities will be developed. Nepal will, most likely, be the first country to implement the Global Strategy through its NACC, with assistance from the Rational Pharmaceutical Management Plus (RPM Plus) Program and WHO.

At the district level, in response to the decentralization of drug management activities, the Strengthening Drug Management at District Level (SDMD) program was developed as a collaborative effort of the MOH/Department of Drug Administration (DDA), MOH/LMD, German Technical Cooperation Agency (GTZ)/Primary Health Care (PHC), Resource Center for Primary Health Care (RECPHC), John Snow, Inc. (JSI), and RPM. RPM worked with the

International Network for Rational Use of Drugs (INRUD) to assess drug management practices related to the use of antimicrobials at the district level. The results of the study were used to develop training materials on rational drug use, estimating drug needs, and dispensing practices. JSI materials on storekeeping practices were incorporated into the training program as well. In April 2000, this program was successfully implemented in two RPM intervention districts, Dhading and Siraha. District-level health supervisors expressed a strong desire to develop indicators for monitoring drug management activities; this activity should be a priority under follow-on district-level activities. Subsequently, the SDMD training materials were used in two intervention districts of the Swiss Development Corporation.

As part of the rational drug use activities, RPM also provided technical assistance and financial support for the third revision of the *Standard Treatment Schedules for Health Post and Sub-health Post*. Ten thousand copies of this manual for diagnosing and treating illnesses at the primary care level were printed in Nepali and English and distributed throughout the 75 districts of Nepal, as well as to the centers for training primary care–level health personnel.

To address drug management practices in the private sector, RPM/Management Sciences for Health (MSH) collaborated with USP to study drug-seller practices in recommending antibiotics and counseling on their use. On the basis results of this study, RPM developed and tested a training intervention to improve these drug-seller practices.

Acknowledgments

RPM would like to acknowledge the following persons for their support of the Nepal RPM country program, as well as the many others who have contributed to the program. Although they are not listed by name, the support of the district health officers from Dhading and Siraha districts was instrumental to the success of the RPM program.

Ministry of Health
Dr. Kalyan Raj Pandey, Director General of the Department of Health Services
Dr. K.B. Singh
Prakash Pant
Dr. Asfaq Sheak, Director, Department of Drug Adminsitration

Tribhuvan University Teaching Hospital
Dr. Mohan Joshi

USAID
Susan Bacheller
Anthony Boni
Matthew Friedman
Molly Gingerich
Charles Llewellyn
Glenn Post
Cathy Thompson

Donors
GTZ
Dr. Hans Steinmann

Swiss Agency for Development and Cooperation
Dr. Albert Burki, Health Advisor

Other Organizations
UNICEF
Lars Wadstein
Dr. Qussay Al-Nahi
Prabhat Bangdel

John Snow, Inc.

Family Health International

Britain Nepal Medical Trust
Dr. Kathy Holloway
Shiba Karkee

United Mission to Nepal
Dr. Richard Harding

MSH
Jim Bates
Queta Clark
Peter Cross
Vimal Dias
Douglas Keene
Christine Kuhn
Anthony Savelli
Kara Suter

USP
Nancy Blum
Keith Johnson
Marilyn Foster

Olya M. Duzey
RPM Nepal Country Program Manager

Acronyms

AMR	antimicrobial resistance
DDA	Department of Drug Administration [Nepal]
EDL	Essential Drug List
EHP	Environmental Health Project [USAID]
GTZ	German Technical Cooperation Agency [German acronym]
HMG	His Majesty's Government
ID	Infectious Disease (Program) [USAID]
INRUD	International Network for Rational Use of Drugs
JSI	John Snow, Inc.
LMD	Logistics Management Division [Nepal]
LMIS	Logistics Management Information System
MOH	Ministry of Health
MSH	Management Sciences for Health
NACC	National Antibiotic Coordinating Committee
NATAC	National AMR Technical Advisory Committee
NCDA	National Chemists and Druggists Association [Nepal]
NGO	nongovernmental organization
PHC	Primary Health Care
PSD	Pharmaceutical Supply Directory
RECPHC	Resource Center for Primary Health Care
RDU	rational drug use
RPM	Rational Pharmaceutical Management (project)
RPM Plus	Rational Pharmaceutical Management Plus (program)
SDMD	Strengthening Drug Management at District Level (program)
SDTS	Standard Drug Treatment Schedule
STS	*Standard Treatment Schedule for Health Post and Sub-Health Post*
TA	technical assistance
UMN	United Mission to Nepal
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Program Overview

The work in Nepal can be divided into two phases: the first phase began when the Rational Pharmaceutical Management (RPM) project began work in Nepal in 1993, to assist the Ministry of Health (MOH) Logistics Management Department (LMD) develop a computerized system to track drug inventory nationwide, and to help RPM establish a drug information network. The second phase began in 1998 when the USAID Mission in Nepal, in collaboration with His Majesty's Government (HMG) MOH, implemented the Program for the Prevention and Control of Selected Infectious Diseases in Nepal.

In the first, pre-1998 phase, an overall strategy was formulated to

- Develop drug management capacity in Nepali district and national public sector counterparts
- Develop capacity of nongovernmental organizations (NGOs) to conduct research and provide technical support
- Work with collaborators (World Health Organization [WHO], John Snow, Inc. [JSI], German Technical Cooperation Agency [GTZ], MOH)
- Provide technical assistance (TA) at district level in response to decentralization of drug management functions
- Address provider and consumer needs for information
- Apply the use of new technologies to drug management activities (primarily computers, and development of new software)
- Begin to address the influence of the private sector on appropriate use of antimicrobials

This strategy was broadly used in Nepal to respond to all three of the project=s mandated technical priorities of drug registration, procurement and inventory management, and drug information and rational use.

Objectives

The following multiple objectives were developed to address these priorities that would also:

- Enhance capacity of local public- and private-sector organizations to conduct and analyze comprehensive and targeted pharmaceutical surveys
- Develop capacity at the national level to automate and maintain the drug registration process

- Develop the capacity within the newly created MOH LMD to collect and manage drug procurement, distribution, and consumption information
- Collect information on sources of public-sector- and donor-supplied drug and medical commodities
- Identify and evaluate existing cost-recovery schemes to develop a long-range strategy for a sustainable supply of essential drugs and other commodities in the public sector
- Increase availability of accurate drug information to consumers through a local consumer-oriented NGO
- Together with United States Pharmacopeia (USP), develop a drug information network in Nepal to provide objective current drug information for a wide range of professional and consumer needs
- Strengthen efforts to enhance rational drug prescribing, dispensing, and use practices
- Develop and implement a strategy for rational drug use (RDU) at district level

When the USAID/Infectious Disease (ID) Program was implemented in 1998, RPM shifted the technical focus of the country program toward providing assistance in antimicrobial resistance (AMR) activities at both the national and the district level; and the second, post-1998 phase began with a program that was designed to simultaneously work on two major streams of activity: vector-borne diseases and antimicrobial resistance. The RPM project and its partners and collaborators were responsible for coordinating the AMR component of the ID Program. USP had been implementing the drug information component of RPM in Nepal since 1992. The AMR surveillance and rational drug use component of the ID Program had three objectives:

1. To strengthen capacity for sustainable antimicrobial resistance surveillance according to standard microbiology guidelines for selected bacterial pathogens
2. To use findings based on AMR surveillance data to guide antimicrobial prescribing policy in Nepal for cholera, dysentery, pneumonia, and gonorrhea at hospitals, health posts, and community levels
3. To improve public-sector facility availability and rational use of appropriate antimicrobial and antiparasitic drugs, particularly those used for treatment of dysentery, cholera, pneumonia in children, tuberculosis, gonorrhea, malaria, and kala-azar

Beginning in 1998, RPM activity concentrated on the last two objectives, with three specific sub-objectives:

1. Increase awareness among counterparts, policymakers, health providers, and consumers of the problem of drug resistance, and develop a strategy to contain the emergence and spread of antimicrobial resistance

2. Develop the capacity at district level to estimate drug needs, engage in appropriate drug storekeeping practices, provide appropriate dispensing, and support rational drug use, particularly of antimicrobials

3. Develop a strategy to link information about AMR surveillance with decision-making on antibiotic use at national level

Six more of the pre-1998 objectives relating to drug information and rational use continued throughout the entire RPM project:

- Enhance capacity of local public- and private-sector organizations to conduct and analyze comprehensive and targeted pharmaceutical surveys

- Collect information on sources of public-sector- and donor-supplied drug and medical commodities

- Increase availability of accurate drug information to consumers through a local consumer-oriented NGO

- Together with USP, develop a drug information network in Nepal to provide objective current drug information for a wide range of professional and consumer needs

- Strengthen efforts to enhance rational drug prescribing, dispensing, and use practices

- Develop the capacity of counterparts to provide training in all aspects of drug management

Implementation Strategy and Major Activities

For effective intervention in Nepal to meet specific predetermined objectives, a basic strategy was outlined and broken down into four specific stages:

1. The first stage included quantitative "indicator surveys" for the documentation of basic patterns of drug use, with surveys conducted in Kathmandu Valley, as well as quantitative and qualitative information that would facilitate and accelerate the development and implementation of cost-sharing programs for essential drugs.

2. The second stage included qualitative methods such as observation, simulated patients, and in-depth interviews and focus groups to identify the reasons for inappropriate drug use behaviors. With identification of the major problems and reasons, activities then moved to the third stage.

3. The third stage included designing, testing, and implementing interventions to instill the necessary behavior changes. RPM assisted country staff in creating a framework for the assessment of irrational behaviors. On the basis of outcomes of this work, interventions

were undertaken to address problem behaviors. Because such interventions are likely to include managerial, regulatory, and/or communications approaches, care was taken to identify the approaches that would be most appropriate in Nepal.

4. The fourth stage included the development of the capacity in the Nepali district and with the national public-sector counterparts. The capacity of the NGOs to conduct research was enhanced in order to provide technical support. RPM worked with various collaborators on this project, including the WHO, JSI, GTZ, and the MOH.

In addition, the USAID's Mission to Nepal requested that RPM collaborate with WHO's planned Essential Drugs Program (EDP) review. Existing materials were reviewed and synthesized before any major new data collection activities were undertaken. Data collection, interviews, and reviews of extant documents were conducted primarily in Kathmandu. The result was a comprehensive and up-to-date description of drug management in the public sector, and the information served to define a program of RPM activities for Nepal.

Second stage, post-1998 RPM work concentrated on the two AMR-specific objectives, resulting in the following implementation strategies and activities for each.

- To use findings based on AMR surveillance data to guide antimicrobial prescribing policy in Nepal for cholera, dysentery, pneumonia, and gonorrhea at hospitals, health posts, and community levels. RPM conducted three baseline studies related to the rational use of antimicrobials: a study of hospital and outpatient antibiotic prescribing habits (Management Sciences for Health [MSH], 1998), a study of district-level drug management and prescribing practices (MSH, 1999), and a study of drug-seller behavior in dispensing antimicrobials and providing patient counseling (USP, 1999). On the basis of these findings, several interventions were developed and implemented, including the following:

    - The Strengthening Drug Management at District Level (SDMD) program was developed as a collaborative effort of the MOH/DDA, MOH/LMD, GTZ/Primary Health Care (PHC), Resource Center for Primary Health Care (RECPHC), JSI, and RPM to address drug management issues at district level.

    - With RPM assistance, the third edition of the *Standard Treatment Schedules for Health Post and Sub-Health Post* (STS) was published in July 1999. For the first time, the STS was printed in Nepali and English to make the document more useful. Ten thousand copies were printed and distributed to approximately 4,000 health posts, subhealth posts, and primary health care centers in all 75 districts of Nepal. Copies were also distributed to educational centers that train health personnel for these posts and to other organizations, on request.

    - As a complement to the *Standard Treatment Schedules*, RPM supported development of training manuals, supervisory materials, and a training program for district level on how to use the STS to improve rational drug use. Implementation was completed in Dhading and Siraha districts in April 2000.

- In coordination with HMG/MOH, other AMR partners, and the WHO, RPM worked to establish a National Antimicrobial Coordinating Committee to be responsible for reviewing AMR surveillance information and making recommendations regarding the appropriate use of antimicrobials on the basis of those data and other currently available information.

- To improve public-sector facility availability and rational use of appropriate antimicrobial and antiparasitic drugs, particularly those used for treatment of dysentery, cholera, pneumonia in children, tuberculosis, gonorrhea, malaria, and kala-azar.

  - Through the SDMD program, RPM supported development of training modules for district level in drug quantification and dispensing, in addition to the rational drug use module. The materials developed by JSI for storekeeping were reprinted for Dhading and Siraha districts. The training for these modules was also completed in the two pilot districts.

  - Following discussion with DDA, RPM, and USAID, the Swiss Development Corporation used copies of the SDMD training manuals to provide training in rational drug use, quantification, and dispensing in two additional districts.

  - RPM supported development and pilot testing of a training intervention for drug sellers to improve their skills in recommending antimicrobials and counseling regarding appropriate drug use.

  - To address the needs of consumers for information about how to use prescribed drugs appropriately, the Bhalakusari consumer drug information bulletin was developed. With RPM financial support, RECPHC publishes and distributes six issues of the newsletter annually.

Challenges Facing RPM Implementation

Nepal assessments relating to the three RPM-mandated technical priorities revealed the following problems, deficiencies, or constraining factors for each.

Drug Registration

The drug system was manual and had at best limited information retrieval capacity. Only with difficulty could staff develop a list of domestic manufacturers producing products on the Essential Drug List. The accuracy of this output was suspect.

371

Procurement and Inventory Management

- Little information was available to inform regional- and central-level procurement decision-making, and informants reported a tendency to simply repeat last year's orders.
- The general practice was to provide all health posts with exactly the same annual consignment of drugs, regardless of the sizes of individual posts or their workloads.
- For most essential drugs, there was no mechanism by which health posts could resupply themselves if they ran out between annual shipments.
- Stock control measures at storage and clinical sites were weak. There was virtually no recovery of information on consumption and balances.
- Storage conditions and stock arrangement were usually poor, resulting in high probable losses from expiration and deterioration.

Cost-Sharing Programs for Essential Drugs

- The MOH's very ambitious goals had stretched its human, technical, and managerial resources beyond realistic assessments of their capacities.
- Approximately 80 percent of the drugs provided through the MOH's facilities were financed by international donors, thereby creating a dependency that makes national programs and policies vulnerable to changes in donor priorities and policies.
- The population not only is willing to pay for drugs, but actually expends approximately ten times as much on drugs as the Ministry of Health, including the donors' contributions. This fact implies that there is no overall shortage of financial resources for drugs. However, often these resources are spent for high-cost combination products and unnecessarily expensive items, such as third-generation antibiotics.
- Consistent with international experience, village health committees, often including elected members of the Village Development Committee, successfully managed health funds under two existing drug cost-sharing models.
- Some NGO-supported drug cost-sharing models have achieved significant improvement in the availability of drugs. The percentage of drug costs recovered has not been an explicit target of these models and has been relatively modest, even when administrative costs are not included.

Drug Information and Rational Use

- Unbiased, current drug references were not available in most clinical facilities, nor was such information available to officials and committees who develop drug lists and make procurement decisions.

- Recent studies showed that most clinical facility staff were unaware of the existence of the official *Essential Drug List* (EDL) or *Standard Drug Treatment Schedule.*

- Insufficient drug supplies at clinical facilities contribute to such inappropriate behaviors as prescribing and dispensing incomplete courses of treatment, and prescribing drugs by brand name from retail pharmacies.

- At most hospitals, there were few or no controls over prescribing practices, nor efforts to promote rational prescribing from the EDL. This meant that, in practice, the all-important medical opinion leadership in rational drug use was lacking.

- Human resource management issues within the MOH constrained efforts to improve prescribing behavior when vacancies in care-provider positions in many clinical facilities or frequent transfers could nullify the effects of training interventions.

Chronological Activity Timeline

Table 1. Activity Timeline

Date	Activity
August 1993	Nepal pharmaceutical sector assessment
November/ December 1994	Launch the Drug Information Network of Nepal
April 1995	Technical assistance to the MOH/LMD on Procurement Information Management Systems; data collection for the Pharmaceutical Supply Directory (PSD); TA in preparation of Kreditanstast Für Wiederanfbau kit distribution list for sub-health posts
May 1995	TA to RECPHC on the Bhalakusari newsletter and other RDU activities
July 1995	TA on RDU activities, including revision of standard treatment guidelines, International Network for Rational Use of Drugs reports on RDU interventions, and RECPHC
August 1995	TA on RDU activities
October/ November 1995	Complete preparation for the Drug Financing Study and initiate data collection
November 1995	TA to develop a coordinated strategy on RDU activities in the public sector
March 1996	TA to the MOH/LMD on design and implementation of pharmaceutical procurement systems
June 1996	Completion of the Nepal Cost-Sharing in Pharmaceutical Distribution Study
July 1996	TA on the revision and printing of the Standard Drug Treatment Schedule (SDTS); development of RDU bulletins in the Bhalakusari; and a field test of an RDU strategy
September 1996	TA to the MOH/DDA and Health Learning Materials Centre on the SDTS and the Bhalakusari

Table 1. Activity Timeline, continued

Date	Activity
September 1996	Participate in USAID planning sessions; formal opening of the Drug Information Network of Nepal
February 1997	Collaborate with MOH/DDA and GTZ on planning and implementation of a field test of an RDU strategy; TA to RECPHC on the SDTS
February/ March 1998	Provide TA to the MOH/LMD on procurement tracking and to the MOH/DDA on developing an memorandum of understanding; work on developing a survey instrument for studying district-level drug management practices
March 1998	Participate in the International Network for Rational Use of Drugs (INRUD)/Nepal Promoting RDU course; continue TA on the SDTS, Bhalakusari, and SDMD activities; participate in the Infectious Disease team to assess capacity for implementation and ID strategy as well as develop a work plan
April/May 1998	TA to set up a training center and project management unit and the procurement tracking and reporting system
June 1998	TA on procurement work at LMD, planning SDMD activities, including the survey of district-level drug management practices
September 1998	Participate in start-up workshop of the USAID ID program, provide TA on SDMD activities, to LMD on the PSD, and to DDA on the DDA Training Center
November 1998	Participate in a hospital-based baseline study with International Centre for Diarrheal Disease Research, Bangladesh; review SDTS progress
November/ December 1998	TA on the DDA Training Center; SDMD activities; collaborate with USAID's Environmental Health Project (EHP) on the AMR hospital basline survey
February 1999	TA to MOH/LMD on the PSD; participate in SDMD planning; renew contract on Bhalakusari
March 1999	Participate in the ID workshop to present findings from the hospital prescribing survey; finalize the SDTS; review the district-level drug management study findings
May/June 1999	Finalize the PSD; provide TA on developing the work plan for SDMD activities; assess district-level procurement activities; review the INRUD SDMD baseline study
July 1999	Provide TA to the SDMD working committee; attend the launch of the STS manuals
December 2000	Meet with partners in the ID Program for a midterm review in Kathmandu
February 2001	Refresher training for technologists and microbiologists participating in AMR surveillance of selected infectious diseases in Nepal
March 2001	Rational Pharmaceutical Management Plus Senior Program Associate Vimal Dias traveled to Nepal to assess the status of the SDMD program

Program Accomplishments

In the scope of both pre- and post-1998 work of the RPM project in Nepal (1993–2000), various important activities and projects were accomplished, thus fulfilling identified needs and objectives. Policy work, pharmaceutical surveys and assessments, drug registration systems, and newsletters and other means for communication were all elaborated. This work was designed and developed by RPM alone as well as with the help of collaborators.

- The capacities of local public- and private-sector organizations were enhanced to conduct and analyze comprehensive and targeted pharmaceutical surveys. Major assessments were

conducted, including the initial assessment; cost recovery, hospital prescribing, district-level assessment; and assessment of drug-seller practices.

- A national, automatic drug registration system was developed, and within the newly created MOH LMD, staff were trained to organize drug procurement, distribution, and consumption information into a cohesive system. Both the LMD and the Logistics Management Information System (LMIS) capacities were improved. The LMIS was designed and implemented.

- Information was collected and disseminated about both public-sector- and donor-supplied drugs and medical commodities.

- Cost-recovery schemes were refined to develop a long-range strategy for a sustainable supply of essential drugs and other commodities in the public sector.

- The availability of accurate drug information was increased for consumers through a local consumer-oriented NGO.

- The RECPHC newsletter (with a circulation of 7,000) was conceptualized, written, and distributed to public health centers nationwide, and a drug information network was created in Nepal to provide current drug information for a wide range of professional and consumer needs.

- Various training activities were conducted to improve rational drug prescribing, dispensing, and usage practices, including revisions of standard treatment schedules, and workshops were held on the development and the implementation of RDU at the district level.

- At the district level, the following capacities were developed: how to conduct an accurate assessment of drug needs; how to engage in appropriate drug storekeeping practices; how to provide appropriate dispensing and support rational drug use, particularly of antimicrobials. Counterparts developed skills to provide training in all aspects of drug management. Awareness was raised among counterparts, policymakers, health providers, and consumers about drug-resistance problems. A strategy was developed to work for the upkeep and proliferation of activities to prevent antimicrobial drug resistance.

- Technical assistance was provided at the district level to respond to the decentralization of drug management practices and functions. The needs of both the provider and the consumer were addressed.

- New technologies were used for more efficient drug management activities. Computers were used extensively, and new software was developed. The influence of the private sector was assessed to determine what its impact was on the appropriate use of antimicrobials. Findings from surveys of prescribing and drug management practices were used to guide antimicrobial prescription policies for selected diseases at hospitals, health posts, and community levels. Beginning in 1998, RPM conducted three baseline studies related to the rational use of anti-

microbials: (1) a study of hospital and outpatient antibiotic prescribing habits (MSH, 1998); (2) a study of district-level drug management and prescribing practices (MSH, 1999); and (3) a study of drug-seller behavior in dispensing antimicrobials and providing patient counseling (USP, 1999). On the basis of these findings, several interventions were developed and implemented.

- With RPM assistance, the third edition of the *Standard Treatment Schedules for Health Post and Sub-Health Post* was published. For the first time, the STS was printed in Nepali and English to make the document more useful. Ten thousand copies were printed and distributed to approximately 4,000 health posts, sub-health posts, and primary health care centers in all 75 districts of Nepal. Copies were also distributed to educational centers that train health personnel for these posts as well as to other organizations, on request.

- As a complement to the *Standard Treatment Schedules,* RPM supported the development of training manuals, supervisory materials, and a training program for the district level in rational drug use based on the STS. Implementation was completed in Dhading and Siraha districts in April 2000.

- In coordination with HMG/MOH, other AMR partners, and the WHO, RPM worked to establish a National Antimicrobial Coordinating Committee. This body was to be responsible for reviewing AMR surveillance information and making recommendations regarding the appropriate use of antimicrobials on the basis of those data, as well as other information available at that time.

- The availability and rational use of appropriate antimicrobials of assured quality was improved through the SDMD program, where RPM supported the creation of training modules at the district level in drug quantification and dispensing, in addition to the rational drug use module. The materials developed by JSI for storekeeping were reprinted for Dhading and Siraha districts. The training for these modules was also completed in the two pilot districts.

- With RPM assistance, an EDL was developed and published, with 259 generically named products, covering the vast majority of drugs procured and distributed by MOH. This measure restricted the availability of inappropriate products within the health services delivery system.

- A *Standard Drug Treatment Schedule* was written, which provided guidance about basic use of the drugs that were listed on the Essential Drugs List.

- An innovative program was created in Nepal for the training of drug retailers in varied skill areas such as safe maintenance of supplies and appropriate prescription practices.

- Country assessments were conducted through the use of data collection instruments and tools, as well as sample surveys of clinical facilities to measure gross indicators of drug use.

- Following a discussion with the DDA, RPM, and USAID, the Swiss Development Corporation used copies of the SDMD training manuals to provide training in rational drug use, quantification, and dispensing in two additional districts.

- RPM supported development and pilot testing of a training intervention for drug sellers to improve their skill in recommending antimicrobials and in counseling regarding appropriate drug use.

- To address the consumer needs for appropriate prescription drug use, the *Bhalakusari Consumer Drug Information Bulletin* was developed. With RPM financial support, RECPHC published and distributed six issues of the newsletter annually, covering topics such as the rational use of antimicrobials.

- RPM worked with INRUD to assess drug management practices related to the use of antimicrobials at district level. The results of the study were used to develop training materials on rational drug use, estimating drug needs, and dispensing practices.

- At the district level, as a result of the decentralization of drug management activities, and on the basis of the findings of an assessment of drug management practices, the SDMD program was developed as a collaborative effort of the MOH/DDA, MOH/LMD, GTZ/PHC, RECPHC, JSI, and RPM to address identified deficiencies.

- To address drug management practices in the private sector, RPM/MSH collaborated with the USP to study drug-seller practices in recommending antibiotics and counseling on their use. On the basis of results of this study, RPM developed and tested a training intervention to improve these drug seller practices.

Collaborations with Major Donors

- The WHO/Geneva Drug Action Program prepared an overall plan to strengthen essential drug management. All recommendations made by RPM in this report were intended to fit in with and support that plan. A plan was also made to focus on developing and implementing this plan at the national level.

- The WHO Country Program provided drugs for the expanding network of Sub-Health Posts. It provided funds to support health post–based drug cost-recovery schemes.

- RPM collaborated with the United Nations Children's Fund (UNICEF) to support a broad range of activities in essential drug management, including central-level activities to revise and print the Essential Drugs List and production of health-worker manuals. UNICEF was also a partner in the study of cost-recovery programs in Nepal.

- In response to the findings of the RPM assessment of district-level drug management practices, RPM supported the Strengthening Drug Management at District Level Working

Committee to develop and implement an intervention designed to improve those practices. Members of this working committee included representatives of GTZ, MOH/LMD, and MOH/DDA.

- Tools developed by RPM, including the STS manual and the district-level training materials were made available for use by other NGOs, public programs, or donors. The decision by the Swiss Development Corporation to use the SDMD training materials in its project districts is a fine example of collaboration and leveraging funds to achieve the objectives of the ID Program.

Needs at End of Project

The basic components of the Infectious Disease Program that have been put into place to meet the program's goals are

- Improve the availability of appropriate antimicrobials of assured quality
- Ensure appropriate use of antimicrobials
- Improve infection control and management of outbreaks (EHP)
- Reduce transmission of disease (EHP)
- Improve or implement surveillance systems and use information for decision-making

Looking forward, there are several streams of activity that build on these activities and accomplishments. Presuming that the Mission Strategic Objectives and the objectives of the AMR program will remain the same, the following are likely to need support:

1. Integrate developed drug management tools and programs with existing training or academic programs

   During the development and implementation of the SDMD training program, it became evident that various donors and NGOs have an interest in improving the capacity to provide health care services at the district level. This capacity is particularly critical in providing pharmaceuticals because shortages have continued, if not gotten worse, since the decentralization of drug procurement in 1998. The staff that is responsible for managing health care services, including estimation of drug needs, procurement, storekeeping, and distribution, consists of a limited number of health care personnel. Rarely are interventions by one donor or contractor coordinated with efforts by others. At best, the participants receive consistent information. At worst, the information may be contradictory. Integration of training activities and materials for drug sellers, for example, would introduce some cost efficiencies in training personnel as well as the possibility of more comprehensive training to drug sellers. A drug seller who is gaining recognition for providing good contraceptive services is, most likely, also a good candidate for providing products and counseling for syndromic sexually transmitted infection treatment, as well as more rational dispensing of antimicrobials.

Rollout of the SDMD training is needed to provide drug management training to district-level personnel in a much larger number of districts. Efforts should be made to identify other parties willing to use the RPM materials and/or training program, or to identify partners that may implement the SDMD program as a component of existing activities. Tools developed by RPM, including the STS manual and the district-level training materials need to be made available for use by other NGOs, public programs, or donors. The STS needs to be incorporated into preservice training. Copies of these manuals are being provided to all 125 training centers of the Center for Technical Education and Vocational Training. The next step would be incorporation of the manuals into the curriculum and providing copies to all students as part of their training.

2. Strengthen monitoring and supervision of district-level drug management

   Work has begun on development of indicators for monitoring drug management activities at district level. These indicators need to be tested and then implemented as part of the regular monitoring and supervisory activities. This activity would also benefit from regular interaction with other organizations that are working in monitoring and supervision. In addition to self-monitoring and supervision by district personnel, the effectiveness of district level training should be evaluated for its impact on drug availability and rational drug use.

3. In hospitals, use surveillance data to make formulary and standard treatment guideline decisions

   The baseline study of antibiotic prescribing practices in hospitals and outpatient facilities showed an uneven pattern of prescribing and significant variation in choice of drug products. RPM supported the training of three individuals to the Drug and Therapeutics Course. It is anticipated that these individuals will be ready to incorporate the concepts they learned in drug information activities, a teaching hospital, and the academic setting. Additional support and technical assistance will be needed, however, to apply these concepts to the hospital setting. Interventions might include development of infection control committees and drug and therapeutics committees, with a specific emphasis on using the appropriate data for guiding clinical practices recommendations at the facility level.

4. Evaluate current schemes for financing drug supply and recommend improvements

   In most countries there are three mechanisms for paying for the drug supply: public-sector funds (MOH), donor financing, and patient payment (cost recovery). One of the main obstacles to improving public-sector availability of antimicrobials and their rational use is the lack of local or national funding for even a limited list of vital drugs. The unavailability of these products in Nepal has resulted in the rapid growth of the private sector to try to meet patient needs for drug products. In a market where enforcement is sporadic, this growth has been largely unregulated, with less desirable aspects, such as improper use of antimicrobials. There are several programs for drug product cost recovery in Nepal, which RPM evaluated in 1995. In the case of HMG's Community

Drug Program, anecdotal reports suggest that when drug supplies are consistent, patient/consumer satisfaction rises considerably. Spillover effects include a greater attention to patient needs, an improvement in services, and physical facilities. However, to date RPM is not aware of any objective evaluation of performance improvement at those sites, nor what level of cost recovery is necessary to support provision of pharmaceuticals without decreasing use of the program because of patient inability to pay. An overall assessment of all three mechanisms is necessary to understand how they interrelate and how to avoid duplication or severe drug shortages. Such an assessment, with a special emphasis on cost recovery, would evaluate the cost-recovery schemes already in place and provide recommendations on making more efficient use of these three streams of financial inputs. RPM provided data on sector drug availability through the first and second editions of the *Pharmaceutical Supply Directory*. As drug procurement was decentralized, and the proportion of public- to private-sector drug supply dwindled, these data have become increasingly more difficult to obtain and evaluate. It is necessary to reevaluate the types of data that are necessary to track public- and private-sector availability to provide the baseline and indicator data that will be needed to evaluate program effectiveness.

MSH has developed mechanisms for evaluating performance improvement in women's health services. These indicators could be applied to evaluate improvements and suggest effective incentives to improving care. RPM could then provide technical assistance in implementing the Community Drug Programs or other program and document other positive outcomes.

5. Strengthen the functioning of a newly established National AMR Technical Advisory Committee

   The notion of having a national-level committee to provide the technical expertise necessary to guide national policy on antimicrobials has gained support since it was first proposed in spring 1999. RPM has enlisted the support and collaboration of the WHO to incorporate the WHO Global Strategy for Antimicrobial Resistance in developing the decision-making framework of this national committee. This committee would benefit greatly from additional technical assistance to get it onto solid ground. Given that the functioning of such a committee is a fairly new concept, interventions that are found to be effective may be applicable to other developing countries.

6. Examine the relationship of the public and private sector to identify incentives to implementation of rational drug use policies and programs

   Finally, regulation of the private sector is problematic in Nepal. Although there was discussion of limiting prescribing authority for antimicrobials to qualified health care personnel, or according to an approved protocol, enforcement of such a requirement is highly questionable in the current environment. The relationship of the public and private sectors needs to be considered realistically in trying to develop and implement interventions and understand the incentives that operate in both sectors.

Lessons Learned

Developing Human Resources

Typical of many developing countries, there is a shortage of qualified health personnel to meet the health care needs of the population. Although preservice training for pharmacists, physicians, nurses, and primary health care workers has improved in Nepal, and specialized training for employed health care workers is available in priority districts, often health care workers are transferred to other districts, creating gaps in available skills and need for refresher training.

A concerted effort needs to be made when working with the private sector not only to train the owners of pharmacies and other retail drug shops, but also to find ways to extend this information to the shopkeepers who actually have patient contact.

Monitoring and Supervision

Nepal does not have a culture of strong enforcement of government regulations. For example, approximately 20 percent of all drug retailers are not licensed, and few inspectors are available to inspect facilities and address deficiencies. In addition, although monitoring and supervision are needed to sustain changes, and district-level personnel have expressed an interest in implementing such programs, to date such programs have not materialized. One impediment is the perception by both supervisors and primary health care personnel that monitoring is a punitive process, rather than one that can be used for quality improvement. Effective implementation of a monitoring and supervisory program will require that such perceptions be addressed.

Financing the Drug Supply

Since RPM published the *Nepal Cost Sharing in Pharmaceutical Distribution Report* in 1996, little has been done to critically evaluate how the Community Drug Programme has been implemented, and how user fees have affected utilization of these services. Although the government has recently published guidance on cost-recovery programs and supports further development of cost-recovery programs with active management and control of Village Development Committees, the Ministry of Health should retain technical leadership of cost-sharing initiatives in terms of overall policy and objectives. Also, the MOH should not be expected to assume implementation responsibilities that are not essential to its leadership role. Drug cost-sharing initiatives should build on existing experience, and be adjusted, expanded, and/or adapted to new conditions. Lastly, maximum possible advantage should be taken of existing human and institutional resources that have experience developing and implementing cost-sharing schemes.

Coordination of Technical Assistance

There are several examples of coordination of technical assistance under the RPM program. During the first phase of RPM involvement in Nepal, RPM assistance was coordinated with efforts by other donors and USAID partners. This strategy resulted in a relatively well-coordinated approach to assisting the MOH to improve its logistics management for drugs and other supplies and to study existing cost-recovery programs. Similarly, for the SDMD work, the working committee included representatives of GTZ, various departments of the MOH, and other USAID partners. This coordination allowed some practical cost sharing to take place, with contributions from the MOH, GTZ, JSI, and RPM. The use of SDMD materials by the Swiss was a fruitful collaboration, where the incremental cost of providing the materials was far outweighed by the ability to reach two additional districts where RPM did not have a presence.

On other fronts, however, there is still a need for better cooperation. The *Pharmaceutical Supply Directory* attempted to document the drugs provided by various donors in Nepal, but getting cooperation from all of the NGOs that supply pharmaceuticals as part of their mission was rather difficult. With the decentralization of drug procurement to district level, save for a small number of drugs used in vertical programs, the current government logistics system will be unable to account for the majority of drugs that are distributed throughout Nepal. Similarly, efforts to train drug sellers are occurring in a disconnected way, using different training approaches. Coordination of efforts would help in the development of an overall comprehensive training program, including monitoring of the process and evaluation of the impact of the training.

Training Programs

Early in the RPM program, the decision was made to provide technical assistance and direct financial support to develop the capacity of Nepali counterparts to train pharmacists, drug sellers, and district-level personnel. In the main, this effort was successful. However, for the most part, collaborators tended to gravitate toward a training model that required significant levels of effort from Kathmandu. This model is an unrealistic one, if training programs are going to go to scale, as it is both time-consuming and expensive. Local implementers and trainers need exposure to innovative and participatory training approaches, which may provide an alternate sustainable means of reaching a larger audience.

There is still a great need to scale up efforts and to reach a maximum number of districts to improve drug management practices at district level. To achieve this goal, future training programs should be implemented not only by RPM Plus, but also by other donors or partners. To be effective, therefore, the training programs should be revised to be easily implemented by district-level personnel, followed by monitoring and supervisory programs that are aimed at identifying gaps in knowledge and skill and addressing them in a constructive way.

Working with the Private Sector

It is well accepted that the first contact with the medical system for approximately 70 percent of the population is with the drug seller. There have been sporadic attempts to work with the drug sellers, primarily through the National Chemists and Druggists Association (NCDA) of Nepal, to improve their understanding of priority health conditions and how to manage them. RPM made a significant contribution in understanding the motivation of drug sellers in recommending antibiotics to consumers. However, the effectiveness of these efforts, particularly at national level, was dependent on the leadership of the NCDA. Over the span of several years, the net effect was quite uneven. There is a need to reassess the approach to training drug sellers, and to provide the MOH with assistance in developing a comprehensive strategy for training new drug sellers, providing refresher training to existing retailers, and monitoring their performance.

Annex 1. Key Documents

Bates, J.A., et al. *Rational Pharmaceutical Management Project, Nepal Pharmaceutical Sector Assessment, Final Report.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, January 1994.

Bates, J.A., et al. *Logistic System Improvement Work Planning Exercise 29 January 1994 to 24 February 1994.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, 15 March 1994.

Bates, J.A., et al. *Work Plan for Drug Information and Rational Use.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, August 1994.

Cross, P.N., et al. *Nepal Cost-Sharing in Pharmaceutical Distribution.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, June 1996.

Chalker, J., et al. *Assessment of Prescribing Practices in Selected Hospitals in Nepal.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, April 2000.

Department of Drug Administration. *Standard Drug Treatment Schedule.* Kathmandu: November 1996.

Department of Drug Administration. *Standard Treatment Schedules for Health Post and Sub-health Post.* Kathmandu: July 1999.

Department of Drug Administration. *Strengthening Drug Management at District Level Training Program (modules on rational drug use, estimating drug needs, and dispensing).* Kathmandu: March 2000.

Department of Drug Administration, *Report on Strengthening Drug Management at District Level program (SDMD).* November 2000.

Dias, V.N. *Nepal Ministry of Health Pharmaceutical Supply Directory.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health. June 1995.

Dias, V.N. *Nepal Ministry of Health Pharmaceutical Supply Directory, Second Edition.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health. June 1999.

International Network for Rational Use of Drugs, Nepal Country Core Group. *Intervention Test of Training, Supervision, and Dispensing Practices.* Kathmandu: 1995.

Ministry of Health, *Logistics Information System Reporting Forms.* Kathmandu, Nepal: no date.

Naimoli, G., et al. *A Study of Drug Retailer Recommending and Counseling Practices in Nepal.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, December 1999.

Resource Center for Primary Health Care. *Bhalakusari, Drug Information Bulletin*. Bimonthly, beginning September 1995 through June 2000. Kathmandu.

Resource Center for Primary Health Care. *Bibliography on Drugs*. Kathmandu: August 1995.

Thapa, B.B., et al. (ed.), *Proceedings of the Dissemination Seminar for a Study on the Recommending and Counseling Practices of Drug Retailers in Nepal.* Rational Pharmaceutical Management: Kathmandu, January 2000.

Peru

Executive Summary

From 1996 to 1999, the Rational Pharmaceutical Management (RPM) Project assisted the Ministry of Health (MOH) of Peru and projects supported by the U.S. Agency for International Development (USAID) to manage and use drugs rationally. The RPM strategy focused on building decentralized drug management programs using the Monitoring-Training-Planning (MTP) methodology, a stepwise tool for participatory training and program implementation. RPM activities in Peru were managed primarily through short-term technical assistance (TA) visits and collaboration with in-country consultants.

RPM's targeted interventions, activities, and technical assistance resulted in several major improvements in drug management. RPM collaborated primarily with three projects and one municipality to improve drug management techniques at the national, regional and local levels.

- DIGEMID, the MOH's Directorate of Drugs and Medical Supplies
  - Brought together technical experts and provide reference information to support DIGEMID in the design and production of the National Drug Formulary (NDF). The NDF was approved and published in October 1997.
  - Provided TA, informational materials, and supplies to DIGEMID to develop the national standard treatment guidelines (STGs)
- Project 2000, to improve pharmaceutical management and rational drug use in MOH hospitals supported by the USAID Mission
  - Assisted Project 2000 to implement the NDF in 21 participating Project 2000 hospitals, working primarily with regional hospital-level pharmacology and therapeutics (P&T) committees
  - Collaborated with Project 2000 to improve hospital drug management, including use of an indicator-based evaluation, in 21 hospitals
  - Sponsored a drug information needs assessment and the design of an electronic drug information system
  - Launched a Peruvian rational drug use Web page in September 1999
- ReproSalud, USAID/Peru's reproductive health project
  - Guided ReproSalud on drug importation issues, including importation mechanisms, customs clearance, and techniques for supplying and distributing reproductive health drugs
- Municipality of Magdalena del Mar, to implement a pilot health education program at the primary school level

- Provided materials and a framework for the pilot implementation of the Rational Drug Use in Schools (URMES) education program in eight public schools in the municipality of Magdalena del Mar

Acknowledgments

Econ. Maria Angelica Borneck, USAID
Dr. Bruno Benavides, Project 2000
Dr. Manuel Izaguirre, DIGEMID
Dr. Hugo Oblitas, Project 2000

Directors of Hospitals and Members of Hospital Pharmacology Committees
Members of Regional Pharmacology Committees, especially
- Lourdes Armas, Trujillo
- Petronila Castro, Ica
- Rejis García, Hipólito Unanue Hospital
- José Alvites, Director, Hipólito Unanue Hospital
- Rubén Orcada, Chosica Hospital
- Alberto Reátegui, DIGEMID
- Frank Lazarte
- Josefa López, Director of ProVida

Senior Program Assistants of RPM
- Inga Adams
- Mehreen Butt

Acronyms

CARE	Cooperative for Assistance and Relief Everywhere, Inc.
CBO	community-based organization
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas [General Directorate of Drugs and Medical Supplies]
DIREMID	Dirección Regional de Medicamentos, Insumos y Drogas [Regional Directorate of Drugs and Medical Supplies]
HF	hospital formulary
INVEC-2	Inventory Control and Management Software, second edition
MMR	Movimiento Manuela Ramos [NGO operating ReproSalud]
MOH	Ministry of Health
MTP	Monitoring-Training-Planning
NDF	national drug formulary
NGO	nongovernmental organization
P&T	pharmacology and therapeutics [committee]
PACFARM	Programa de Administración Compartida de Fármacos [Program for Shared Administration of Pharmaceuticals]
PAR	Programa de Apoyo a la Reforma del Sector Salud [World Bank]
RDF	revolving drug fund
RDU	rational drug use
RH	reproductive health
RPM	Rational Pharmaceutical Management [Project]
STG	standard treatment guideline
TA	technical assistance
URMES	Uso Racional de Medicamentos en Escuelas Secundarias [Rational Drug Use in Schools]
URMH	uso racional de medicamentos [rational drug use]
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development

Program Overview

From 1996 to 1997, USAID/Peru allocated a total of $499,000 in field support funds to RPM. RPM assistance in Peru began in mid-1996 with an assessment and planning visit by the RPM Assistant Director. The Peru country work plan was developed as result, which identified eight areas of involvement with three principal counterparts. RPM programming was launched in the second half of 1997. USAID's priority for RPM work in Peru was to provide assistance to—

- DIGEMID, the MOH's Directorate of Drugs and Medical Supplies
- Project 2000, to improve pharmaceutical management and rational drug use in MOH hospitals supported by the USAID Mission
- ReproSalud, USAID/Peru's reproductive health project
- Magdalena del Mar, to apply RPM's Rational Drug Use in Schools program

Primary Collaborators

DIGEMID

In the early nineties, DIGEMID established a decentralized drug supply system, PACFARM, with regional purchasing and supply centers to sell drugs to MOH ambulatory units. These units, in turn, apply a modest markup, sell the drugs to patients, and repurchase drugs from PACFARM. In 1996, RPM was asked to assist the design of a national directive to formalize the PACFARM revolving drug funds. Then, in 1997, DIGEMID requested specific RPM assistance in the development and implementation of regional and national drug formularies and the national standard treatment guidelines.

Project 2000

Project 2000 is a major USAID/Peru initiative to strengthen the Ministry of Health's maternal-child health services. Project 2000 has focused on improving the quality of obstetric and perinatal service in 18 regional and national hospitals. These "centers of excellence" then train service providers from secondary hospitals and primary care facilities. In 1998, when Project 2000 learned of the NDF that was developed with DIGEMID, Project 2000 requested that RPM support the development and implementation of hospital formularies to improve drug management and use in the project's 18 hospitals. This number grew to include 21 hospitals. Once the rational drug use activities were completed in the initial hospitals in 1999, they were to be expanded to more than 100 other facilities.

ReproSalud

ReproSalud is operated by a local nongovernmental organization (NGO), *Movimiento Manuela Ramos* (MMR), which supports community-based organizations (CBOs) in promoting reproductive health (RH) in remote rural areas. RPM assisted MMR to design a medical service and drug delivery system based on local service providers and on imported RH drugs. Over-the-counter drugs were to be supplied from local service provider units to CBOs with revolving drug funds (RDFs) to maintain drug supplies and sell drugs to members, using profits to defray drug costs for indigents.

Magdalena del Mar

In the latter half of 1999, in response to an initiative by the municipality of Magdalena del Mar in metropolitan Lima and with support from Health Action International, RPM assisted with the pilot implementation of the Rational Drug Use in Schools (URMES) program in eight public schools. URMES is a modular health education program that teachers and community volunteers can implement in schools. RPM designed and applied URMES in Ecuador. Each URMES module covers four aspects of a health condition: cause, symptoms, prevention, and treatment. In 1999 RPM worked with eight pilot schools in Magdalena del Mar to apply three of the eight URMES modules.

Objectives

Since 1996, RPM's general objectives in Peru have been to—

1. Support development and implementation of national, regional, and hospital-level drug formularies and standard treatment guidelines

2. Improve drug management in MOH hospitals and health centers

3. Assist ReproSalud to develop systems to import and distribute RH drugs and to formalize and structure revolving drug funds

4. Assist ReproSalud to build rational drug use into CBO responses to priority RH problems

5. Apply a pilot URMES program in Magdalena del Mar

Implementation Strategy

The RPM strategy in Peru was to help counterparts to implement their programs using RPM's Monitoring-Training-Planning (MTP) methodology. This tool for program implementation and training has been useful to ministries of health, NGOs, and health-service providers in many countries. The approach was well suited to the decentralized drug management structure of the

MOH, Project 2000, and ReproSalud. The principles of the MTP tool, summarized at right, were easily applied to the Peruvian health system.

Principles of the MTP Methodology

1. Stepwise implementation, usually through monthly meetings
2. Detailed planning so expectations and materials are clear
3. Specific products or goals for each meeting
4. Recognize efforts of participants
5. Participatory
6. Group supervision
7. Short meetings
8. Adaptable to different settings

The principles that underlie the MTP tool informed much of RPM's work in Peru. The first principle is that the program is continuous, stepwise, and implemented in a structured fashion. Second, every step to implement the program is planned out in advance and detailed in the instructions—no guesswork, no improvisation. Third, the programs lead to concrete products that are shared and exhibited among peers. Fourth, since most MTP participants are volunteers who often don't have much time to dedicate, the institution should recognize their efforts and thank them. Fifth, work is spread among the team of participants so that everyone takes part and no one person is left with all of the responsibilities. Sixth, supervision by all participants of each other's responsibilities and tasks increases accountability and improves problem-solving skills. Seventh, MTP sessions must be consistently short and punctual. Therefore volunteers are asked to devote only a couple of half days or evenings per month for short, prompt meetings. Finally, the materials and approach allow for adaptation to the particular needs of each locale.

In addition to designing and applying the MTP tool, RPM provided direct technical assistance and informational materials on drug management to collaborators and interested parties.

Major Activities

In carrying out the implementation strategy, RPM conducted the following major activities:

- Provided technical assistance and material resources to DIGEMID to design and produce the National Drug Formulary (NDF)
- Organized systematic implementation of the NDF through Regional Drug Directorates as well as regional and hospital-level pharmacology and therapeutics (P&T) committees using the MTP methodology
- Supported DIGEMID with technical assistance, equipment, and supplies to develop the national standard treatment guidelines
- Designed and implemented a self-sustaining system for Project 2000 and the MOH to improve hospital drug management, including indicator-based evaluation, using MTP
- Guided ReproSalud on importation (including registration and customs clearance) and distribution of RH drugs

- Worked with ReproSalud and CBOs on the incorporation of drug management activities into the RH efforts using MTP

Chronological Activity Highlights

RPM assistance in Peru began in mid-1996 with an assessment and planning visit by the RPM Assistant Director. The first Peru country work plan that was developed identified eight areas of involvement with RPM's four principal counterparts: DIGEMID, Project 2000, ReproSalud, and the SHIP project. The activities were adapted over time to the actual needs of the organizations, NGOs, MOH, and the USAID/Peru Mission.

The SHIP activities planned for at the start of RPM programming in Peru were never funded and did not take place. The SHIP North and South projects were USAID-funded contracts with University Research Corporation and CARE (Cooperative for Assistance and Relief Everywhere, Inc.), which included systems for the distribution and rational use of pharmaceuticals in health centers in Chiclayo and Puno health regions. RPM was asked to assist with training in drug selection, rational prescribing, and cost-efficient therapies as well as install the RPM inventory control software, INVEC-2. A further activity to develop a manual for revolving drug funds was discussed.

Activity highlights for each of the three main RPM collaborators can be found on the following pages.

DIGEMID Activity Highlights

As work with DIGEMID evolved and the NDF was officially completed in mid-1998, RPM proposed an implementation strategy to achieve adoption and application of the NDF in hospitals supported by Project 2000. The MTP methodology was adapted to the Peruvian hospital context and was applied by hospital directors and P&T committees in 12 health regions.

Table 1. DIGEMID Activity Timeline

Date	Activity
June and July 1996	Preliminary visit to define technical assistance needs and prepare RPM work plan.
June 1997	Assistance to DIGEMID on a directive for administration of revolving drug funds.
August 1997	Assistance to DIGEMID to implement and supervise the drug revolving funds. Prepare scope of work to support ReproSalud drug importation, distribution, and resupply. Initial discussions with Project 2000 to improve hospital drug management.
April 1998	Technical assistance and material resources to plan and execute a workshop with members of regional P&T committees from 34 health regions to design and produce the National Drug Formulary.

Table 1. DIGEMID Activity Timeline (cont'd.)

May 1998	Technical assistance in planning and execution of a workshop to introduce the MTP methodology to hospital directors and members of 20 hospital P&T committees. Technical assistance to Chosica Hospital to develop tutorial for MTP module on P&T for hospital directors and members of 21 hospital P&T committees.
July 1998	Technical assistance to Chosica Hospital to plan and execute a workshop to apply the Drug Selection MTP module for hospital directors and members of 21 hospital P&T committees.
November 1998	Technical assistance and material resources to plan and execute a workshop for members of 34 regional P&T committees to introduce and adopt the NDF.
December 1998	Technical assistance to develop guidelines for elaboration of drug formularies for health centers.
January–December 1999	Continuing technical assistance, equipment, and supplies to develop the national standard treatment guidelines.

Project 2000 Activity Highlights

Table 2. Project 2000 Activity Timeline

Date	Activity
May 1998	Technical assistance to plan and execute a workshop to introduce the MTP methodology to hospital directors and members of P&T committees of Project 2000 hospitals. Technical assistance to Chosica Hospital to develop tutorial for first MTP module for hospital directors and members of P&T committees.
July 1998	Technical assistance to Chosica Hospital to plan and execute a workshop to develop MTP tutorial for Drugs Selection Module for hospital directors and members of 21 hospital P&T committees.
September 1998	Technical assistance to Belen Hospital of Trujillo to plan and execute the MTP session on Prescribing Practices for hospital directors, members of 21 hospital P&T committees, and members of 12 regional P&T committees.
November 1998	Technical assistance to Hipolito Unanue Hospital of Lima to plan and execute a workshop to apply MTP module on Hospital Pharmacy for hospital directors, members of 21 P&T committees, pharmacy chiefs, and members of 12 regional P&T committees.
December 1998	Technical assistance to plan and execute a workshop to address the resistance by doctors and prescribers to the use of STGs and other rational drug use methods in hospitals. A workshop was conducted for hospital directors, members of 21 hospital P&T committees, and members of 12 regional P&T committees. Initiation of MTP module on Evaluation of Drug Management by Indicators for hospital directors, members of 21 hospital P&T committees and members of 12 regional P&T committees.
April 1999	Technical assistance to hospital directors and members of 21 hospital P&T committees to plan and execute a workshop to show results of indicator-based evaluation to MOH authorities.
May 1999	Technical assistance to plan and execute a workshop to show changes achieved in hospital pharmacies. Initiate MTP modules on P&T Committee Management and Patient Education for hospital directors, members of 21 hospital P&T committees, and members of 12 regional P&T committees.
June 1999	Technical assistance for monitoring RPM implementation and second and third self-evaluation using indicators in 21 hospitals.

Table 2. Project 2000 Activity Timeline (cont'd.)

May–June 1999	Technical assistance to regional P&T committee for rational drug use in hospitals (URMH) program implementation in all Ica Health Centers.
January–July 1999	Technical assistance to regional P&T committee for URMH implementation in all Ucayali Health Centers.
December 1998–August 1999	Technical assistance to regional P&T committee for URMH implementation in all San Martin Health Centers.

ReproSalud Project Activity Highlights

An RH drug purchase for ReproSalud had been negotiated in 1995–96 by USAID/Peru before RPM was called on to advise on the importation, distribution, and cost-recovery of the drugs. A number of discussions were held with USAID and MMR to develop a plan to deal with the RH drugs through Peruvian institutions such as PRISMA (to clear customs and manage paperwork for the donation to the MOH), DIGEMID-PACFARM (to absorb the donated drugs into the national distribution system and recover costs through the existing revolving drug funds), and regional health directorates (to ensure that RH services were provided in response to CBO needs). The following time line shows the sequence of activities initiated in 1997, which were finally halted in December 1998 because MMR had decided to eliminate drug provision from an already ambitious project agenda.

Table 3. ReproSalud Activity Timeline

Date	*Activity*
August 1997	Prepare scope of work and budget to support ReproSalud drug importation, distribution, and resupply.
April 1998	Assist MMR to complete importation of RH drugs and plan to use PACFARM infrastructure to achieve distribution and cost-recovery in MOH health centers and posts in project sites. Meeting to involve local NGO PRISMA for customs clearances.
May 1998	Design MTP modules to organize drug use by CBOs with assistance from MOH units in the area.
July 1998	Technical assistance to design and test MTP module in Puno with regional MMR office and CBO.
November 1998	Draft clauses for agreements between regional MMR and MOH offices to include provision and use of RH drugs in MOH service facilities. Plan closeout of support to ReproSalud.
December 1998	Technical assistance to prepare checklist for drug management considerations to be incorporated into agreements between MMR and regional MOH offices to ensure availability and appropriate use of RH drugs. (Incomplete.)

Challenges Facing Program Implementation

At the time that RPM began to discuss potential activities in Peru, DIGEMID and Project 2000 each conducted an assessment of the national drug management situation. DIGEMID conducted an assessment using RPM's pharmaceutical sector assessment tool. Project 2000 contracted a

396

local NGO, ProVida, to conduct an assessment of Project 2000 hospitals. ProVida did not use the RPM assessment methodology.

It was clear from the two independent assessments that there were several pharmaceutical sector issues that RPM programming could address, including the following:

- Hospital P&T committees did not exist or were inactive in the hospitals surveyed.
- Hospital formularies, where they existed, were limited to informal lists of most frequently procured drugs.
- There were serious drug stocking and dispensing problems.
- There were no formal STGs in the hospitals, and only some Project 2000 hospitals with maternal-child health services had limited STGs for specific primary child-care conditions.

Furthermore, the MMR, which operated USAID's ReproSalud project, had a profound distrust of MOH services. MOH services, specifically hospital and primary care facilities, were seen by ReproSalud as nonresponsive to the RH needs of CBO members. MMR identified obstacles such as culturally inappropriate attention, lack of medicines, absence of service providers, and the like. Thus, MOH facilities were not seen as acceptable service providers or suppliers of RH drugs to CBO members.

In addition to these challenges, the MTP methodology was unknown in Peru. RPM's collaborators, many accustomed to lengthy one-time workshops, were hesitant to commit to a long-term training and implementation program. The basic RPM strategy needed to be explained to stakeholders and counterparts and tested by them in order to demonstrate its effectiveness.

Program Accomplishments

This section on program accomplishments begins with a summary of results and achievements from RPM's collaboration with DIGEMID, Project 2000, and ReproSalud, followed by a general discussion of overall improvements and trends in drug management in Peru.

RPM Collaboration with DIGEMID

Created a National Drug Formulary

RPM assisted DIGEMID in the production and publication of the National Drug Formulary (NDF) by convening 21 Peruvian experts to participate and provide clinical input during the

NDF Workshop in April 1998. In addition to technical support, RPM provided financial assistance to hold the workshop. Because of the need to process drug monographs and the text of the NDF, RPM provided a computer to DIGEMID. The NDF was officially published in October 1998 and rules for regional and local implementation of the NDF were issued by DIGEMID in November of that year.

Developed Standard Treatment Guidelines

RPM assisted DIGEMID to develop and draft standard treatment guidelines, *Guía Farmacoterapéutico*, to be published in early 2000. RPM provided an expert consultant to assist in the STG editorial process and contributed a photocopying machine, paper, and other materials. The STG document will help prescribers to standardize prescribing practices for the 50 or so most common conditions seen in hospitals. It will also focus rational drug use on the most cost-effective therapies.

RPM Collaboration with Project 2000

Implemented the National Drug Formulary in Hospitals

While RPM helped DIGEMID develop the NDF, the actual implementation of the new formulary standards was conducted in collaboration with Project 2000. At the time that RPM worked with DIGEMID on the NDF, Project 2000 became interested in incorporating rational drug use techniques into its programming in 18 hospitals around the country. The new NDF was seen as a vehicle for launching rational drug use activities. The implementation used DIGEMID's NDF guidelines and RPM's MTP methodology to introduce the NDF and have formularies adopted as routine practice in the Project 2000 hospitals. As a result, all participating hospitals developed and published their own drug formularies. This accomplishment was supported by new policies implemented by the hospital director in each hospital, making NDF use officially binding for prescribers. In the end, 21 regional and national hospitals around Peru are applying the NDF to improve drug selection, prescribing, and use practices.

Produced MTP Modules for Drug Management in Hospitals

In addition to implementing the NDF in 21 hospitals, RPM worked with Project 2000 to improve other aspects of drug management and rational use. For eight months RPM helped apply MTP modules or rational drug use in hospitals (URMH in Spanish), including P&T Committee, Drug Selection, Hospital Pharmacy, and Good Prescribing Practices modules. A full set of the MTP training modules is available on request (see Annex 1 of this report). For further explanation of the MTP methodology, please refer to the Implementation Strategy section of this report.

The following are key accomplishments of RPM's drug management work with Project 2000 hospitals and staff.

- About 800 people who manage drugs in 21 national hospitals participated in the project activities over a period of about 20 months.

- The key elements of drug management (such as selection, supply, distribution, and use) were all addressed in a structured, participatory, and sequential fashion.

- Eight MTP modules were designed, tested, revised, and applied to implement the rational drug use training and implementation program (see Annex 1).

- Hospitals produced concrete, measurable products in a very short time. Results included the development and adoption of hospital formularies and treatment protocols and increased use of generic names (see the Discussion of Outcomes for Drug Management in Peru section below). The products were evaluated by the hospitals themselves using eight self-assessment indicators. Results of the self-assessments were posted on the MOH's Rational Drug Use Web site. (See Annex 1.)

- Regional P&T committees have adopted the responsibility for continuing to support drug management at the regional and provincial hospitals. Recently developed workplans indicate that the P&T committees will continue to apply MTP modules to improve drug management in primary care facilities.

As mentioned above, once the modules were implemented in each Project 2000 hospital, the hospitals conducted a self-evaluation using eight of the RPM rapid drug management assessment indicators. These indicators included the following:

- Existence of a hospital P&T committee
- Percentage of drugs out of stock
- Percentage of drugs prescribed from the National Drug Formulary
- Percentage of prescribed drugs that are actually dispensed
- Percentage of patients who are exonerated of charges for the purchase of drugs
- Percentage of patients prescribed antibiotics
- Percentage of patients prescribed injections
- Percentage of drugs prescribed using generic names

Sponsored a Drug Information Needs Assessment

RPM sponsored a study of the need for drug information in participating Project 2000 hospitals. Once levels of need were established, RPM commissioned the design of an electronic drug information system for use by the different hospitals and regions. Ideally, this system can be expanded for use nationwide. DIGEMID has assumed responsibility and management of the drug information system. (See Annex 1 concerning availability of the study and an overview of the system that was designed to address the drug information needs.)

Launched a Rational Drug Use Web Page

Project 2000 and RPM collaborated to develop and launch a Web page supporting rational drug use activities. RPM designed the Web page in coordination with the MOH's Institutional Development Office. The Web page contains the following elements:

- Description and content of MTP modules for URMH
- Frequently asked questions about URMH
- Indicators of drug use and management by hospital and quarter
- Subscription to URMH electronic conference

At the end of the RPM Peru project, the Web page was turned over to DIGEMID. DIGEMID will provide ongoing technical support and plans to launch the Web page on the Peru MOH Web site. As of December 30, 1999, the URL for the page was *http://www.lanet.com.pe/urm.* After the MOH adopts the site, the URL will be *http://www.minsa.gob.pe/urm.*

RPM Collaboration with ReproSalud

RPM's assistance to ReproSalud achieved results primarily in the policy and operational areas. In the early 1990s, DIGEMID established a decentralized drug supply system, PACFARM, with regional purchasing and supply centers to sell drugs to MOH ambulatory units. These units, in turn, apply a modest markup, sell the drugs to patients, and repurchase drugs from PACFARM. At the time that DIGEMID was developing the PACFARM program, USAID planned to import drugs for use by ReproSalud facilities. PACFARM's revolving drug fund program appealed to the ReproSalud program, managed by the local NGO *Movimiento Manuela Ramos* as it researched methods to manage the drug donation. For this reason, MMR asked RPM to assist in the design of a national directive to formalize the PACFARM revolving drug funds. To assist in the design of this operation, RPM prepared recommendations on drug importation mechanisms, customs clearance, and donation of RH drugs to PACFARM.

RPM helped MMR design a revolving account mechanism so that drugs could be withdrawn from the PACFARM system at MOH units. Under the plan, CBO members able to pay for drugs were to be charged by the MOH facility. Those unable to pay would receive drugs at reduced prices. RPM helped define the drug management roles for the regional MMR offices and the MOH services and agreements were drafted and signed on the basis of these definitions. As a result, MMR and MOH regional offices have service provision agreements to benefit CBO members with RH drugs and other services.

In the end, USAID did not import the drugs, and the revolving drug fund program was never launched. However, the process of planning for the drugs helped ReproSalud and participating CBOs incorporate drug management issues into their routine responsibilities. The MTP methodology was introduced to one ReproSalud CBO in an attempt to create a system in support of the appropriate use of drugs. MMR adopted certain aspects of the MTP methodology but found that it did not completely respond to MMR's training and implementation approach.

Drug Use Education in Schools (URMES)

In the latter half of 1999, in response to an initiative by the municipality of Magdalena del Mar in metropolitan Lima and with support from Health Action International, RPM assisted with the pilot implementation of the URMES program in eight public schools.

URMES is a modular health education program that teachers and community volunteers can implement in schools. RPM designed and applied URMES in Ecuador. Each URMES module covers four aspects of a health condition: cause, symptoms, prevention, and treatment. In practice, one module is applied each month, and the modules address colds, diarrhea, scabies, malnutrition, parasitism, and anemia. Implementation follows a four-hour MTP session in which teachers review their experience with the previous module, learn about the four key aspects of the illness and how to use teaching materials, and then plan activities to apply the module within various subjects: science, language, arithmetic, and the like. (For further explanation of the MTP methodology please refer to the Implementation Strategy section of this report.)

In 1999 RPM worked with eight pilot schools in Magdalena del Mar to apply three of the eight URMES modules. The municipality of Magdalena del Mar evaluated the pilot program and found improvements in students' and teachers' knowledge of the prevention and treatment of health conditions. It also identified widespread enthusiasm for the program. The results of the evaluation were sufficiently strong and positive that Magdalena del Mar has approved a policy to implement all of the URMES modules throughout the municipality during the 2000–2001 school year. The United Nations Children's Fund (UNICEF) and USAID have both offered support for the program.

Discussion of Outcomes for Drug Management in Peru

This section presents a discussion of some of the general outcomes for drug management of RPM's activities in Peru. The outcomes are grouped by drug management issues, specifically availability, rational use, qualitative improvements, and program sustainability.

Much of the information presented below is based on several drug management assessments conducted before and while RPM was active in Peru. First, DIGEMID evaluated the drug management situation in Peru[1] using RPM's rapid assessment methodology. The study was carried out in 1996 in 20 MOH facilities in four health regions. The facilities studied included hospitals, health centers, and health posts. The assessment detected serious problems in both drug logistics and rational use.

In 1998, RPM began working with Project 2000 hospitals to improve rational drug use techniques via the MTP process. In March 1999, 21 Project 2000 hospitals conducted self-assessments, with each hospital using the same set of drug management indicators. In October 1999, 9 of the 21 hospitals conducted follow-up assessments.

[1] *Evaluación de la Situación de Medicamentos en el Perú.* DIGEMID, Ministerio de Salud, Lima 1997.

Sample baseline data from the 1996 DIGEMID assessment are presented in Tables 1 and 3 below. Data from the two 1999 Project 2000 self-assessments are found in Tables 2 and 4.

Drug Availability

Two summary indicators of drug availability from the 1996 DIGEMID study were—

Average percent of a set of 40 tracer drugs available in service facilities. This indicator is intended to show the availability of drugs determined to be essential for operation of the facility in order to treat the most prevalent and/or therapeutically important conditions.

Percent of drugs prescribed actually dispensed. This indicator measures the availability of drugs and the ability of the health facilities to meet the pharmaceutical needs of their users.

The data collected by DIGEMID on these two indicators are presented in Table 4.

Table 4. Summary Indicators of Drug Availability in Peruvian Health Facilities, 1996

Indicator	Hospitals	Centers	Posts
Average percent of a set of 40 tracer drugs available in service facilities	63	74	58
Percent of drugs prescribed actually dispensed	38	57	40

According to Table 4, less than two-thirds of the 40 tracer drugs were available in hospitals. Such a low level of availability indicated an inability to properly treat common illnesses. In addition, only two-fifths of prescribed drugs were actually dispensed by the hospital pharmacy, indicating that prescribed drugs were probably not available in the pharmacy. These findings were marginally better in health centers, but the levels in health posts were essentially the same as in hospitals. Combined they show limited drug availability among the health facilities studied.

As mentioned above, in March and October 1999, hospitals participating in Project 2000's rational drug use program conducted similar drug management self-assessments. The findings for the same indicators, as reported in March (by 21 hospitals) and October 1999 (by 9 hospitals), are summarized in Table 5:

Table 5. Indicators of Drug Availability in Project 2000 Hospitals, 1999

Indicator	March (21 hospitals)	October (9 hospitals)
Average percent of a set of 40 tracer drugs available in service facilities	89	90
Percent of drugs prescribed actually dispensed	73	78

The data reported by Project 2000 hospitals indicated a high level of availability in hospitals. Table 5 shows that by March 1999, after approximately eight months of participation in the URMH program, the availability of 40 tracer drugs in the 21 hospitals was 20 percentage points higher than the sample of hospitals in the DIGEMID study in 1996. The high level of availability found in March 1999 was unchanged six months later in a subset of 9 hospitals. It is important to note that the 1996 DIGEMID assessment and the two sets of self-assessments were not conducted in the same hospitals. Therefore, direct comparisons cannot be made. However, the DIGEMID assessment, which studied several types of facilities, was considered a representative "snapshot" of the drug availability situation in the country as a whole in 1996.

For drugs actually dispensed, by eight months into the program, 21 hospitals were dispensing 73% of drugs prescribed, which shows significant drug management capacity within the hospitals. This indicator increased to 78% in the subset of nine hospitals in October 1999. The 1996 pre-RPM assessment by DIGEMID found that DIGEMID hospitals were dispensing only 38% of drugs prescribed.

An additional indicator, the *percent of drugs in the hospital pharmacy not present on the hospital formulary,* was used by Project 2000 hospitals. It measures how well hospitals are eliminating drugs that are not on the hospital's formulary list (or nonessential drugs) from stock. This indicator was 29% for 21 hospitals in March 1999 and 24% for 9 hospitals in October 1999, suggesting that participating hospitals are increasingly eliminating nonessential drugs from their inventories.

Though the DIGEMID assessment was conducted in a different sample of hospitals from those in the Project 2000 orbit, the combined results suggest a tendency toward improved drug availability.

Rational Drug Use

In addition to drug availability, the 1996 DIGEMID study looked at several rational drug use indicators. In 1996, DIGEMID reviewed the following:

- *Percent of drugs prescribed by generic name,* since prescribing by generic name helps control costs
- *Percent of drugs prescribed from the national Essential Drugs List (EDL),* which contributes to cost control and proper prescribing and use practices

The results for rational drug use from the 1996 DIGEMID study are shown in Table 6.

Table 6. Summary Indicators of Drug Use in Peruvian Health Facilities, 1996

Indicator	Hospitals	Centers	Posts
Percent of drugs prescribed by generic name	31	58	53
Percent of drugs prescribed from EDL	45	63	65

The results showed that in hospitals, less than one-third of drugs were prescribed using the generic name, meaning that two-thirds are prescribed by commercial, or brand, name. In addition, in the hospitals surveyed, less than half of drugs prescribed are listed on the national EDL, meaning that more than half are not authorized by the MOH for prescription in public facilities.

These same indicators were measured in the self-assessment conducted by the 21 Project 2000 hospitals. Results reported in March 1999, after six months of the program, and in October 1999 suggest improvements in rational drug use, as shown in Table 7.

Table 7. Indicators of Rational Drug Use in Project 2000 Hospitals, 1999

Indicator	March (21 hospitals)	October (9 hospitals)
Percent of drugs prescribed by generic name	64	75
Percent of drugs prescribed from EDL	73	81

Table 7 reveals that in March 1999, after six months in the rational drug use training program, the 21 hospitals prescribed 64 percent of all drugs by generic name. In October 1999, seven months later, this figure had increased to 75 percent. When compared, these figures indicate improvement in rational drug use practices among the hospitals studied.

Findings for the second rational drug use indicator, percent of drugs prescribed using the EDL, also show improvement over the seven months. While hospitals prescribed 73 percent of drugs from the EDL in March 1999, by October 1999, with 13 months total of RPM programming, prescribers had improved this figure to 81 percent.

The March 1999 figures indicate rational drug use levels about 30 percentage points higher than the 1996 DIGEMID figures. By October 1999, a subset of nine Project 2000 hospitals had achieved reports of 75 percent or more for both indicators, an increase of about 40 percentage points over the 1996 DIGEMID findings. This suggests that hospitals participating in the Project 2000 program exercise better prescribing practices than those that had not yet received RPM programming and that drug use practices improved over time.

RPM also reviewed some additional rational drug use indicators, specifically the development of P&T committees and the use of drug formularies. As mentioned in the section Challenges Facing Implementation, prior to RPM programming—

404

- Hospital P&T committees did not exist or were inactive in the hospitals surveyed.
- Hospital formularies, where they existed, were limited to informal lists of most frequently procured drugs.

By December 1999, at the end of the RPM Project, all of the participating Project 2000 hospitals had active P&T committees and officially sanctioned hospital formularies.

Qualitative Improvements

Some aspects of drug management in hospital pharmacies have reportedly been qualitatively improved. Using the MTP module structure, RPM assigned pharmacy personnel the task of developing pharmacy improvement plans and provided the comparative information to accomplish the task. As a result, most of the Project 2000 hospitals have developed pharmacy improvement plans that include specific structural and functional changes. For example, the Yarinacocha Maternal-Child Hospital began to build a new pharmacy with improved functionality and the Hipolito Unanue Hospital pharmacy opened a drug dispensary in the emergency room.

In addition, hospitals have begun to procure drugs based on morbidity profiles rather than solely historical consumption. Drug storage has been consolidated in the hospital pharmacy following appropriate technical and storage standards. Drug distribution, control, dispensing, and information provision to patients have also been standardized using guidelines for the organization and operation of hospital pharmacies. RPM jointly developed these standards with the hospitals, in the absence of such norms from the central MOH.

Program Sustainability

The following facts support the sustainability of RPM project activities in Peru:

1. Hospital personnel have stated that they consider the URMH program to be their own because the MTP methodology lets them design and manage the drug management improvement process based on their own institutional situation and goals.
2. P&T committees have become important, recognized leaders in drug management in most of the hospitals, especially in the development and maintenance of hospital formularies. This suggests that their new role and expertise will continue to be utilized after the end of the RPM Project.
3. Regional P&T committees have developed work plans for applying MTP drug management modules in secondary health services (small hospitals, health centers, and posts) after the end of the RPM Project in Peru.
4. The revolving drug funds that were implemented in most of the Project 2000 hospitals allow the hospitals to maintain and increase their financial resources and are extremely

popular with hospital management. This institutional support indicates that the RDFs will remain in place after the end of RPM programming.

5. The indicator-based assessments of key drug management and rational drug use functions in hospitals have been incorporated into a popular Web page. Each participating hospital measures the indicators periodically and submits the results to the Web page. After viewing the Web page and assessing its benefits, a large teaching hospital not originally in the URMH (Hospital Loayza) recently decided to participate, apply the URMH training modules, and submit information to the Web page. The Web page is set up to handle 21 hospitals, but can easily be expanded, with MOH approval, to include many additional hospitals.

6. DIGEMID has stated that it will continue to promote the use of MTP modules to expand the drug management training program to other regions. A formal agreement between DIGEMID and Project 2000 has been drafted to this effect.

7. Two World Bank Peru projects have declared their intent to apply the MTP drug management modules in new sites and regions around the country.

8. The new National Drug Formulary with which RPM assisted has been officially published and distributed to all MOH facilities, where it is being applied to improve drug selection and use.

9. The national standard treatment guidelines are nearly completed and, once published and distributed to all MOH facilities, will be a strong stimulus for institutionalizing rational drug use.

10. The World Bank's Basic Health and Nutrition Project is negotiating with MSH to adapt and apply the MTP drug management modules in eight additional health regions.

Activities Not Completed

The following activities were included in work plans but were not completed.

1. USAID planned to import drugs for use by ReproSalud facilities. PACFARM's revolving drug fund program appealed to the ReproSalud program, managed by the local NGO *Movimiento Manuela Ramos*, as it researched methods to manage the drug donation. For this reason, MMR asked RPM to assist in the design of a national directive to formalize the PACFARM revolving drug funds. RPM helped MMR design a revolving account mechanism so that drugs could be withdrawn from the PACFARM system at MOH units. In the end, USAID did not import the drugs, and the revolving drug fund program was never launched. However, the process of planning for the drugs helped ReproSalud and

participating CBOs incorporate drug management issues into their routine responsibilities.

2. The SHIP activities were never funded and did not take place. The SHIP North and South projects were USAID-funded contracts with University Research Corporation and CARE, which included systems for the distribution and rational use of pharmaceuticals in health centers in Chiclayo and Puno health regions. RPM was asked to assist with training in drug selection, rational prescribing, and cost-efficient therapies as well as install the RPM inventory control software, INVEC-2. A further activity was discussed, specifically to develop a manual for revolving drug funds.

3. The MTP module on Drug Information was not implemented in the Project 2000 hospitals. Project 2000 management requested that this activity be delayed until February 2000, after the end of RPM programming.

4. With respect to ReproSalud, RPM did not complete the development of the drug management checklist for MMR agreements with the MOH. The checklist would help ensure adequate RH drug supplies in MMR service facilities. MMR decided in November 1998 to suspend drug-related work in the ReproSalud project and RPM was so advised in December, halting further development of the checklist.

Likely Needs at End of Project

Rational drug use programming, including implementation of the National Formulary and standard treatment guidelines, should be expanded to the rest of the country under the auspices of DIGEMID (possibly with financial support from PAR, a World Bank project). Such an effort primarily would be the responsibility of the regional drug directorates (DIREMID) and regional P&T committees, with direct participation and support from regional hospitals. This would follow the organizational example of San Martín, Ucayali, and Ica health regions.

DIGEMID did not issue legal regulations to incorporate P&T committees into the organizational structure of the hospitals and establish revolving drug funds for drug management. These two points represent uncertainty for hospital managers and could cause resistance to adoption of these drug management tools.

Another area that needs support and development is the integration of drug management into the various government-supported insurance schemes, including the school and maternal insurance programs. The former of these vertical programs has been a major impetus for the adoption of generic drugs by Peruvian hospitals. However, the lack of coordination between it, DIGEMID, and PACFARM has led to important discrepancies between the National Formulary and the insurance program's approved drug lists.

Programs supporting improved drug management should be extended to all Project 2000 health establishments and to facilities in the other 22 health regions. Drug management modules were applied in all health centers of San Martín, Ucayali, and Ica health regions under the guidance of the regional hospitals. Similar drug management activities need to be replicated in the rest of the country under auspices of DIGEMID. However, DIGEMID will need financial support, possibly from PAR.

Several other activities were discussed with Project 2000 management for future development as time and financing permit.

1. MTP modules on Hospital Pharmacy Management and Drug Utilization Studies should be designed and implemented.

2. DIGEMID did not issue legal regulations to incorporate P&T committees into the organizational structure of the hospitals and establish revolving drug funds for drug management. These two points represent uncertainty for hospital managers and cause resistance to adoption of these management tools.

3. A software system is needed to support Hospital Pharmacy Management, including point of sale, inventory management, and basic accounting and cash-flow management.

Drug-use education in schools has been shown to improve students', teachers', and parents' knowledge and behavior about diseases. The AVISA-URMES pilot activity in Magdalena del Mar municipality in Lima can be expanded to the rest of the schools in the municipality. As experience is gained, the program would benefit from institutionalization in a national sponsoring institution and promoted through health services of the MOH.

Finally, a management information system is needed to support hospital pharmacy management, including point of sale, inventory management, and basic accounting and cash-flow management.

Lessons Learned

1. To have a strong, positive, and long-term impact, the Peru MOH needs continued support to develop capacity in all aspects of sound drug management systems. This includes capacity building in management support systems and the legal and policy aspects of a functioning drug management system.

2. Experience has amply demonstrated that P&T committees are in many cases mere formalities and often do not fulfill the functions they were set up to do. Since effective P&T committees are so critical in upholding the commitment to rational drug use, they often need training to help them understand their roles and responsibilities. RPM/Peru showed that assigning monthly tasks is a good way to augment their skills and to keep them in operation.

3. Tools are not enough. A rational pharmaceutical management system consists of tools and procedures. RPM/Peru worked with hospitals to build and organize effective drug management systems.

4. Upper management must participate. The hospitals with directors committed to rational drug management are the ones that improved the most.

Annex 1

Three annexes are available upon request to supplement this report.

1. A compendium of eight rational drug use MTP modules used by Project 2000 hospitals.

2. CD-ROM disc with the contents of the Peruvian MOH's Rational Drug Use Web site. Like the Web site, the CD-ROM contains MTP modules, Frequently asked questions, Drug-use indicators for 21 hospitals, and ListServ subscription guidelines.

3. Report on drug information needs in Peruvian hospitals, accompanied by an overview of the information system proposed to address drug information needs.

Poland

Executive Summary

This report is intended to provide detail on the main activity of the Rational Pharmaceutical Management (RPM) Poland Country Program, the U.S. Study Tour on Hospital Formulary Development, as well as serve as its final report.

In August 1995, following discussion with the Mission in Poland, RPM received funding to initiate a country program in rational drug management. The purpose of RPM activity in Poland was to assist local governments in the development of mechanisms for cost-effective delivery of pharmaceuticals to inpatient and outpatient populations as these jurisdictions take on more responsibility for direct delivery of health care and payment for services.

The Harvard University Data for Decision Making (DDM) Project began working on the Strengthening Local Government in Health (SLGH) Project at approximately the same time that RPM was to begin working in Poland. The DDM Project would work in a number of health areas, including contracting for physician services, cost accounting, quality assurance, and planning. Because of potential mutual benefit under the same strategic objective, USAID/Poland suggested that RPM work in coordination with the DDM project and carry out a program of activities for strengthening pharmaceutical management.

The RPM Poland Program consisted of the following activities:

- A planning meeting with the Harvard DDM Poland Project in Boston, Massachusetts, in April 1996
- A reconnaissance visit to Poland in April 1996
- Participation in the Strengthening Local Government in Health: Steering Committee Meeting in Krakow, Poland, in May 1996
- A brainstorming session of RPM staff with the Polish counterpart, Tomasz Bochenek, in Washington, D.C., in August 1996
- A meeting with the Harvard DDM Poland Project in Boston, Massachusetts, in November 1996
- A study tour for Polish participants at the University of Maryland at Baltimore, Washington, D.C., in October 1997

Results of these activities are summarized below; full descriptions can be found in proceedings and other reports issued throughout the life of the project.

The major activity of the RPM Poland Program focused on formulary systems development and implementation in the hospital setting. Although initially it had been hoped that a comprehensive program would be funded and implemented, this did not occur. The Study Tour in Hospital

Formulary Development, held at the University of Maryland at Baltimore, was the final activity of the program. It was successful in introducing the participants to formulary system concepts and providing them with the tools necessary to strengthen or initiate formulary activities in their respective institutions. It is anticipated that the participants will also introduce rational pharmaceutical management concepts to health professionals through the academic and university hospital setting.

Acronyms

ABC	ranking of drugs according to frequency of use and cost
ADR	adverse drug reaction
ASHP	American Society of Health-System Pharmacists
BH	Biernacki Hospital
DDM	Data for Decision Making [Project of Harvard University]
DUR	drug use review or drug utilization review
JU	Jagiellonian University
MIS	management information systems
RPM	Rational Pharmaceutical Management [Project]
SLGH	Strengthening Local Government in Health [Project]
USAID	U.S. Agency for International Development
USP	United States Pharmacopoeia
VEN	ranking of drugs as vital, essential, or nonessential

Background

In August 1995, following discussion with the Mission in Poland, the Rational Pharmaceutical Management (RPM) Project received funding to initiate a country program in rational drug management. As RPM prepared to conduct an assessment in November 1995, however, this trip was called off by USAID/Poland.

The Harvard University Data for Decision Making (DDM) Project began working on the Strengthening Local Government in Health (SLGH) Project at approximately the same time that RPM was to begin working in Poland. The DDM Project would work in a number of health areas, including contracting for physician services, cost accounting, quality assurance, and planning. Because of potential mutual benefit under the same strategic objective, USAID/Poland suggested that RPM work in coordination with the DDM project and carry out a program of activities for strengthening pharmaceutical management.

RPM was asked to participate in the Steering Committee Meeting for the SLGH Project in May 1996 and to present its findings and preliminary recommendations for interventions in the realm of identified drug management problems. Therefore, in April 1996, RPM conducted a brief reconnaissance visit to Poland. Key drug management issues identified were—

- The perceived high cost of drugs
- The gap between the budgetary needs for pharmaceuticals and the ability of the government to meet those needs
- A financing mechanism that adversely affects attempts to implement efficiencies in the management of health care institutions
- A generous publicly funded entitlement program for pharmaceuticals to outpatients in certain population groups or patients with certain diseases
- A lack of systematic information about drug selection, procurement, and use
- Insufficient evaluation and monitoring of prescribing and dispensing (both inpatient and outpatient)

There is a serious gap between actual expenditures and financing of the drug budget at the national level, both inpatient and outpatient. In addition, there is suboptimal coordination between legislation of prescription drug benefits and their implementation at the regional and local levels.

There is a generous publicly funded entitlement program to provide pharmaceuticals to outpatients in certain categories, or for certain diseases. In addition to the three categories of discounts available to certain patient populations, the Ministry of Health recently added another

category of discounted drugs. Unfortunately, no clear analysis of the financial impact of doing so was available.

Drug management information systems (MIS) are seriously lacking at the institutional and local government level, and there is a lack of incentives for implementing them. There were no mechanisms found for reporting expenditures by disease state, drug, or prescriber. A hospital pharmacy director may be responsible for purchasing drug products, but he or she may have no knowledge of the total accounts payable, nor when they will be paid. Without the information an MIS system would provide, such as information about drug consumption and prescribing patterns and their budgetary implications, local governmental units are hampered in their ability to do strategic planning in drug management and to allocate resources objectively.

There is insufficient evaluation and monitoring of prescribing and dispensing (both inpatient and outpatient). Although the concept of formulary systems is known, there are no incentives to implement formularies to improve drug selection and procurement. Efficiencies that might reduce expenditures on the hospital ward, for example, result in a reduced budgetary allocation for the following year, creating a perverse disincentive to introducing cost efficiencies.

There are several undocumented problems, including the lack of appropriate drugs for inpatient use, and inpatient use of drugs purchased outside the hospital by patients' families or through the *refundacja*[1] program. This has resulted in cost-shifting from inpatient to more expensive outpatient categories.

In May 1996, Jagiellonian University in Krakow hosted the Steering Committee Meeting for the Strengthening Local Government in Health (SLGH) Project. Representatives of various national, regional, and local governmental, health administration, and consumer groups participated in the three-day meeting. Jagiellonian University personnel presented findings of the assessments, including the RPM reconnaissance trip in April 1996, and RPM and DDM group leaders presented information on international experience that might be effective in addressing problems in all six areas.

The initial comprehensive work plan was developed to include two phases.

1. The first phase would include defining options for improving drug procurement and drug use decision making.

2. The second phase would include development of interventions, testing, implementation, evaluation, and dissemination of results.

The work plan was based on the assumption that RPM would receive additional funding to be able to carry out both phases. Subsequently, USAID notified RPM that additional funding would not be forthcoming, so alternate work plans were developed for a level of activity that remaining funding could support.

[1] The *refundacja* program is a government-mandated prescription drug benefit program that pays for all or part of the cost of drugs provided to patients with specific diseases or to patients in certain population groups. It has been estimated that up to 90% of the population is eligible for benefits under this program.

416

RPM developed two options to address the issues of cost-effective drug product selection and improving rational prescribing practices. On Jagiellonian University's suggestion, the work plan was developed for Biernacki Hospital in Krakow, which was undergoing the change from public to private ownership, with potentially increased incentives for change. The two options (see Appendix 1) included—

- A Study Tour in Hospital Formulary Development and Drug Utilization Review, to be held in the United States
- An assessment and workshop to be conducted at Biernacki Hospital in Krakow

Subsequently, Polish counterparts selected the option to hold the Study Tour in Hospital Formulary Development and Drug Utilization Review in the United States. Participants were selected from three different types of health care institutions, representing private, regional, and national hospitals, and Jagiellonian University.

Objectives

The purpose of RPM activity in Poland was to assist local governments in the development of mechanisms for cost-effective delivery of pharmaceuticals to inpatient and outpatient populations as these jurisdictions take on more responsibility for direct delivery of health care and payment for services.

There were three USAID/ Poland strategic objectives. RPM activity falls under the third strategic objective: Local government becomes effective, responsive, and accountable.

Constraints

An assessment was planned for November 1995 in Poland; however, that trip was called off by USAID/Poland. Unfortunately, this action deprived RPM of the opportunity to plan and carry out a standard indicator-based assessment. Instead, RPM conducted a brief reconnaissance trip in April 1996 in preparation for the May Steering Committee Meeting.
The initial work plan developed for an RPM Country Program was based on assurances that additional funding would be forthcoming; however, that never materialized. The revised options for RPM work in Poland had to be considerably scaled down.

Working essentially as a component of the SLGH Project provided both pluses and minuses. On the plus side, all parties acknowledged drug management activities as an area that would affect a number of the project component areas, including quality assurance, hospital contracting, cost

analysis, and planning. Full-fledged participation in the SLGH activity might have resulted in significant measurable impact.

Progress to Date

The RPM Poland Program consisted of the following activities:

- A planning meeting with the Harvard DDM Poland Project in Boston, Massachusetts, in April 1996
- A reconnaissance visit to Poland in April 1996
- Participation in the Strengthening Local Government in Health: Steering Committee Meeting in Krakow, Poland, in May 1996
- A brainstorming session of RPM staff with the Polish counterpart, Tomasz Bochenek, in Washington, D.C., in August 1996
- A meeting with the Harvard DDM Poland Project in Boston, Massachusetts, in November 1996
- A study tour for Polish participants at the University of Maryland at Baltimore, Washington, D.C., in October 1997

Reconnaissance Visit

The purpose of the first trip to Poland in April 1996 was to meet with Polish counterparts at Jagiellonian University and then with various officials at the ZOZ,[2] city, and *voivodstvo* levels. Objectives included—

- Developing a working relationship with faculty at the School of Public Health, Collegium Medicum, Jagiellonian University
- Reviewing materials collected to date in the four areas identified by the Harvard DDM Project

[2]The ZOZ is a local integrated health care services unit. This entity usually includes a hospital and outpatient clinics to provide continuity of care. Although it most often corresponds to the *voivodstvo* (local governmental unit analogous to a state), it may provide services to more than one voivodstvo.

- Meeting with decision makers at Krakow Voivodstvo, Leczyca ZOZ, and, if possible, Nowy Sacz Voivodstvo
- Developing a sense of what "drug management" means at all levels
- Developing a list of identified problems in drug management
- Identifying innovative approaches to controlling drug costs
- Identifying individuals and organizations that might be good candidates for collaboration in future activities

Meetings with counterparts from Jagiellonian University and two sites that expressed interest in working with the Pharmaceutical Component of the project were successful. The sites visited provided information that was identified in the objectives for this trip.

Prior to the RPM visit, counterparts from Jagiellonian University had begun data collection from the DDM-identified collaboration sites of Krakow and Suwalki voivodstvos and from the Leczyca ZOZ. Data were abundant relative to hospitals, but very sparse regarding drug management issues. Anecdotal information indicated that problems exist regarding availability of pharmaceuticals, cost accounting, cost-shifting from inpatient to outpatient expense categories, drug selection, prescribing practices, and the refundacja program. Actual data indicate that there is a serious gap between actual expenditures and financing of the drug budget.

Various individuals and organizations have identified drug costs as problematic and have begun to formulate and/or implement innovative strategies designed to reduce drug expenses. Among the individuals interviewed, there is a tendency to look toward the Western European models of health care and health finance. Budgetary, human resource, and technological constraints are cited among the reasons for limited data collection, lax enforcement of regulations and, basically, limited attention to problems in drug management.

Strengthening Local Government in Health Steering Committee Meeting

The purpose of this trip was to take part in the Steering Committee Meeting for the Strengthening Local Government in Health Project, May 7–9, 1996, in Krakow, Poland, organized by the Harvard Data for Decision Making Project. In addition, the trip provided an opportunity to meet with Polish counterparts at Jagiellonian University in Krakow and with USAID/Poland officials.

Objectives of the trip included—

- Reviewing the data collected to date by RPM and Jagiellonian University counterparts and discussing these findings in the context of the meeting

419

- Presenting a session on international experience in dealing with drug management problems identified in Poland
- Meeting and developing a working relationship with the team leaders in the other component areas of the SLGH Project
- Meeting with appropriate officials from SLGH project sites in Poland who have an interest in drug management and might be project sites for the RPM Country Program
- Developing an illustrative RPM Country Program work plan together with Polish counterparts
- Meeting with USAID/Poland officials to present the illustrative work plan
- Attending the First General Project Meeting

The trip was successful in meeting all of its objectives. The format of having the Polish counterparts present the problems and having the group leaders from the United States present international experience and how it might apply to Poland was both an astute political move and very well accepted. The RPM presentation on international experience in dealing with drug management problems was very well accepted and prompted interest from various local participants.

Participation in the meeting also highlighted the unfortunate beginning of the RPM Poland Country Program. RPM was at a definite disadvantage as compared to the other component areas, since there was very little time to assess definitively the problems and sites that might be most amenable to RPM intervention. One of the objectives of the Steering Committee Meeting was to familiarize all of the participants with each component area because project sites would be working in a limited number of technical areas. The U.S. team leaders were to present a sketch of probable activities in their respective areas. Whereas the other SLGH project leaders had been working in Poland for six months before the meeting, USAID/Poland approved a limited RPM reconnaissance trip only in April 1996. Beginning on the same ground floor might have allowed a greater momentum to carry RPM activities forward from the Steering Committee Meeting. For example, rather than meeting interested parties for the first time, RPM might have already developed a work plan and used the opportunity of this gathering to plan concrete steps in specific locations.

Brainstorming Meeting in Arlington, Virginia

RPM technical staff gathered in Arlington on August 8, 1996, in order to discuss the Poland Country Program and to collectively discuss the respective roles of RPM and Jagiellonian University. Tomasz Bochenek, the designated RPM counterpart, was attending a summer program at Harvard University School of Public Health. In order to clarify relevant issues in drug management in Poland, Bochenek was invited to the Management Sciences for Health office in Arlington.

Objectives of the meeting included—

- Identifying the drug management problems
- Identifying possibilities for intervention
- Defining possible outputs
- Structuring the situation analysis
- Identifying sources and types of data to be collected
- Specifying next steps and parties responsible

The meeting was successful in meeting its objectives. Bochenek presented additional data, which had been collected since the last RPM visit to Poland in May 1996. As a result of the discussion, a comprehensive plan emerged that would provide baseline and end-of-project data to evaluate the impact of the RPM interventions in Poland.

The Study Tour in Hospital Formulary Systems Development

Because additional funding was not forthcoming, RPM developed two options to best use the remaining funding. Polish counterparts selected the option for a U.S. Study Tour in Hospital Formulary Systems and Drug Use Review; the study tour took place in October and November 1997. The purpose of the study tour was to present options for development and implementation of hospital formulary development and drug use review and to see how they are applied in the United States to achieve cost-effective drug product selection and use. The two-week study tour included both didactic elements, small group exercises and site visits in the Baltimore and Washington, D.C., areas.

As a result of participating in the study tour, participants would be expected to be able to do the following:

- Describe the role of formularies in the United States in hospitals, other institutions, and third-party payment programs (private insurance and governmental)

- Describe the incentives and disincentives to implementation of a mandatory formulary system in the United States and in Poland, including the effects of various types of health care finance

- Understand the steps to follow in the formulary system development process

- Understand how to gain administrative support for formulary system development

- Describe the composition and role of a Pharmacy and Therapeutics Committee in formulary systems

- Perform a ranking of drugs according to their frequency of use and cost (ABC) or position as vital, essential, or nonessential (VEN), given appropriate data

- Provide specific formulary recommendations when provided with clinical efficacy and cost-of-therapy data

- Understand the drug use review (DUR) process, its role and importance in promoting rational drug prescribing and use

- Describe the general concepts of pharmacoeconomics, including the costs associated with the use of duplicative, unsafe, and ineffective drugs

- Describe an adverse drug reaction (ADR) monitoring program

- Describe the interrelationship among the use of a formulary, an ADR monitoring system, and DUR

- Describe how the three processes above may influence physician prescribing behavior

- List the most useful types of drug information that should be included in a formulary manual

- Understand the role of software programs in the development and maintenance of a formulary system and in collecting and analyzing data needed to make rational drug selection and procurement decisions

Topics that were covered included development of standard treatment guidelines, clinical pharmacy practice, methods of evaluating the effectiveness of these programs, and the use of the formulary in making procurement decisions. The course outline is attached (see Appendix 2).

The objectives of the study tour were met in most regards and exceeded in some. There were four participants (list attached as Appendix 3). Of these, two were physicians and two were pharmacists. One represented Jagiellonian University as an instructor in the Department of Drug Management and Pharmacoeconomics at the School of Public Health. The other three represented hospitals at the national, regional, and local levels. One participant represented the first private hospital in Poland, with approximately 150 beds. Another represented a local integrated health care system (ZOZ) hospital, with approximately 300 beds. The last was a national teaching hospital with about 2,000 beds.
In general, participants had an elementary grasp of what a formulary system is. The study tour provided more in-depth information and allowed participants to see how the system is applied in practice in U.S. hospitals and outpatient settings. It is hoped that this information will be sufficient to adapt this method of cost-effective product selection to their individual institutions. In fact, all three hospitals have initiated various means of controlling drug costs, including—

- The establishment of a drug list

- A list of restricted drugs that can be prescribed only under certain conditions, or by specialists, such as certain antibiotics

- The use of drug budgets by ward

Prior to completion of the study tour, participants prepared action plans for development and implementation of formulary systems in their institutions. These action plans included the following:

- Forming a formulary committee
- Disbanding the current nonfunctioning committee and forming a new committee, including the appropriate clinical and administrative personnel
- Using hospital morbidity and drug consumption data to perform ABC and VEN analyses
- Identifying drug categories that account for most of the hospital drug budget and performing those drug therapeutic class reviews first
- Making arrangements for clinical pharmacology consultation to the committee
- Evaluating whether nonessential, duplicative, or ineffective drugs are currently in stock at the hospital
- Reviewing current mechanisms to see if they encourage or discourage cost-efficiencies and initiate corrections, if necessary
- Instituting mechanisms for checking drug interactions and incompatibilities of concurrently administered intravenous medications
- Incorporating rational pharmaceutical management principles into the curriculum of the Institute of Public Health
- Adapting the RPM Formulary Development Manual to the Polish health care system

As part of the study tour, participants received volumes from the United States Pharmacopeia (USP) and the *American Hospital Formulary Service* from American Society of Health-System Pharmacists (ASHP). Participants will be able to use this objective drug information in their respective institutions to make more rational drug selection decisions.

In preparation for the study tour, the *RPM Manual on Development and Maintenance of Hospital Formulary Systems* was translated into Polish. Participants received draft copies; however, the manual in Polish is undergoing review for accuracy and will be available shortly. After the final copy is approved, it is anticipated that the manual will be distributed and used at Jagiellonian University in the medical, pharmacy, and public health curricula.

Participants were asked to complete an evaluation on each session at the end of each day and a final evaluation of the entire study tour. The evaluation was a mixture of objective and subjective categories. In general, the participants rated the course quite highly, with an average rating of 8

(9 = outstanding, greatly exceeded expectations). Achievement of personal objectives and relevance to their job situations were rated by participants at 7.67 and 8, respectively. The participants assigned an average rating of 8 to both effectiveness of training methodology and organization of the seminar. It is worth noting that one of the participants also provided consecutive interpreting throughout the study tour. In retrospect, this participant did not feel this posed a burden for him, nor did it decrease the level of his participation in the course. The other participants particularly appreciated the fact that, because the participant was familiar with the terminology and concepts, they benefited by getting a high level of accuracy in the interpreting.

Sessions the participants found most relevant to their work situations included—

- DUR basics
- The site visit to the ASHP
- The site visit to Advance Paradigm

Participants indicated that they would have liked to spend more time on the following:

- Pharmacoeconomics and its applications
- Drug utilization review and its practical implementation
- Drug purchasing practices in the United States
- Methodology of pharmacoeconomic studies
- Computer software in pharmacy management
- Standard treatment guidelines
- General business administration issues
- Economics of pharmacies
- More hands-on time with formularies
- Organization and management of hospital pharmacy
- The role of the hospital pharmacist in providing scientific information on drugs in the hospital

When asked to predict any potential difficulties in implementing the ideas and concepts presented in the seminar in their home organization, participants listed the following:

- Resistance of the medical establishment, mostly physicians, to implement formularies
- Lack of managerial thinking and skills among pharmacists

- General resistance to new ideas because drug management is a new concept in Poland
- Lack of educational materials for those interested in making drug use more rational
- Lack of personnel and equipment to introduce the unit dose system
- Lack of networked computer systems in hospitals
- Lack of a reliable source of financing for health care facilities
- Lack of well-trained personnel in the hospital pharmacy

All of these difficulties, based on RPM experience elsewhere and the U.S. experience, are not insurmountable and are quite similar to issues that arise in other countries. Fortunately, the participants also reported that the study tour equipped them with tools to be able to improve the functioning of their hospital pharmacies and to allow them to develop and implement hospital formularies in their institutions. The course also had the beneficial by-product of broadening participants' perspectives of the role of the hospital pharmacist in rational pharmaceutical care. The one problem that won't be readily solved is the unavailability of objective, current drug information in Poland; such information is still expensive and not widely available.

Summary

The study tour provided a good platform from which participants will be able to develop and implement programs in formulary systems and drug use review. The fact that two of the participants have an affiliation with Jagiellonian University provides the opportunity to expose additional health professionals to rational pharmaceutical management concepts. Subsequent contact with participants has confirmed this impression. One of the participants is continuing training in pharmacoeconomics and the management of change in the institutional setting. Jagiellonian University is entering another partnership with the Center for Health and Related Research at the University of Sheffield in the United Kingdom; it is anticipated that work in pharmacoeconomics will be a major focus. Other participants are using these concepts to strengthen existing committees and provide justification for implementing the formulary process in their institutions.

Although all signs are that the study tour achieved its objectives and will produce positive outcomes, this can only be objectively assessed in the future, after the end of project. In addition, the need for current, objective drug information and further training in clinical pharmacology will need to addressed in order to apply these concepts effectively to a larger number of institutions and in the outpatient setting.

425

Appendix 1. Summary of Options for RPM in Poland

During Tomasz Bochenek's (Jagiellonian University) visit to the RPM office in Arlington, Virginia, in August 1996, a number of problems in drug management in Poland were considered. These included limited drug budgets, uneven availability of high-quality efficacious drugs, questionable prescribing habits and irrational drug use, high drug costs, lack of information on drug utilization, cost shifting from inpatient to outpatient categories, and unclear incentives for change. The change from public to private ownership of Biernacki Hospital in Krakow may provide a unique circumstance, in which incentive for change is stronger than it would be otherwise. The two basic issues to be confronted are cost-effective drug product selection and rationalization of prescribing practices. The strategies for managing these issues are development and implementation of drug formularies and drug utilization review (DUR).

Taking into consideration the modest amount of funding available, RPM proposes two options that are very limited in terms of both the scope of work to be carried out and the proposed time frame. These options share the common objective of exposing counterparts at Biernacki Hospital (BH) and Jagiellonian University (JU) to approaches to formulary development and DUR activities and development of work plans for implementing them. Significantly, however, in neither case can RPM be responsible for further technical assistance or local costs of implementing the plans, or evaluating the results.

Option 1. Study Tour in Hospital Formulary Development and Drug Utilization Review

Three persons from BH and one from JU would travel to the United States for a two-week study tour of hospital formulary development and drug utilization review. The purpose of this visit would be to learn about options for development and implementation of these concepts and to see how they are applied in the United States to achieve cost-effective drug product selection and use. The most probable site is the University of Arizona at Tucson. Depending upon needs, other topics that could be covered include development of standard treatment guidelines, clinical pharmacy practice, methods of evaluating the effectiveness of these programs, and/or the use of the formulary in making procurement decisions. Prior to departure from the United States, participants would develop a work plan to implement these concepts.

The role of RPM would be to plan and direct the study tour, provide the necessary materials, and participate, as needed, in discussions during the tour. The role of JU would include limited assistance with communications with participants at the Poland end, providing one participant for the tour, and collaboration in development of the BH work plan. It does not seem to us that this requires an agreement as JU's primary involvement would be providing a participant whose costs would be supported by RPM. We feel that it is reasonable that the Strengthening Local Government in Health (SLGH) Project management unit, which is after all a USAID-funded operation, could provide the modest amount of logistics support required within the context of its existing mandate and funding.

In addition to the four counterparts that RPM would support, DDM may wish to support other participants, and these could be from other areas in which the SLGH Project is working. RPM's direct involvement ends with the work described above. For follow-on implementation and evaluation activities in which BH and/or JU staff might participate, it will be necessary to locate other funding.

Option 2. Assessment and Workshop to Be Conducted at Biernacki Hospital

One RPM technical staff person would spend three weeks in Poland and work on site at BH with hospital staff and two experts from Jagiellonian University. During this period, the RPM/BH/JU team would attempt to carry out the following work: (1) conduct a focused assessment of drug management at the hospital, including data collection and analysis; (2) identify product-specific opportunities for cost-efficiencies; (3) assess the feasibility of implementing the formulary development and drug utilization review mechanisms at BH; and (4) using relevant materials developed and tested by RPM, begin training the BH staff in these procedures, if warranted.

Thus, in the three-week period, the team would simultaneously collect data relevant to drug management problems and attempt to devise a strategy for remedying those problems. Special attention would be given to ABC analysis of drug procurement and use, with the objective of identifying opportunities for achieving economies through rationalization of product selection and prescribing practices.

The role of RPM would include the following: assistance with preparation of an assessment document, participation in gathering necessary data, provision of technical assistance in data analysis, identification of product-specific options for rationalizing selection and use, and providing relevant RPM materials. The role of JU would be facilitation of the planned trip; participation in data gathering, entry, and analysis; and assistance in development of the BH work plan. This option, unlike the preceding one, probably does require an agreement with JU. We hope that actual implementation of the work plan and evaluation of results would involve JU, but as noted above, RPM cannot directly participate or provide the funding.

There is one important caveat concerning this option: A certain amount of data on drug procurement and/or use must be available. If it were decided to pursue this option, it would first be necessary to make an assessment of data availability before RPM would commit resources. RPM staff are prepared to communicate with JU and BH staff concerning what types of data are required. Given the relatively modest effort required, RPM feels that it is reasonable for the SLGH Project management unit to support whatever local costs may be incurred in taking this preliminary step.

Appendix 2. Schedule of Study Tour in Hospital Formulary Development and Drug Utilization Review October 25, 1997 to November 8, 1997

DATE	AGENDA	PLACE/SPEAKERS
Monday, October 27, 1997	9:00–12:00 Welcome & Overview of Program/Tour of UMB Campus Catered lunch	UMB–100 N. Greene Street McKercher/Smith/Duzey/ Bergquist/Gilner/Weiss/ Mullins/Orsini
	1:00–4:30 Rational Use of Drugs History & Role of Formularies in U.S.	UMB – 100 N. Greene Street Smith/McKercher
Tuesday, October 28, 1997	9:00–12:00 DUR Basics, DUE, Retro vs. Prospective Introduction to Clinical Pathways, Guide for Use and Disease State Management	UMB: CB Room 315 McNally/Bergquist
	1:00–4:30 Drug Information Systems Future of Prescribing Management	UMB: CB Room 315 Mays
Wednesday, October 29, 1997	9:00–12:00 Pharmacoepidemiology & Adverse Drug Reactions	UMB – 100 N. Greene Street Weiss
	1:00–4:30 Drug Use Review/ Procurement/ Software	UMB – 100 N. Greene Street Orsini/Weiss
Thursday, October 30, 1997	9:00–12:00 Site Visit: United States Pharmacopeia (USP)	USP, Rockville, Maryland Duzey/Bergquist/Gilner
	1:00–4:30 Site Visit: USP	USP, Rockville, Maryland Duzey/Bergquist/ Gilner
Friday, October 31, 1997	9:00–12:00 Recap of Week's Activities Orientation to ABC Analysis	UMB – 100 N. Greene Street Smith/Duzey/McKercher
	1:00–4:30 Group Project Site Visit: UMMS	UMB – 100 N. Greene Street Smith/Duzey/McKercher/ Bergquist
Monday, November 3, 1997	9:00–12:00 Pharmacoeconomics – Application of Principles to Formulary Management	UMB – 100 N. Greene Street Mullins
	1:00–4:30 Case study – Group Project	UMB - 100 N. Greene Street Smith/Mullins/Weiss

428

DATE	AGENDA	PLACE/SPEAKERS
Tuesday, November 4, 1997	9:00–12:00 Site Visit: Food & Drug Administration Drug Information	FDA, Rockville Blum/Bergquist/Gilner/Goldman
	1:00–4:30 Site Visit: American Society of Health Systems Pharmacists (ASHP)	ASHP, Bethesda Duzey/Bergquist/ Gilner
Wednesday, November 5, 1997	9:00–12:00 Site Visit: Maryland DHMH	UMMS - 22 S. Greene Street Joseph Gallina
	1:00–4:30 Group Project	UMB - 100 N. Greene Street Smith/Duzey/Bergquist/Weiss/ Mullins
Thursday, November 6, 1997	9:00–12:00 Site Visit: Advance Paradigm	Advance Paradigm, Hunt Valley Ober/ Duncan/ Bergquist/ Gilner
	1:00–4:30 Site Visit: Advance Paradigm	Advance Paradigm, Hunt Valley Ober/Duncan/Bergquist/ Gilner
Friday, November 7, 1997	9:00–12:00 Recap of Week's Activities Group Project Catered Lunch	UMB - 100 N. Greene Street Smith/Duzey/Bergquist/Gilner/ Weiss/Mullins/Orsini/Knapp
	1:00–4:30 Group Evaluation & Award of Certificates	UMB - 100 N. Greene Street Smith/Duzey/Bergquist/Gilner/ Weiss/Mullins/Orsini/Knapp

Appendix 3. List of Participants

Bochenek, Tomasz
Professor, Department of Drug Management and Pharmacoeconomics, School of Public Health, Collegium Medicum, Jagiellonian University, Krakow, Poland

Chmal-Jagiello, Krystyna
Director of Pharmacy, XXX National Hospital, Krakow, Poland

Professor, School of Pharmacy, Collegium Medicum, Jagiellonian University, Krakow, Poland

Trygar, Jadwiga
Director of Pharmacy, Jan Grandy Hospital, Krakow, Poland

Walasek, Izabella
Deputy Chief Physician, Director of Emergency Medicine, Gzicko ZOZ, Gzicko, Poland

Russia

Acronyms

ADR	adverse drug reaction
AED	Academy for Educational Development
AIHA	American International Health Alliance
CA	Cooperative Agreement
DIC	Drug Information Center
DUR	drug utilization review
IR	intermediate results
MOH	Ministry of Health
MSH	Management Sciences for Health
NIS	Newly Independent States
oblast	Russian administrative unit corresponding most closely to a U.S. state
OHA	Oblast Health Administration
Pharmedinfo	Center for Pharmaceutical and Medical-Technical Information [MOH]
ROCH	Ryazan Oblast Clinical Hospital
RPM	Rational Pharmaceutical Management (Project)
SO	strategic objective
STG	standard treatment guideline
TA	technical assistance
TB	tuberculosis
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeial [Convention]
WHO	World Health Organization

Project Overview

Project Objectives

The Rational Pharmaceutical Management (RPM)-Russia Project began with add-on funds to the RPM/Worldwide Cooperative Agreement (CA) in 1993. Additional funds, in the form of a separate CA, were provided in 1994 to expand the activities being undertaken through the add-on. The project was implemented collaboratively by two U.S. organizations through two separate cooperative agreements: Management Sciences for Health (MSH) and the U. S. Pharmacopeial (USP) Convention. The MSH component was completed by December 31, 1998, while the USP component end date is September 1999.

The goal, purpose, and technical focus for the RPM-Russia Project were as follows:

Goal: To improve the health status of the target population through the empowerment of local capacity to allocate and use financial, human, and informational resources within the health sector.

Purpose: To demonstrate that improvements in access to affordable, quality care can occur through building local capacity in the allocation, use, and management of health sector resources, and enhancing access to and dissemination and utilization of unbiased drug information.

Technical Areas: The RPM[1] Project goal and purpose were to be achieved through work in six technical areas, described below:

- Drug Selection: Drug Formulary Development and Maintenance
- Drug Utilization Review (DUR)
- Drug Procurement: Management of Competitive Procurement/Tendering
- Rational Drug Use
- Management and Economic Viability of Pharmacies
- Establishing Drug Information Services (USP/RPM component)

Strategic Importance: RPM-Russia began work in Russia during the Health Care Improvement Project under the rubric of a pharmaceutical security component, focusing on improving drug availability through rational procurement and inventory management. As drug supply in Russia improved, RPM-Russia's focus shifted to introducing new forms of service delivery.

The U.S. Agency for International Development (USAID) mission has a results framework that includes three strategic goals, one of which applied to RPM-Russia: Strategic Goal 3 (Respond to humanitarian crises and strengthen the capacity to manage the human dimension of the transition to democracy).

[1] Although implemented by two organizations, for the purposes of this report hereafter RPM refers to the MSH component unless otherwise clearly stated.

433

The RPM-Russia Project supported Strategic Goal 3, which included two Strategic Objectives (SOs) and a number of intermediate results (IRs). One was SO 3, PO 3.1 (New and improved cost-effective interventions developed and disseminated). In Russia, RPM developed drug formulary implementation methodologies and training materials that have been widely disseminated and put into practice. Development of drug formularies has resulted in the elimination of unsafe, ineffective, unnecessary, and overly expensive drugs in 61 hospitals in three target *oblasts*. DUR programs under way in oblast hospitals helped to ensure that physicians comply with the established formulary, assist hospital therapeutics committees to assess prescribing and use patterns, and identify opportunities for improvement. Formulary development and DUR manuals developed by RPM have been widely distributed and are in use throughout Russia and the Newly Independent States (NIS).

Under SO 3, RPM also supported SO 3.2 (Improved effectiveness of selected social benefits and services). Under SO 3.2, RPM contributed to the achievement of Intermediate Results 3.2.1 and 3.3.2. Policies, laws, and regulations that improve effectiveness have been approved (IR 3.2.1), and new approaches to service delivery have been adopted (IR 3.3.2).

Initial Findings

Needs Assessment

RPM-Russia activities were carried out through the development of a demonstration site in one oblast, with rollout to two additional sites. Two reconnaissance visits, in November 1993 and February 1994, led to the selection of Ryazan Oblast as the demonstration site. The rollout oblasts of Novgorod and Pskov were chosen in April 1995. The field work for the Ryazan pharmaceutical sector assessment was conducted in May 1994, and the Novgorod and Pskov assessments were conducted in November and December 1995.

Key assessment findings were grouped into five distinct areas: drug selection, drug utilization review, drug procurement, rational drug use, and community pharmacy management.

Drug Selection

Systems did not exist at the health administration or facility levels for rationally selecting drugs for procurement and use in any of the three oblasts. The funds for drug procurement were extremely limited and cost-effectiveness was not considered when selecting drugs. Some drugs used were of unproven quality or efficacy. There had been a significant increase in the number of drug suppliers operating in oblasts and an increase in the number of therapeutic alternatives and drug products available on the market. Although many previously unknown drug products had been introduced, decision makers did not have access to unbiased sources of drug information for making rational drug-selection decisions. Physician and pharmacist training in clinical pharmacology was also needed to make adequate selection decisions.

Drug Utilization Review

The oblasts had no systems in place for the regular and continuous review of drug prescribing and use. Public health officials and decision makers did not have tools to evaluate whether drugs were being used rationally. If problems were detected in drug use, interventions were punitive, resulting in disincentives to collecting information about drug prescribing and use.

Drug Procurement

Determining drug needs and quantities was done manually and based on historical ordering information without the use of standard formulas. The drug supplier market, on the whole, was very fragmented. Competitive tender practices were not employed and drug purchases were most often made through negotiations with a large number of drug distributors and manufacturers, which led to financial waste. Decision makers often used information provided by pharmaceutical sales representatives, rather than current objective information, to make procurement decisions. Health facilities and pharmacies reported long delivery times for getting drugs from wholesalers.

Rational Drug Use

Standard treatment guidelines (STGs) were present and in use at public health facilities, but were in need of revision. Prescribing was excessive for patients eligible to receive drugs free of charge or at reduced prices, and it was not limited by restricted drug lists.

Community Pharmacy Management

Delays in reimbursement for exempt prescriptions, as well as punitive tax structures, contributed heavily to the financial difficulties of community pharmacies. Although pharmacy managers may have functioned well under a centralized system, there were significant gaps in the knowledge and experience necessary to operate efficiently in a market economy.

Challenges Facing RPM-Russia: Constraints Encountered and Program Adjustments

The principal goal for RPM at the regional level was to establish a properly managed rational pharmaceutical system. To achieve that, RPM had to respond to certain challenges.

Russian Exasperation with Being Assessed and Studied

Start-up activities and assessments were initially met with the skepticism of Russian health care providers who felt "overassessed" during the initial years following the collapse of the Soviet

Union. The constraint was overcome by RPM-Russia by creating a highly participatory process of assessment tools development and use.

Atmosphere of Liberalization and Freedom after Centralized Control

The idea of drug formularies was, at first, seen to be in conflict with the atmosphere of freedom of choice that followed centralized control. RPM-Russia spent considerable time discussing the clinical and economic benefits of formularies with Russian counterparts and enlisted U.S. specialists to make key presentations at early activities.

Concerns about Motivations behind Any U.S. Pharmaceutical Assistance

Initially, Russians expressed concern that the motivation behind assistance in pharmaceutical reform was to promote the use of drugs produced by U.S. companies. These concerns decreased over time, partially because the RPM–Russia-introduced formulary development process involved drug selection only by generic name.

Lack of Managerial Skills and Know-How

The highly centralized drug supply system of the Soviet Union required few managerial skills of local health officials. Even the position of head of oblast health administration did not require any special managerial skills because key decisions were made at the central level. With the dissolution of the Soviet Union and the collapse of centralized procurement, local health authorities faced the challenge of managerial responsibilities and decision making for which they had never been trained. During the course of RPM implementation, special attention was given to training decision makers and involving them in project implementation.

Low Prestige and Role of the Pharmacist in the Russian Health Care Setting

In the Russian health care system, pharmacists have not traditionally played any significant role in the drug selection and use process. At the same time, due to the specifics of Russian medical schools' curricula, physicians had very little knowledge of drugs: They were trained to prescribe a certain drug for a certain condition without clear understanding of the pharmacokinetics and pharmacodynamics of the administered drug. From the very start, the RPM project worked at bridging the gap between physicians and pharmacists through involving both specialties in the development of a formulary system.

Different Pharmaceutical Concepts

Several RPM concepts were new to Russian health providers and required additional explanation and training. Those concepts included "drug formulary," "drug information," "drug utilization review," and "generic drug name."

The concept of restricting drug use and procurement to a formulary list was initially received with skepticism by Russian counterparts. This attitude decreased with time as the first formulary list was developed at the demonstration site, where it proved to reduce drug expenditures and improve clinical outcomes. With the establishment of drug information centers (the USP component), the very notion of drug information utilization also changed from "information on drug availability at pharmacies" to "drug information as a means of making educated selection decisions."

In the former Soviet Union, most drugs came from domestic or Eastern Bloc manufacturers, and were marketed only under brand names. In 1991–1992 the Russian market was opened to foreign drugs, and Russian health providers were seldom able to identify generically similar brand-name products as the same drugs. This inability led to utilization of duplicative drugs in hospitals, resulting in financial waste. The approach to drug selection by generic name, introduced by RPM, eliminated duplication and reallocated funds to purchases of essential drugs. Although the problem with unjustified inclusion of brand names into hospital formularies still persists, the majority of drugs in oblast formularies appear under generic names.

Political Situation

Among the biggest challenges for RPM-Russia were the unstable political situation in RPM oblasts and changes in the Ministry of Health. The project started its activities in Russia when democratic forces were in power in the RPM oblasts. During the course of the RPM project, each oblast set its own implementation pace. Ryazan Oblast concentrated on reforming one pilot site first, and then moved to introducing changes to its public health system. Reforms in Novgorod Oblast were very fast due to the strong political will of the head of health administration and the governor, which allowed the oblast to pass comprehensive health and drug laws and establish a rationally managed centralized health system. In Pskov Oblast, the 1996 elections brought to power the Liberal-Democratic party, known for its traditionally negative attitude to foreign aid and international projects. Although RPM continued work in Pskov during 1997–1998, many legislative initiatives of the previous administration were not adopted, considerably slowing the overall pace of health reforms.

Economic Situation

The economic situation in RPM oblasts and in Russia in general did not improve during the life of the project, and drug budgets steadily decreased. In Ryazan, for example, the overall annual per capita drug expenditures went down from $8.41 in 1994 to $4.50 in 1997. In Novgorod Oblast these went from $4.70 in 1995 to $3.90 in 1997. It should be noted, though, that due to RPM reforms conducted in these oblasts, even small drug budgets allow health administrations to provide the necessary minimum of formulary drugs to health facilities.[2]

[2] See, for example, the RPM report *Availability and Procurement Methods of First-Line Tuberculosis Drugs in Novgorod, Pskov, Ryazan, and Yaroslavl Oblasts* (October 1998; results from study commissioned by USAID/Moscow).

Implementation Strategy

The RPM-Russia implementation strategy was developed on the basis of the assessment findings, local challenges and situations, and building stakeholders at each level of the project. The following strategy was believed to be successful in establishing sustainable pharmaceutical systems in RPM sites.

1. Combination of national and state approaches
2. Creation of stakeholders
3. Study tours to the United States
4. Development of demonstration sites
5. Training of Russian counterparts
6. Russian RPM-trained experts as technical assistance (TA) providers
7. Tools development
8. Information dissemination
9. Collaboration with international organizations
10. Collaboration with educational institutions
11. Fostering cooperation among Russian oblasts
12. Limited provision of equipment
13. Development of MSH/RPM-Russia Moscow office

The key activities of RPM-Russia are listed by modes of implementation in Annex 1.

Project Implementation

Combination of National and State Approaches

The nonprofit sector has only recently begun to develop in Russia. Therefore, when RPM-Russia began its activities, most efforts were spent on developing relationships with government organizations at both the national and regional levels. These included the Ministry of Health (MOH) organizations, oblast health administrations, and medical universities. Although the project was designed to work at the regional level in Russia, considerable effort was made to capacitate a national-level organization to serve as a medium between RPM and Russian regions and thus ensure the sustainability of reforms after the project finished its activities in the country.

One such important collaborative relationship at the national level was developed with the Ministry of Health Russian Center for Pharmaceutical and Medical-Technical Information (Pharmedinfo). Pharmedinfo was formally designated as RPM's official collaborating organization by the MOH, and very soon it became the major link between RPM and Russian health officials at all levels.

To empower Pharmedinfo and enhance its role in pharmaceutical sector reforms in Russia, RPM involved Pharmedinfo staff in every stage of project implementation. Pharmedinfo made

considerable input in adapting RPM-developed indicator-based assessment tools, conducting assessments of the pharmaceutical sector in RPM oblasts, and producing assessment reports. Pharmedinfo provided speakers at RPM workshops and maintained links with health officials in the oblasts and MOH.

In 1995, Pharmedinfo signed an agreement with the USP that allowed it to translate, adapt, and disseminate the USP drug information database in Russia. The agreement made it possible for RPM to assist oblasts in developing and producing Russian oblast formulary manuals.

Due to the continuous efforts of RPM and Pharmedinfo to promote rational drug use ideas in Russia, and impressive results achieved in three pilot oblasts, the MOH decided in 1998 to commence work on a Russian National Drug Formulary. Pharmedinfo was nominated by the MOH to head this national project.

At the state level, RPM invested considerable effort in promoting both top-down and bottom-up activities. In the traditional Soviet system, the grassroot levels of public health were never part of the decision-making process. At the time of RPM interventions, this system was in disaccord with the evolving democratic relations in the country. The challenge for RPM was to empower all levels of the public health system by involving them in a collaborative process of developing new health management structures. One mechanism for establishing collaboration and dialogue between oblast health administrations and health practitioners was involving both parties in formulary system development. As will be shown in the following sections, oblast formulary committees became democratic decision-making bodies where top and bottom levels met.

Creation of Stakeholders

The MSH RPM-Russia Project was a unique activity that addressed critical problems in the Russian pharmaceutical sector through a highly participatory process at the local decision-making level.

RPM start-up activities were initially met with skepticism. Russian health care providers felt "over-assessed and helped" by various international donors during the initial years following the collapse of the Soviet Union. To overcome the skepticism, RPM-Russia gave special attention to ensure that the implementation process was "owned" by local decision makers and health providers, and not forcibly imposed on them from the outside.

To achieve this end and to create strong stakeholders, at every stage of the project RPM-Russia used the following effective approaches.

Pharmaceutical Sector Assessments

At the initial stage of project implementation RPM worked in close cooperation with all interested parties. Assessment tools were adapted to the Russian environment with the help of central-level consultants from Pharmedinfo, but mostly by Ryazan Oblast public health decision makers. By involving Russian specialists in this activity, RPM provided informal training in

conducting indicator-based assessments, imparting to them the necessary managerial skills and an understanding of the assessment process. By the time of the assessment, Ryazan health officials were already strong supporters of RPM initiatives. The support of the Ryazan Oblast Governor resulted in a very high quality data collection process because it was possible to have highly qualified pharmacists and university associates as data collectors.

Data Analysis and Report Writing

Assessment data was computer-analyzed and worked into a draft report by RPM specialists in Washington. The draft report was then extensively revised by two teams of Russian experts who were invited to the MSH office in Washington. The first team consisted of national-level experts, with Pharmedinfo playing the leading role. The second team was composed of Ryazan officials and experts, including the Ryazan Oblast Lieutenant Governor, Head of Oblast Health Administration (OHA), Chief Physician of the pilot Ryazan Oblast Hospital, the head of the Pharmaceutical Department of OHA, and representatives of drug information and procurement bodies. Involvement of those key players resulted in a comprehensive assessment report fully endorsed by Russian counterparts.

Problem Identification

A key outcome of the assessment activities was problem identification in the oblast-level pharmaceutical sector, made by Russian experts according to local setting of priorities.

Presentation of Findings and Policy Options Analysis

Presentations of the assessment findings and possible interventions were done by Russian national- and oblast-level experts at policy options workshops. Pharmaceutical sector problems were identified and discussed by approximately 100 Russian specialists.

Work Plan Creation

The principal achievement of involvement of Russian experts at the early stage of RPM implementation was the final definition of RPM technical areas for Russia and the development of a realistic RPM work plan. At the Ryazan Policy Options Workshop, the OHA requested specific types of RPM assistance in drug selection/formulary development, procurement/tender management, rational drug use, drug utilization program implementation, development of local sources of drug information, and community pharmacy management. The implementation plan was endorsed by the Governor of Ryazan Oblast, which helped ensure the work plan's fulfillment.

Rollout to Other Oblasts

Because of the fast progress and success of RPM in the initial pilot site, rollout to Novgorod and Pskov Oblasts in 1995 was greeted by recipients with enthusiasm. In fact, officials and specialists in both oblasts readily recognized the need for drug formulary systems. Enthusiasm was so great that RPM technical activities started even before the pharmaceutical sector assessment was completed and the work plan for the rollout oblasts finalized. In both oblasts, the RPM activities and work plan were endorsed by the governors.

Man and Drugs Congress Presentations

RPM-Russia participated in four annual Russian National Man and Drugs Congresses, conducting symposia and roundtable sessions. The sessions at the last three congresses focused on project accomplishments, and most presentations were made by local officials and specialists. Because the rational drug use implementation approaches taken by the leaders of the three RPM oblasts were slightly different, actively involving oblast specialists in the presentation of the results gave the audience a chance to consider and discuss the variety of locally tailored RPM options. Presentations by local specialists put RPM oblasts in the center of pharmaceutical reforms in Russia.

Study Tours to the United States

Another approach to stakeholder building that proved very effective was study tours to the United States. Study tours allowed Russian decision makers to see how the health system changes they were working on together with RPM actually worked in another country. RPM conducted three study tours.

- Ryazan Oblast officials participated in a Health System Overview Study Tour to Texas in June 1995. The ideas gained from this experience contributed to the creation of a reformed system of providing prescription services to exempt patients in the oblast. Visits to hospitals reinforced the importance of drug formularies and accelerated this process at the Oblast Hospital. Exposure to U.S. buying groups accelerated the formation of the oblast tender committee.

- Seven Ryazan and Novgorod officials received advanced training in formulary development, drug utilization review, use of drug information databases, and desktop publishing during a U.S. study tour to the University of Arizona and Washington, D.C., in October 1995. The tour facilitated rapid reforms in the Novgorod Oblast health system, including the development of oblast drug legislation based on formulary system principles, enhancement of the role of the USP-established Drug Information Centers, and acceptance of DUR as part of the drug selection process.

141

- Eleven health professionals from RPM oblasts and Moscow participated in a Community Pharmacy Management Study Tour to Michigan, August 10–24, 1996. The purpose of the study tour was to give participants firsthand exposure to established and innovative pharmacy management practices studied during the previous two and one-half years of RPM community management activities. They also studied several pharmacy curricula and the role of a pharmacy association in professional, political, and economic spheres. Upon their return to Russia, participants shared firsthand knowledge of the U.S. pharmaceutical system with their colleagues as trainers in local pharmacy management workshops.

Development of Demonstration Sites

For the success and replicability of RPM-Russia, the choice of the demonstration site as the starting point for project dissemination throughout Russia was very important. Given the large size of the country, it was initially decided that the RPM Project begin by working in one Russian oblast, an administrative unit corresponding most closely to a U.S. state, with rollout to two additional territories.

Selection Criteria

Project sites were chosen using established criteria after extensive discussion among RPM Project staff, USAID/Moscow, USAID/Washington, MOH, Pharmedinfo, and local consultants. In the case of the pilot site, RPM wanted to work in an oblast that met the following criteria:

- Interest on the part of local officials and specialists in implementing pharmaceutical sector reforms
- Policies that support the introduction of competitive procurement techniques
- Logistics feasibility for bringing high-level U.S. consultants to the site
- Presence of medical and pharmacy schools
- Representative of a typical Russian oblast
- Interest in serving as a model for other oblasts as the project expanded

After two reconnaissance visits to Russia, including visits to Saint Petersburg, Perm, Ryazan, and Kaluga Oblasts, Ryazan Oblast was selected as a demonstration site in 1994. Selection of Ryazan Oblast as a pilot site was a joint decision of MOH, RPM, Pharmedinfo, and Ryazan Oblast Health Administration. In 1995, with the awarding of the MSH RPM-Russia CA, the project was able to roll out to two additional oblasts, Novgorod and Pskov, and start disseminating information throughout Russia and the NIS.

Demonstration Sites

The RPM implementation strategy focused on local capacity building and not on imposing RPM principles. By the end of the project in 1998, RPM had developed several demonstration sites, each with distinctive characteristics and strengths due to differences in local conditions and health decision makers' visions.

Ryazan Oblast

- RPM pioneered drug selection activities at the 1,100-bed Ryazan Oblast Clinical Hospital and developed and published Russia's first Hospital Formulary Manual.

- The Ryazan Drug Information Center established at the Ryazan Oblast Clinical Hospital is a model of expertise in hospital formulary development. During 1995–1997, the Drug Information Center assisted in the development and revision of formulary lists of 18 oblast hospitals.

- The Ryazan State Medical University Drug Information Center, which was also established within the RPM implementation framework, introduced model changes to undergraduate and postgraduate medical curricula to incorporate the notions of cost-effective drug selection, drug utilization review, rational drug use, and drug information development. It also conducted numerous continuing education programs for local and visiting physicians and pharmacists.

- Community pharmacies in Ryazan Oblast are an example of the successful implementation of business turnaround plans that ensure pharmacy viability.

Novgorod Oblast

- As a result of RPM Study Tours and the Policy Options Workshop, the oblast focused on developing policies and procedures for a full-scale regional formulary system. By May 1998, a package of laws and regulations was passed, including a comprehensive Law on Drugs. Because of its leading role in drug legislation development in Russia, Novgorod Oblast was also designated to be the Russian Federation Ministry of Health Demonstration Site.

- Of the three RPM oblasts, Novgorod is the best replicable model of centralized (at the oblast level) competitive drug procurement for public health.

- The RPM-established Drug Information Center has a different role in Novgorod than in Ryazan or Pskov by serving the Health Administration in managing the oblast formulary system.

Pskov Oblast

Other RPM oblasts started the drug formulary development process with the assumption that all drugs currently in use were the initial formulary, subject to revision. However, Pskov Oblast started this process by first revising its standard treatment guidelines and then building the drug formulary list from scratch by therapeutic categories.

The RPM demonstration sites provide free technical training to all interested specialists from Russian regions.

Training of Russian Counterparts

Training was an important component of the RPM implementation strategy. Many of the RPM-introduced activities, such as cost-effective drug selection, drug formulary management, and drug utilization review, were not previously known in Russia. Thus, RPM designed and conducted a series of training sessions and workshops to address the training needs at every level of project implementation. Training was provided in various ways.

On-Site Training by Visiting Experts

Formulary development began at Ryazan Oblast Clinical Hospital through direct technical assistance by RPM/Washington experts. Direct technical assistance was combined with ad hoc training sessions as needs emerged. This approach gave RPM the opportunity to rapidly identify training needs and develop appropriate educational materials and formal training courses.

Workshops

Formal training was tailored to the needs of Russian counterparts and consisted of workshops on (1) cost-effective drug selection/formulary development, (2) drug utilization review, (3) rational drug use, (4) community pharmacy management, and (5) drug information development and maintenance.

Specialized Training

At the early stage of the project it became clear that Russian physicians lacked training in clinical pharmacology and thus were unable to approach the drug comparison and selection process scientifically. However, though clinical pharmacology is a relatively new science in Russia, Russian medical universities have already built a strong training capacity of their own. RPM, in collaboration with the Russian State Medical University in Moscow, trained approximately 150 physicians from Novgorod and Pskov so that they could take the lead in drug selection activities in their hospitals.

For a full list of RPM training activities see the Workshops and Training section in Annex 1.

Russian RPM-Trained Experts as TA Providers

The RPM implementation strategy was aimed at building a strong local training capacity. To this end, RPM established a team of Russian experts capable of providing training in rational drug use issues to Russian regions and of specialists interested in implementing RPM-style pharmaceutical sector reforms.

To ensure the sustainability of the RPM project, educational functions and TA to non-RPM regions were delegated to Drug Information Centers (DICs). Currently, ten DICs are operational in providing both on-site and academic training in formulary system implementation issues throughout Russia.

Ryazan State Medical University Educational Information Center

The Ryazan Medical University proved to be a good partner for reaching the educational objectives of the RPM Project. The university employs highly qualified faculty members and has access to a broad audience of health providers. The university has 11 teaching departments for students as well as a Department of Postgraduate Education for physicians and pharmacists.

Ryazan State Medical University actively disseminates RPM materials throughout Russia. Training in RPM concepts was provided to more than 220 health specialists from Perm, Ekaterinburg, Tula, Kurgan, Chelyabinsk, Magnitogorsk, and other cities.

Direct technical assistance was provided by the university faculty to Ryazan Oblast health facilities that joined the project in 1996–1997.

RPM-Russia Consultants

In the course of implementation, RPM trained and involved several consultants from the Russian State Medical University, Friendship University Medical School, and Saint Petersburg Medical University. These specialists provided direct technical assistance to oblast formulary committees by revising oblast formulary lists and working directly with health facilities on drug use evaluation programs.

Oblast Drug Information Centers

Oblast DICs provided training to oblast prescribers on-site. The Ryazan DIC not only focused its activities on providing assistance to oblast hospitals on formulary development but also worked with individual health providers from the Ryazan Oblast Clinical Hospital, the Ryazan Oblast Children's Hospital, and physicians and pharmacists from *rayons*. In 1997, the Ryazan DIC conducted two seminars on drug selection and clinical pharmacology. It also trained specialists from Lukhovicki Rayon Hospital of the Moscow Region in drug information and the principles of formulary system implementation.

446

In Novgorod, the DIC conducted two seminars on drug procurement issues and several seminars on rational use of antimicrobials. The DIC was also responsible for monitoring drug utilization review programs in the Novgorod Oblast Hospital. Special attention was given to DUR of gentamicin, cefazolin, aminophylline, and ranitidine. The DUR results were presented at a physicians conference and an Oblast Formulary Committee meeting. Educational interventions were undertaken to ensure that the antibiotics are used properly. The Novgorod DIC also developed educational information newsletters on drug-food interactions, drug-drug interactions, and antimicrobial resistance.

Tools Development

RPM-Russia developed a number of tools in the Russian language, tailored to the needs of Russian counterparts. In many cases Russian experts were widely involved in tools development and adaptation. Those tools were—

- The MSH 1993–1994 *International Drug Price Indicator Guide* was translated into Russian and distributed to every Russian oblast.

- Existing MSH pharmaceutical management training materials, including the *Managing Drug Supply* training series, have been adapted and translated into Russian and subsequently used in numerous training activities.

- New training materials were developed on drug procurement, community pharmacy management, formulary development, drug utilization review, and rational prescribing.

- RPM-Russia adapted and translated into Russian the MSH pharmaceutical sector assessment manual *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach.*

- RPM developed individually tailored and structured assessment tools for each of the three oblasts in which the project worked.

- Based on experience gained in Ryazan, RPM-Russia created the *Manual for the Development and Maintenance of Hospital Drug Formularies*. The manual is geared toward hospital administrators and operational-level personnel, to enable them to understand the goals of formulary systems and the steps involved in implementation and maintenance.

- As a companion volume to the *Manual for the Development and Maintenance of Hospital Drug Formularies*, RPM-Russia wrote *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.*

- In cooperation with the World Health Organization (WHO), RPM-Russia adapted and translated the *WHO Guide to Good Prescribing* into Russian.

- As a result of community pharmacy management training activities, RPM-Russia wrote a draft *Community Pharmacy Management Manual.*

- RPM-Russia designed a tool for collecting financial information to perform financial analysis of retail pharmacies.

- INVEC-2, the MSH inventory management software program, was translated for use in Russia.

- Russian/English language formulary computer software (*Formular)* was developed and used at the Ryazan Oblast Clinical Hospital.

RPM Information Dissemination

Russia is made up of almost 100 oblasts, and the 3 RPM oblasts make up only a very small part of it. Thus, the project constantly looked for opportunities to reach a broader audience. Russian health care providers were exposed to rational pharmaceutical management concepts through a variety of dissemination activities and informational products, including—

- Newspaper articles in local papers in all three RPM oblasts
- Magazine articles in the nationally distributed *Pharmacia Journal*
- Articles in the *Pharmaceutical Gazette*
- An article in *Chief Physician Magazine*
- RPM-Russia appearances on Russian television programs in Ryazan and Novgorod
- Radio interviews
- A televised press conference in Ryazan

The annual Russian National Man and Drugs Congresses were an excellent venue for the dissemination of RPM-developed materials, including *Manual for the Development and Maintenance of Hospital Drug Formularies* and *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.* At the Congresses in 1996, 1997, and 1998, more than 500 copies of each manual were distributed to the participants.

The Internet has also proved to be an effective means of information dissemination. Because demand for manuals exceeded RPM's capacity to print copies, the electronic version of the formulary package was placed on the MOH Web page. As a result, RPM received inquiries and requests for assistance from other Russian oblasts, mainly from Russian medical schools that had access to the Web. Among them were such celebrated institutions as the Moscow Medical Academy, Volgograd Medical Academy, Stavropol Medical University, and Tomsk Institute of Cardiology.

An article on the formulary development activity was published by the *Journal of the American Society of Health-System Pharmacists*, and a paper on formulary development was accepted for presentation at the 1997 National Council for International Health Conference on Building Strategic Alliances for Global Health.

RPM-Russia's *Manual for the Development and Maintenance of Hospital Drug Formularies* was included on a CD-ROM disk containing Russian-language health sector reference materials produced by the Abt Associates ZdravReform Project.

The RPM collaborative activities with other organizations discussed below also had strong RPM information dissemination components.

Annex 2 provides a list of publications on RPM issues in Russia.

Collaboration with USAID-Funded Organizations and International Donors

RPM collaborated with other USAID-funded projects and international organizations working in the health sector in Russia. RPM materials were disseminated at major meetings held by those organizations.

- RPM collaborated with the USP component of the project throughout the project's duration in Russia. The USP technical experts participated in all major workshops conducted in Russia by RPM/MSH, including two joint symposia at Man and Drugs Congresses in 1995 and 1996. RPM also participated in the USP-organized practical conference, Drug Information for Health Care Professionals in June 1997, with a workshop on formulary development and DUR. Training was provided for 110 participants from different Russian regions and most NIS countries.

- Two courses titled Issues in Pharmaceutical Policy and Management were conducted by MSH with USAID funds provided through Partners for International Education and Training. Forty-three participants from Russia and the Central Asian Republics attended the courses, with heavy involvement of RPM-Russia staff members. Russian language training materials were developed. RPM-Russia gained experience in working with Russian health officials and learned about the status of the pharmaceutical sector.

- MSH and Howard University collaborated on three pharmaceutical courses during 1994 with funds provided by the Academy for Educational Development (AED):

  - Drug Information and Use
  - Health Care Delivery and Pharmaceuticals: Private Sector Management
  - Health Care Delivery and Pharmaceuticals: Private Sector Management II

- MSH conducted a follow-on Pharmaceutical Sector Management and Training Workshop for AED in Ryazan Oblast in May 1995 for 35 participants from these U.S. courses and 14 additional participants selected by RPM-Russia. AED also provided funds for 10 participants to attend the Ryazan DUR Workshop in 1996.

- Howard University and MSH conducted a Pharmaceutical Sector Management Training Program for eight participants from RPM-Russia oblasts and Moscow in July 1996.

- RPM-Russia and the Abt Associates' ZdravReform Project have collaborated on a number of activities.
  - RPM-Russia conducted a session at a national conference on Health Reform in Russia: Experience of Russian-American Cooperation organized by Abt. Abt sponsored the attendance of several RPM-Russia participants.
  - Abt sponsored the attendance of participants from four ZdravReform oblasts at RPM-Russia's Formulary Development Workshop.
- RPM-Russia collaborated with the American International Health Alliance (AIHA) Hospital Partnership Project and disseminated RPM materials.
  - RPM-Russia made a presentation on drug selection at the AIHA Partnership Conference for the NIS in Des Moines, Iowa.
  - Interest generated at the conference resulted in a joint workshop on formulary system development for 21 participants from partnership hospitals in Russia, Georgia, and Armenia. RPM-Russia was responsible for the technical content of the conference.
- The WHO worked in the NIS with funds provided by the UK Know-How Fund and USAID. RPM-Russia collaborated with WHO in the area of rational prescribing:
  - RPM-Russia worked with WHO to adapt the WHO *Guide to Good Prescribing* for use in Russia. The Guide was one of the manuals reproduced with funds provided by Abt Associates for wide dissemination.
  - RPM-Russia and WHO conducted a workshop on Integration of Rational Prescribing Practice in Medical Undergraduate Curricula in the NIS, based on the *Guide to Good Prescribing*.

Collaboration with Russian Educational Institutions

An important component of the RPM-Russia strategy was to foster collaboration with Russian educational institutions. By involving medical universities in RPM activities, the project reached the goals of material dissemination to a large audience of medical students and health care providers and of training university experts to provide technical assistance on RPM issues.

The most productive relationship was established with the Ryazan State Medical University. The university introduced changes to the undergraduate and postgraduate curricula to incorporate the concepts of cost-effective drug selection, rational prescribing, drug utilization review, and drug information development. The university also developed RPM-based training materials for advanced education and provided training in RPM methodology to more than 220 health specialists from Perm, Ekaterinburg, Tula, Kurgan, Chelyabinsk, Magnitogorsk, and many other regions of Russia.

Other collaborating medical educational institutions included the following:

- The Saint Petersburg Chemical-Pharmaceutical Institute established a training center in rational pharmaceutical management using RPM materials. Several dissertations on formulary development were written and defended under the supervision of the institute professors.

- The Russian Academy of Advanced Medical Training hosted and provided speakers for an RPM workshop on formulary development in 1996, which included lectures on formulary systems in the curricula for postgraduate students.

- Russian State Medical University (Moscow) faculty members were involved in RPM implementation during the early stages, and they gained experience in RPM technical areas through direct observation of RPM experts. The university faculty later provided specialized training to RPM oblast physicians and pharmacists in clinical pharmacology and rational selection of drugs.

- The Saint Petersburg State Medical University developed and implemented a formulary system in the university clinic. This work was conducted without direct RPM participation, but was based on the RPM *Manual for the Development and Maintenance of Hospital Drug Formularies.* The experience gained by the university staff during this process allowed RPM to involve university experts in providing direct technical assistance to RPM oblasts. The university staff provided significant input in revising oblast formulary lists in both Novgorod and Pskov oblasts. Three members of the university faculty were extensively involved in RPM workshops and presentations in oblasts during 1997–1998, as well as during the two last Man and Drugs Congresses.

Fostering Cooperation between Russian Oblasts

The last important strategic step for RPM was to establish ongoing cooperation between RPM sites in the three oblasts and collaborating institutions from non-RPM regions of Russia. RPM faced the challenge of overcoming the traditional "separatist" tendencies in oblasts and the bias of regional health authorities against communicating with each other. In the former USSR, health system regional health administrations reported to the MOH, and they were not encouraged, nor had they any incentive, to work collaboratively.

To tackle this problem, RPM used traditional vertical links of regions with the center and established new means of cooperation. The following approaches were used.

- Pharmedinfo acquired the role of a central linking body between regional health administrations. Pharmedinfo staff were trained by RPM, and they developed expertise in new pharmaceutical management methods by working side by side with RPM experts. As the organizer of the Russian National Man and Drugs Congresses, Pharmedinfo coordinated oblast participation and presentations. Pharmedinfo was also a prime

collaborator of the USP/RPM component, and it coordinated work in oblasts on drug information development and the production of formulary manuals.

- DICs provided opportunities for less formal "horizontal" communication between oblasts at the level of health facilities and health care providers. Being connected with each other via the Internet, DICs have easy access to each other's experience in pharmaceutical management and drug information databases, and willingly share information.

- High-Level Technical Meetings. One successful way to establish cooperation between RPM sites was to physically bring together oblast experts from all levels to share the RPM implementation experience. RPM did this in early 1997 through a workshop entitled High-Level Technical Meeting. The agenda for the workshop was developed together with interested parties and covered the relevant issues of pharmaceutical management that oblasts faced. Although RPM/Washington experts attended the workshop, the discussion was mainly among oblast health providers, who successfully found answers to their own questions during the workshop discussions. The immediate result of the workshop was the planning of a series of trips oblast specialists made to each other to learn from each other on-site.

Limited Provision of Equipment

The RPM-Russia Project was not designed with an emphasis on providing equipment to Russian counterparts to achieve the project goals. However, a limited amount of equipment was provided to pilot sites at the initial stages of project implementation. The following was provided to the RPM collaborators:

- The Ryazan Oblast Clinical Hospital, which pioneered formulary drug selection activities in Russia, received a computer and a printer. The equipment was used to develop *Formular* software and establish hospital formulary system maintenance programs. The *Hospital Drug Formulary Manual* was developed and prepared for printing on the equipment provided through RPM. The hospital computer specialist used the computer to develop hospital drug inventory management software and to regularly perform ABC/VEN analysis.

- The Ryazan Medical University received a computer, printer, and overhead projector. It used the equipment for RPM-based educational and practical activities, including assistance in the development of the Ryazan Oblast Clinical Hospital formulary manual and the development and use of educational programs for undergraduate and postgraduate students.

- In preparation for competitive drug procurement activities, the Pskov Oblast Pharmacia received a computer and printer. Although the RPM technical assistance in drug procurement to Pskov Oblast did not take place because of changes in the RPM work plan and priorities, the equipment was used by the Pharmacia to improve its inventory management.

- After the RPM-Russia Moscow office moved from its original location to Pharmedinfo, its equipment was shared with Pharmedinfo staff. The staff used it to assist RPM to conduct two tuberculosis (TB) studies in Russian hospitals and to prepare materials and presentations for the Fifth Annual Russian National Man and Drugs Congress.

In December 1998, the RPM-Russia Project, following the USAID regulations on property disposition, acquired permission to transfer the equipment purchased for Russian activities to its Russian counterparts. The inventory and recipients list can be found in Annex 3.

Development of MSH/RPM-Russia Moscow Office

In July 1995, the MSH/RPM-Russia Moscow office was established. The office was staffed with a full-time MSH employee and three outside service providers: an office manager and two physicians.

The Moscow office not only facilitated RPM management and logistics but also served as a base for providing direct technical assistance and training to RPM oblasts. The specialists assisted oblasts in finalizing and producing their formulary lists and formulary manuals and helped start drug utilization programs in selected hospitals.

The Moscow office facilitated communications with other USAID-funded and international projects in Russia that resulted in joint activities with the Abt ZdravReform project, AIHA, and WHO.

Impacts and Accomplishments

The MSH/RPM Project goal and purpose in Russia were achieved through work in five technical areas, described below:

- Drug Selection: Drug Formulary Development and Maintenance
- Drug Utilization Review
- Drug Procurement: Management of Competitive Procurement/Tendering
- Rational Drug Use
- Management and Economic Viability of Pharmacies

In the fall of 1997, RPM conducted a project impact study in Ryazan, Novgorod, and Pskov oblasts, with an emphasis on formulary system development, DUR implementation, and drug procurement. The objective of the study was to assess the applicability and effectiveness of the above-described implementation strategy, methodology, and tools, particularly in terms of the project's sustainability.

452

Data were collected from oblast health administrations and 32 major oblast health facilities. The survey instruments were built around two RPM manuals: *Manual for the Development and Maintenance of Hospital Drug Formularies* and *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals*. Both manuals offered Russian specialists a step-by-step approach to the implementation of formulary systems in oblasts and health facilities.

The evaluation tools were designed with the assumption that compliance of Russian counterparts with the recommended methods would result in rationalizing drug management, selection, and use. This, in turn, would contribute to the establishment of rational, market-driven, and clinically oriented pharmaceutical systems.

The major survey results are briefly summarized below.

Drug Selection: Drug Formulary Development and Maintenance

The Formulary System Was Institutionalized in the Oblasts

The formulary system became a part of all three oblasts' health development plans, which were formally approved by local governments. Formulary committees were established in 61 hospitals and in all three oblast health administrations. Written policies and procedures regulating drug selection and use were developed and approved by hospital and oblast health administrations.

A model of legislative reform related to rational drug management was developed in Novgorod. Drug management and rational use activities are outlined in the oblast law "On the Legal and Organizational Basis of the Oblast Health System." Competitive procurement is codified in the oblast decree "On State Guarantees on Drug and Medical Supplies Procurement."

Drug Selection/Formulary Development Was Performed according to Standard Procedures

All surveyed hospitals followed the step-by-step methodology for selecting drugs recommended by RPM in the *Manual for the Development and Maintenance of Hospital Drug Formularies*. Printed versions of the manual were widely disseminated in Russian, and an electronic version was made available on the Internet.

Formulary Implementation Resulted in Drug Selection Based on Cost, Safety, and Efficacy

By the fall of 1997, 61 formulary drug lists were developed in the three oblasts. The survey of 32 selected hospitals showed that, through the process of formulary system development, the number of drugs used in all the hospitals was reduced by an average of 34 percent. The majority of drugs were deleted from formulary lists because they were determined to be of low efficacy. The second most frequent reason for deletion was unproven safety, followed by high cost and

453

lack of availability from suppliers. In 24 hospitals (75%), not only the cost of a drug but also the cost of the course of treatment was calculated and taken into consideration.

It is important to note that, given the still-diminishing health care budget in the majority of Russian oblasts, it is not reasonable to think in terms of overall expenditure reductions for drug products. However, it is possible to evaluate impact in terms of maintaining a consistent supply of cost-effective products and of reallocating scarce resources toward essential drug purchases. Financial data obtained from several hospitals show that significant sums were reallocated for the procurement of selected essential drugs.

Another effective mechanism for enhancing the rational use of drugs implemented in the three oblasts was setting prescribing restrictions of selected products to specific departments or specialists. In 38 percent of hospitals, prescribing restrictions were introduced for products with high drug costs, narrow therapeutic index, potential for significant adverse reactions, complex administration regimens, and need for special monitoring.

Aspects of a Comprehensive Formulary System Were Established in Oblast Facilities

Drug information systems were developed and implemented in all three oblasts to provide reliable, current, and unbiased information to prescribers. Mechanisms were established to make this information available at any time. Between 1995 and 1997, six DICs were established, two in each of the RPM oblasts. These centers were equipped with computers, Internet access, and printers. They were also provided with comprehensive drug information sources in both paper and electronic formats, and RPM assisted oblasts in developing their own reliable local drug information sources. In April 1997, Ryazan Oblast Clinical Hospital published the first Russian hospital formulary manual, which is currently being used by 59 percent of the surveyed hospitals. The Novgorod formulary manual was printed in May 1998, and the Pskov Oblast formulary manual was published in November 1998.

Oblast DICs are active in providing drug information to prescribers, reviewing hospital formulary lists, and participating in formulary system development at the oblast level. The Ryazan Educational Information Center, located at Ryazan Medical University, is active in promoting the RPM methodology through its medical school curricula for students and postgraduate continuing education programs.

Mechanisms for updating formulary lists have been developed in all the hospitals that were surveyed. The principal changes to date are the deletion of less efficacious and unsafe drugs and the addition of drugs of proven efficacy and safety. In some cases, inclusion or deletion from the formulary was based on drug cost. Nearly 20 percent of drugs were deleted because they were not readily available from suppliers or because they were no longer manufactured.

Although RPM activities in the oblasts did not specifically target the development or revision of standard treatment guidelines, formulary implementation resulted in the development of new STGs or the review of existing STGs, in a number of hospitals. The introduction of new STGs led to the deletion of drugs by formulary committees. However, formulary lists in 75 percent of

hospitals were drafted in compliance with existing STGs, while STGs were modified in 15 percent of hospitals during the course of formulary implementation.

The formulary system development process also calls for establishing adverse drug reaction (ADR) monitoring systems by health facilities. RPM did not provide direct technical assistance or training in the development of such systems, although their importance was continuously emphasized in the *Manual for the Development and Maintenance of Hospital Drug Formularies* and at RPM workshops. An ADR monitoring program is fully functional in only one hospital, although ADR reporting forms were developed in three hospitals. A number of hospitals are attempting to establish an ADR reporting system. Six of them have completed tables on adverse drug reactions reported in the past six months. Other hospitals indicate a lack of data on ADRs or that no ADRs had taken place in the previous six months.

DICs and collaborating medical universities have also been involved in educational activities. They are active in providing on-site and academic training in formulary system implementation issues. The most comprehensive changes were made at the Ryazan Medical University to the standard curricula for medical students and postgraduates. The university adapted RPM materials for use in courses. During 1996 and 1997, it provided training for about 2,150 third- and fourth-year medical students and more than 220 health specialists from other cities, including Perm, Ekaterinburg, Tula, Kurgan, Chelyabinsk, and Magnitogorsk.

Drug Utilization Review

DUR is a continuous review process used primarily as a means to detect irrational, inappropriate, and unnecessarily costly drug therapy. It is performed by the medical staff as a criteria-based, ongoing, planned, and systematic process designed to continuously improve the appropriate and effective use of drugs. The process is well described in *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.* The criteria for selection should be STGs.

DUR programs have been implemented in seven hospitals. Among the reviewed drugs were antibiotics, H_2 antagonists, bronchodilators, and antidepressants used in risk group patients. It is anticipated that, as hospitals continue development of their formulary systems, a greater number will implement DUR programs. The collegial process that is essential to helping physicians become better prescribers is a new approach for physicians and administrators alike. Working together on formulary committees has contributed to forming a solid basis for proceeding to DUR.

Drug Procurement: Management of Competitive Procurement/Tendering

Formulary-based drug procurement was successful in limited trials. Several trial competitive procurement activities took place between 1995 and 1997. In 1995, the Ryazan Health Administration conducted a limited tender for insulin that resulted in savings of $585,000 compared with what would have been paid for the same product through direct purchases.

455

In 1996, the Pskov Health Administration conducted a restricted tender for cardiovascular drugs, antibiotics, and antispasmodics for oblast health facilities, and achieved savings of approximately 10 percent, when compared to wholesaler price lists. On the basis of this experience, the governor of the oblast issued a decree mandating competitive procurement for drugs and medical supplies. The Novgorod Oblast Health Administration estimated that the 1997 limited tender led to total savings of 970.2 million rubles (approximately $165,000 dollars).

Novgorod Oblast implemented the widest application of competitive procurement. The 1998 procurement list was created on the basis of the Novgorod Oblast Formulary. It contained approximately 400 drugs to be procured competitively. Novgorod estimated that this process would reduce expenditures for 1998 by 60 to 80 percent compared with 1997 levels.

Rational Drug Use[3]

The RPM-Russia Project took several approaches to promoting the rational use of drugs, including working with medical schools on curriculum reform, direct training of Russian counterparts, assisting in the establishment of DUR programs, and disseminating project results.

Training assistance consisted of developing and distributing written reference materials, presentations at meetings, on-site technical assistance by RPM staff and consultants, study tours, workshops, and courses. Reference materials developed include the adaptation and translation of the WHO *Guide to Good Prescribing*, manuals on formulary development, and DUR implementation manuals.

Presentations on rational drug use were made at the Russian National Man and Drugs Congresses, AIHA Annual Conference in the United States, Abt-sponsored ZdravReform conference, RPM/WHO conference in Moscow, and at conferences at Saint Petersburg State Medical University.

As noted earlier, the most impressive results were achieved by RPM in collaboration with Ryazan Medical University, which introduced dramatic curricula changes to incorporate principles of rational drug use. However, measuring impacts from curricula reform requires a long-term approach.

Management and Economic Viability of Pharmacies[4]

RPM community management activities took place only in Ryazan Oblast, by request of the Ryazan Oblast Health Administration. These activities focused on identifying and designing interventions to fill the gaps in the management skills of community pharmacy managers in the face of a rapid transition from a centralized to a market system. Although the pharmacy directors exhibited proficiency in various aspects of pharmacy management, RPM activities provided opportunities to learn new information and skills related to pharmacy operations, human resource

[3] Not studied in the RPM Impact Evaluation
[4] Not studied in the RPM Impact Evaluation

management, financial analysis and decision making, and marketing. Pharmacy managers developed and implemented business plans according to a template developed by RPM. The regional pharmacy licensing authority used these same processes to develop and successfully implement business turnaround plans for several failing pharmacies. As a result, a number of aspects of business plans were incorporated as requirements for obtaining new pharmacy licenses or renewals.

At the beginning of the project, the Oblast Health Administration had a pronounced tendency to regulate the pricing and activities of pharmacies. This issue was addressed in the RPM Report "Pricing Options for Pharmacies in Ryazan Oblast." Administrative authorities became more flexible and were willing to adopt the pricing recommendations when they saw the positive effects of competition. These benefits included an increased assortment of pharmacy goods, decreased cost of pharmaceuticals to patients, and an increase and improvement in pharmacy services, particularly among those pharmacies participating in RPM programs.

An unanticipated, but gratifying, result of the pharmacy management activities was that participants adapted RPM teaching methodologies to their work environments. Small group activities, role playing, and case studies were new methods not traditionally experienced by these participants. Encouraging nonjudgmental feedback was of particular value in increasing their ability to think creatively outside of the accepted norm. Their feedback indicated that the concepts and skills learned in RPM activities were not too complex, and the framework provided by RPM helped them organize data into valuable information for decision making.

One of the most difficult concepts for pharmacy managers and oblast administrators alike was that a market economy provides the opportunity to either succeed or fail. This concept was particularly threatening to the post-Soviet population, where the expectation of and need for a safety net was great. A reason for the success of the activities in Ryazan Oblast was the willingness on the part of the administration to accept that good management concepts can be applied in either public or private settings. In addition, there was sufficient time to put these concepts into practice and to see results.

Planned RPM-Russia Activities Not Completed

Most of the activities planned but not fulfilled by RPM were due to unfavorable political and economic developments in Russia described in the first section. According to the last RPM-Russia work plan approved by the USAID/Moscow Mission, covering the time period of January 1997–April 1998, RPM-Russia did not carry out the following activities.

Direct technical assistance to oblasts for pooled procurement. During the course of the project this activity was postponed several times due to requests from oblasts. It was decided that RPM first had to concentrate on drug selection and formulary development, procurement being the next step in the drug supply process. By the time oblast formulary lists were in place at the end of 1997, it became clear that pooled procurement was not viable as a method of drug supply

457

for oblast public health systems. The existing Russian federal regulations did not allow hospitals to merge drug funds, without which pooled procurement could not take place. Instead, Ryazan and Novgorod oblasts successfully implemented individual formulary-based centralized procurement methods. Under this system, drug funds for the whole oblast are controlled by the OHA, and, depending on the availability of cash or barter trade, procurement is done either on a competitive basis (Novgorod) or by centralized direct negotiation (Ryazan). It should be noted that RPM oblasts could have benefited from formal training in competitive procurement methods, but such training was not planned for the discussed period.

High-level technical meetings. The success of the first high-level technical meeting in October 1996 resulted in RPM including an additional meeting in its work plan. A meeting was scheduled for the first quarter of 1998, and it was expected that Ministry of Health representatives would attend it. However, changes in the MOH made it impossible to conduct the meeting on time.

Rational Prescribing Workshop with WHO. This workshop was planned for the end of 1997, and was to be the second in the proposed series of workshops on rational drug use. The workshop did not take place due changes in the WHO work plan.

Distribution of community pharmacy manual. RPM began to develop the manual in 1995, but during the course of development it became clear to USAID/Moscow and RPM that privatization and improvement in economic viability of community pharmacies were progressing adequately in Russia without outside assistance. It was decided to discontinue this activity in favor of other project components.

RPM TB Surveys in Russian Oblasts

By April 1998, MSH/RPM-Russia activities were completed. However, because of RPM expertise in the Russian pharmaceutical sector, the USAID Mission in Moscow commissioned two studies of the situation of tuberculosis in Russia. The study of TB treatment methods was conducted during April and May 1998. A study on the availability and procurement methods of TB drugs was performed during July and August 1998, in both RPM and non-RPM oblasts and TB facilities. In conducting the studies, RPM relied upon its Russian collaborators in oblasts, Pharmedinfo, and former MSH/RPM Moscow office consultants.

The key results of the studies are briefly described below.

Diagnosis and Treatment of Tuberculosis in Five Russian TB Hospitals

The diagnosis guidelines in all five surveyed hospitals appeared to be similar. However, sensitivity testing takes three months in all hospitals except Novgorod TB Hospital, where it takes only 15 days. There is a high incidence of drug-resistant TB in some hospitals. Pskov TB Hospital, for example, reported that 36 percent of patients showed primary drug resistance and

54 percent acquired resistance during the course of therapy. Thus, TB drug resistance could become a major issue in Russia.

Treatment regimens varied among TB hospitals and deviated from internationally accepted treatment guidelines. For example, the duration of inpatient therapy for the same stage of TB ranged from 2 to 6 months, and total treatment lasted from 18 months to three years in one method. The use of large numbers of drugs for the treatment of side effects and for maintaining therapy was also a deviation from international norms.

Availability and Procurement Methods of First-Line Tuberculosis Drugs in Four Russian Oblasts (Ryazan, Novgorod, Pskov, and Yaroslavl)

The study showed that, although the domestically produced first-line antituberculosis drugs isoniazid, rifampicin, pyrazinamide, streptomycin, and ethambutol were all available on the Russian market, oblasts experienced periodic stock-outs of these drugs. No correlation was identified between the amount of money spent per capita in the oblasts on drug purchases and the availability of TB drugs to patients. The availability of drugs was determined mainly by procurement methods.

There was a clear relationship between the type of procurement (centralized versus decentralized) and the cost of TB drugs for oblasts, irrespective of means of payment (barter or cash purchases). Barter trade, when managed centrally, can ensure good prices and availability because of volume discounts and oblast government guarantees for suppliers. Likewise, a relationship existed between procurement methods and the cost of TB drugs to the oblasts. Competitive tendering made prices and drug expenditures significantly lower than any other procurement method.

It should be noted that despite similar economic situations in the surveyed oblasts, the availability of TB drugs to patients was significantly better in the two oblasts (Ryazan and Novgorod) that went further in the implementation of the RPM project. In both Novgorod and Ryazan, drug selection is strictly determined by the oblast formulary system, procurement is centralized, and procurement is based on the formulary. Yaroslavl (a non-RPM oblast) and Pskov, where RPM reforms were slowed down by political changes in local government, spend twice as much on pharmaceuticals per capita as Novgorod and Ryazan, and yet experience severe drug shortages.

The results of both studies were reported to USAID in September 1998 and they are expected to assist the Mission in developing its TB strategy for Russia.

The RPM recommendations on possible interventions to tackle the TB problem in Russia are summarized in the last section, Likely Needs After the End of the Project.

Sustainability

The RPM-Russia experience and materials dissemination activities resulted in growing interest throughout Russia in formulary system implementation. Formulary systems were implemented without RPM technical assistance in Saint Petersburg Medical University Hospital, in Vladivostok Krai Hospital, Ekaterinburg Oblast hospitals, Tomsk Cardiological Hospital, and in other sites. The interest in, and acceptance of, RPM concepts became even wider with establishment of the All-Russia Drug Information Network, developed through the USP component of RPM.

By request of Ekaterinburg Oblast Health Administration in December 1998, RPM participated in the Urals Regional Conference, dedicated to issues of formulary system implementation. The conference was attended by approximately 200 participants representing the Urals region: Sverdlovsk, Perm, Chelyabinsk, Kurgan, and Tyumen oblasts; and two republics, Udmurtia and Bashkortostan. These oblasts are planning to commence formulary system development activities.

Although RPM-Russia was designed to work at the oblast level and did not plan to provide any technical assistance to the Russian Federation Ministry of Health, the success of formulary systems in RPM oblasts made the MOH decide to initiate work on developing a Russian National Drug Formulary.

As the first step in this process, the MOH asked Pharmedinfo to organize a national conference to discuss formulary system options. The national conference, "Drug Formulary Implementation in Russia," was held in Moscow from December 7–8, 1998. The conference was sponsored and supported by the Russian Federation Ministry of Health, Pharmedinfo, USAID, USP, and MSH. Approximately 150 participants representing national organizations and ministries discussed the future of the Russian formulary system.

Among the most important outcomes of the conference was the decision to initiate formulary system development at the national level and to devote the 1999 Russian National Man and Drugs Congress to issues of formulary system development.

The agendas for the Ekaterinburg and Moscow Conferences can be found in Annex 4.

Likely Needs after the End of the Project

National-Level Needs

Given the latest decision of the MOH to initiate the national formulary development process, the technical assistance to Russia after RPM may be focused on the following:

- Help the MOH develop a national approach to formulary system development
- Design an implementation plan for national formulary development that would include appropriate training of national-level experts
- Assist the MOH in designing changes in national health legislation that may be required to support the formulary system
- Assist the MOH in tackling the growing TB problem, including assistance in the implementation of new treatment standards and competitive procurement of TB drugs

Oblast-Level Needs

At the oblast level, further efforts may be required to assist health administrations in the development of drug and health legislation in order to enhance the sustainable efforts made by RPM. Policy and enforcement mechanisms are needed to maintain the commitment of oblast health administrations to ensuring adequate drug supply for public health facilities. Such policies may include—

- Development of, and strict adherence to, local essential/formulary drug lists
- Harmonization of formulary lists with modern treatment standards
- Utilization of ABC/VEN analysis as a tool for prioritizing drug selection
- Implementation of modern drug quantification techniques
- Centralized procurement for public health facilities based on a list of preselected drugs
- Strict control of drug distribution through every step of the system, down to the patient level
- Implementation of drug utilization review programs
- Control of drug-related morbidity and adverse reaction reporting
- Drug use restrictions

Russian oblasts may benefit from formal training in competitive procurement techniques. The RPM experience proved that competitive procurement methods are most beneficial for health systems in the environment of severe funds shortages. Since the economic situation in Russia is not likely to improve in the near future, drug tenders may be the only solution to provide adequate drug supply for public health facilities. Federal institutions responsible for training in public procurement should develop a course in competitive drug procurement.

Further efforts may also be required for establishing legal support for pooled procurement at the oblast level.

Tuberculosis Situation

The two RPM/USAID TB studies recommended possible interventions to improve TB diagnosis and treatment in Russia and included the following suggestions.

Diagnosis and Treatment Study Suggestions

- Assistance in the implementation of rapid methods of sensitivity testing, such as the BACTEC method
- Promotion of internationally accepted treatment regimens of proven efficacy
- Use of ABC/VEN analysis as a method of determining the exact allocation of funds for TB treatment

Availability and Procurement Study Suggestions

- Further study may be required to investigate the quality of domestically produced TB drugs.
- Russian regions may benefit from establishing a system to report TB drug stock-outs.
- Effort should be made to promote centralized and competitive procurement of TB drugs at the oblast level.
- Policy and enforcement mechanisms are needed to show commitment of oblast health administration to having adequate drug supply for public health facilities.
- Oblasts should consider ways of making outpatient treatment more effective by facilitating the purchase of TB drugs for outpatients rather than erecting new facilities that encourage extended inpatient treatment.
- In light of the serious situation of TB in Russia, efforts should be made to guarantee funds for the purchase of TB drugs.

Annex 1. RPM-Russia History by Mode of Implementation

Reconnaissance Visits

November 1993 to January 1994: Two reconnaissance visits were made to Russia after receiving add-on funds in order to establish relationships with the MOH and to select the pilot oblast. Pharmedinfo, a quasi-governmental organization responsible for the provision of drug information in Russia, was chosen by the MOH as RPM-Russia's official collaborating organization. Ryazan Oblast, located south of Moscow, was chosen as the pilot site in January 1994.

July to August 1995: RPM team visited Novgorod and Pskov Oblasts and discussed possibilities of roll out with oblast health administrations. Oblast health authorities expressed willingness to commence RPM activities.

Pharmaceutical Sector Assessments

May to November 1994: RPM conducted an in-depth pharmaceutical sector assessment of Ryazan Oblast. Preparation included substantial adaptation of existing assessment tools and the orientation of local officials and specialists to western pharmaceutical terminology and concepts. The entire assessment process resulted in the creation of a large number of local stakeholders.

November to December 1995: Assessments were conducted in Novgorod and Pskov Oblasts, relying heavily on local specialists to collect and analyze indicator data. In the rollout oblasts, initial enthusiasm was so great that technical work began even before the assessments were conducted.

Policy Options Dialogue

November 1994: A Policy Options Workshop was held in Ryazan Oblast for approximately 80 officials and specialists from Ryazan, Moscow, Saint Petersburg, and the United States. Assessment findings were presented and participants drafted work plans for each RPM-Russia technical area. The workshop resulted in further creation of stakeholders.

March 1996: RPM conducted a joint Novgorod and Pskov Oblasts Policy Options Workshop for 64 participants representing all levels of oblast health system. Both oblasts adopted RPM as a means of reforming the pharmaceutical sector. The project implementation plan became part of oblast health development programs approved by local governments.

463

Direct Technical Assistance

February 1995: RPM provided direct TA to Ryazan Oblast in formulary development. As a result,

- A formulary committee was established in Ryazan Oblast Clinical Hospital.
- Policies and procedures of the formulary committee were developed.
- A plan for formulary development and implementation was established.
- A therapeutic classification scheme was established.
- Computer software was developed to facilitate the drug class review process.
- A review of antibiotic drugs was performed.

February 1995: Direct TA to Ryazan Oblast in drug procurement. Outcomes:

- Drug quantification needs were identified for 1995 procurement.
- INVEC software for inventory control was demonstrated.
- A sample tender contract was developed in Russian.
- A tender committee was established in Oblast Health Administration.

April 1995: Direct TA to Ryazan Oblast. Outcomes:

- The antibiotic formulary list was finalized.
- Formulary activities were initiated at Ryazan City Hospital #11.

May 1995: Direct TA to Ryazan Oblast. Outcomes:

- The cardiovascular formulary list was finalized at Ryazan Oblast Clinical Hospital (ROCH).
- A pilot DUR study was initiated at ROCH.
- RPM-based training materials developed by Ryazan Medical University were reviewed.

September 1995: Direct TA to Ryazan Oblast. Outcomes:

- Draft hospital formulary list was developed at ROCH.
- Business plans were developed at 25 community pharmacies in Ryazan.

November 1995: Direct TA to Ryazan Oblast. Outcomes:

- Hospital drug formulary list was approved for use and procurement at ROCH.
- ROCH staff received on-site training in DUR concepts.
- Drugs were selected and schedules developed for DUR at ROCH.

February 1996: Direct TA to Novgorod and Pskov Oblasts. Outcome:

- Draft health reform implementation plans were developed by OHAs in preparation for Policy Options Workshop.

March 1996: Direct TA to Ryazan community pharmacies. Outcome:

- Action plans were developed by community pharmacies for 1996.

May 1996: Direct TA to Novgorod and Pskov Oblasts. Outcomes:

- Formulary committees were established at oblasts' health administrations.
- Policies and procedures of the formulary committees were drafted.
- Therapeutic classification scheme was established.

September 1996: Direct TA to three oblasts. Outcome:

- Oblast health officials drafted plans for implementation of DUR programs in oblast health facilities.

November 1996: Direct TA to Novgorod and Pskov in DUR and formulary development. Outcomes:

- DUR activities were initiated in ten hospitals.
- Policies and procedures of oblast formulary committees were developed.

February 1997: Direct TA to Ryazan Oblast in Hospital Formulary Manual development. Outcome:

- Draft formulary manual was approved by ROCH and prepared for printing.

March to May 1997: Direct TA to Novgorod and Pskov Oblasts in formulary development. Outcome:

- Draft oblast formulary lists were developed and approved by oblasts' health administrations.

April 1997: Direct TA to Ryazan Oblast in Hospital Formulary Manual development. Outcome:

- Ryazan Oblast Clinical Hospital Manual was published.

September 1997: Direct TA to Novgorod and Pskov in formulary development. Outcomes:

- Oblasts' formulary lists were revised.
- First edition of Novgorod Oblast Formulary Manual was approved for use in oblast.

November 1997: Direct TA to Pskov in formulary development. Outcome:

- Second revised edition of Pskov Oblast formulary list was approved for use in the oblast.

Meetings

April 1995: RPM participated in the Second Russian National Man and Drugs Congress with symposium and roundtable discussions. A wide audience of Russian health providers was familiarized with rational pharmaceutical management concepts and with plans for reforming the Ryazan pharmaceutical sector within the framework of RPM.

April 1996: RPM participated in the Third Russian National Man and Drugs Congress with symposium and roundtable discussions. At RPM sessions, Ryazan Oblast shared its experience of the initial stage of formulary system implementation at the hospital level. Ryazan Medical University discussed changes it made to undergraduate and postgraduate curricula to incorporate RPM materials in rational drug selection, use, and drug information development.

October 1996: RPM-Russia made presentations on drug selection and use at the American International Health Alliance Annual Conference in Iowa.

November 1996: RPM conducted a session at the Russian conference on "Health Reforms in Russia: Experience of Russian-American Cooperation" organized by the Abt ZdravReform Project.

January 1997: RPM-Russia made two presentations at a Pharmacology Conference held at Saint Petersburg Medical University.

April 1997: RPM participated in the Fourth Russian National Man and Drugs Congress with symposium and roundtable discussions. Presentations were made by RPM oblasts' health administrations on specifics of RPM implementation in individual oblasts.

April 1998: The results of the RPM impact survey were discussed by oblast participants at the Fifth Russian National Man and Drugs Congress.

December 1998: RPM-Russia made three presentations at the Urals Region Conference "Clinical Pharmacology and Rational Pharmaceutical Management" organized by Sverdlovsk Oblast Health Administration in Ekaterinburg.

December 1998: RPM made presentations at the "Drug Formulary Implementation in Russia" conference organized by the Russian Federation Ministry of Health.

Study Tours

June 1995: Health System Overview Study Tour, Texas. Four Ryazan Oblast officials participated in a Health System Overview Study Tour in Texas. Visits to hospitals reinforced the importance of drug formularies and accelerated the formulary development process at the Ryazan Oblast Clinical Hospital. Likewise, exposure to U.S. buying groups accelerated the formation of a Ryazan Oblast tender committee.

October 1995: Formulary System Development Study Tour, Tucson, Arizona, and Washington, D.C. Seven Ryazan and Novgorod officials received advanced training in formulary development and orientation to drug utilization review (DUR), use of drug information databases, and desktop publishing. The tour facilitated acceptance of DUR as part of the drug selection process.

August 1996: Community Pharmacy Management Study Tour, Michigan. Eleven health professionals from Ryazan, Pskov, and Novgorod oblasts and from Moscow participated in the study tour. The tour highlighted established and innovative U.S. pharmacy practices.

Workshops and Training

May 1994: *Indicator-Based Assessments.* RPM-Russia trained 20 data collectors from Ryazan Oblast in use of indicators in evaluating pharmaceutical systems.

November 28 to December 2, 1994: *Policy Options Workshop.* In Ryazan Oblast, 70 participants discussed and drafted the RPM implementation plan for the oblast.

May 15 to 20, 1995: *Practical Pharmacy Management: Application in Russia.* A workshop conducted by RPM with AED funds provided practical follow-on training for participants of U.S. training programs and representatives from Ryazan. A total of 47 participants were trained in clinical pharmacy and formulary development, management of drug information, pharmacy management, and medical insurance.

May 1995: RPM-Russia trained Ryazan Medical University faculty in use of drug information software and Ryazan Oblast Clinical Hospital staff in use of formulary development software.

September 1995: *Community Pharmacy Management.* RPM-Russia conducted an Advanced Community Pharmacy Management Workshop in Ryazan Oblast for 20 pharmacy directors. The main goal was to introduce the process of business plan development. Participants attended a second, more intense workshop in March 1996.

September 1995: *Indicator-Based Assessments.* RPM-Russia conducted a pre-assessment workshop for 24 Novgorod and Pskov specialists in the use of indicators in evaluating pharmaceutical systems.

September 1995: *Formulary Development.* RPM-Russia conducted a mini-workshop on formulary development for 46 participants from Novgorod and Pskov Oblasts at the request of local officials eager to begin work in this area.

February 12 to 23, 1996: *Formulary Development and Maintenance*, Moscow. The first major training in step-by-step formulary system development for 67 participants from RPM oblasts Ryazan, Novgorod, and Pskov. Abt Associates sponsored additional participants from ZdravReform Project regions: Tomsk, Kemerovo, and Novosibirsk Oblasts, Altai Krai, and Moscow.

March 11 to 15, 1996: *Pharmacy Management Intensive*, Ryazan. RPM provided training for 15 community pharmacy directors of Ryazan Oblast in pharmacy management issues.

March 18 to 22, 1996: *Policy Option Workshop for Novgorod and Pskov Oblasts*, Valdai. The status of pharmaceutical sector of the oblasts was reviewed, problems were identified, and RPM technical areas were defined. Training in the pharmaceutical sector was provided for 45 participants.

May 20 to 24, 1996: *Formulary Development and Maintenance II.* The workshop was held for 61 specialists from Ryazan, Novgorod, and Pskov.

September 30 to October 4, 1996: *Drug Utilization Review Workshop*, Sosnovy Bor, Ryazan Oblast. Instruction for stepwise implementation of a drug utilization review program was provided for 60 participants from RPM oblasts.

September 1996: RPM-Russia conducted a lecture on Cost-Effective Drug Selection for 200 medical students at the Ryazan Medical University. The university Pharmacology Department adapted the lecture and presented it as a three-hour lecture for 144 physician interns. It has been incorporated into the medical school curriculum and used in the Information Education Center opened with USP support.

October 28 to 31, 1996: *High-Level Technical Meeting: Formulary System Implementation Problems.* The meeting included training of 53 participants from Novgorod, Ryazan, and Pskov Oblasts and from Saint Petersburg in specific drug selection, steps of DUR implementation, ABC/VEN analysis, pooled procurement, and drug information development.

January 31, 1997: *Formulary System Options*, Saint Petersburg. RPM gave a presentation of formulary system options for 35 participants from Saint Petersburg.

February 1997: *Formulary System Implementation.* As a result of the RPM-Russia presentation at the AIHA Annual Conference in late 1996 in Iowa, USA, a workshop was held in Moscow for 21 participants from partnership hospitals in Russia, Georgia, and Armenia.

May 21 to 23, 1997: *Rational Drug Use.* RPM-Russia collaborated with WHO to conduct a workshop on Integration of Rational Prescribing Practice in Medical Undergraduate Curricula in the NIS. The workshop focussed on the WHO *Guide to Good Prescribing* that was adapted by

RPM-Russia for use in Russia. The workshop was attended by approximately 75 participants from seven NIS countries.

June 9 to 11, 1997: *Formulary Development and DUR*, Moscow. RPM/USP organized a practical conference on Drug Information for the Health Care Professionals that included a workshop on formulary development and DUR. Training was provided for 110 participants from Russian regions and most NIS countries.

Courses

November 1995: Knowledge of clinical pharmacology is critical to successful implementation of drug formulary systems, but it is an area in which local physicians consistently say they need more training. RPM technical staff, in collaboration with the faculty of Russian State Medical University, conducted a three-week course in clinical pharmacology and drug selection issues by therapeutic categories for 140 Novgorod and Pskov physicians.

MSH/RPM Moscow Office Development

June to July 1995: The MSH RPM-Russia office was established in Moscow with the capacity of providing on-site technical assistance to RPM oblasts by its staff. In the course of the project, the Moscow office also played an important role in disseminating of RPM methodology and materials, leveraging efforts with other USAID and international projects, and maintaining RPM activities in oblasts.

RPM-Russia Surveys and Studies

September 1997 to February 1998: Following recommendations of the RPM evaluation team, RPM developed questionnaires and conducted assessment of RPM impact on oblasts' health systems. The collected data and the analysis showed that formulary systems were successfully established in three RPM oblasts.

March to April 1998: At the request of the USAID Mission in Moscow, RPM conducted a brief survey of diagnosis and treatment methods of tuberculosis in five Russian hospitals, including three TB hospitals located in RPM oblasts. The survey resulted in a proposal to the Mission for further study of the TB problem in Russia.
July to August 1998: The USAID Mission in Moscow commissioned a study of the availability and procurement methods of first-line TB drugs in four Russian oblasts. The results of the study were summarized in a report that helped the Mission to develop its TB strategy for Russia.

MSH/RPM-Russia Close-Out

August 1998: RPM-Russia close-out plan was developed and discussed with USAID/Moscow. RPM-Russia was to complete all activities by December 31, 1998.

November 1998: RPM developed and delivered a presentation on the impacts of its activities in Russia for a broad audience from USAID/Washington.

December 1998: RPM received confirmation on RPM-Russia property disposition. The recipients were Russian collaborators: Ryazan Oblast Clinical Hospital, Ryazan State Medical University, RC Pharmedinfo, and Pskov Oblast Pharmacia.

December 1998: The final RPM-Russia report was submitted to USAID, and all activities completed.

Annex 2. RPM-Related Publications

A. Abstracts on RPM in Man and Drugs Congresses Materials

Second Russian National Man and Drugs Congress, 1995

Makarova V.G., Semenchenko M.V., Yakusheva E.N. *Educational Center of the Drug Information Service*. Ryazan State Medical University.

Popova N.N. *Reformation of the Drug Distribution System on the Regional Level.* Ryazan Oblast APO "Pharmacia."

Voronkov D.V., Grechenko V.I., Dykin V.A., Tarasov A.V. *Rational Pharmaceutical Management on the Regional Level.* Ryazan Oblast Clinical Hospital; Pharmaceutical Committee.

Third Russian National Man and Drugs Congress, 1996

Armstrong E., Savelli A., Schwarz H., Bykov A.V., Zagorski A.P. *Drug Utilization Review (DUR).* College of Pharmacy, University of Arizona; Management Sciences for Health.

Armstrong E., Smith G., Savelli A., Bykov A.V., Zagorski A.P. *Pharmacoeconomic Aspects of Rational Pharmaceutical Management.* College of Pharmacy, University of Arizona; Management Sciences for Health.

Bykov A.V., Belousov Y.B., Savelli A., Tkhostova E.B. *The Importance of Post-Graduate Education in Implementation of Rational Pharmaceutical Management Project.* Management Sciences for Health; Russian State Medical University, Moscow.

Kotov G.N., Voronkov D.V., Minashkina L.A., Stepanova L.A., Sallet J.P. *Informational-Reference System "Formular."* Ryazan Oblast Clinical Hospital; Management Sciences for Health.

Minashkina L.A., Voronkov D.V., Yakushin S.S., Savelli A., Stepanova L.A., Markov A.I., Dragunkin Y.V., Kupriyanova T.A. *Drug Selection and Formulary Development in Ryazan Oblast Clinical Hospital.* Ryazan Oblast Clinical Hospital; Management Sciences for Health.

Savelli A., Schwarz H., Zagorski A.P., Bykov A.V., Afanasiev N.Y. *Formulary as a Basis for Rational Pharmaceutical Management.* Management Sciences for Health; USAID.

Semenchenko M.V., Makarova V.G., Savelli A. *The Experience of Formulary Manual Drug Monographs Development.* Ryazan State Medical University; Management Sciences for Health.

Stepanova L.A., Voronkov D.V., Minashkina L.A., Schwarz H., Dobrovolskaya T.F. *Modern Concepts of Informational Drug Formulary Development.* Ryazan Oblast Clinical Hospital; Management Sciences for Health.

Fourth Russian National Man and Drugs Congress, 1997

Artemieva G.B., Arhipov A.E. *Role of Formulary System in Health Care Quality Assurance.* Ryazan Oblast Health Administration.

Belousov Y.B., Bykov A.V. *Principles of Rational Drug Use: Role of Clinical Pharmacology.*, Russian State Medical University; Management Sciences for Health.

Bykov A.V., Zagorski A. *Clinical and Economical Aspects of Cost-Effective Drug Selection.* Management Sciences for Health.

Dobrovolskaya T., Voronkov D., et al. *Role of Drug Information Center in Formulary System Development.* Ryazan Oblast Clinical Hospital.

Dmitriev A., Artemieva G. *Formulary System in Pediatrics.*, Ryazan Oblast Children's Hospital; Ryazan Oblast Health Administration.

Ignatov Y., Zaitsev A., et al. *Drug Formulary Development in the Medical University Hospital.* Saint Petersburg State Medical University.

Makarova V., Semenchenko M., Yakusheva E. *Integrated Course on Rational Pharmaceutical Management in Ryazan Medical University.* Ryazan Medical University.

Makarova V., Semenchenko M., Yakusheva E. *Methodological Background for RPM-Based Teaching Programs.* Ryazan Medical University.

Medik V.A. *Legislative Basis for Rational Pharmaceutical Management on Regional Level.* Novgorod Oblast Health Administration.

Medik V.A. *Oblast Drug Formulary Development.* Novgorod Oblast Health Administration.

Minashkina L., Makarova V., et al. *Drug Utilization Review Implementation in Ryazan Oblast Clinical Hospital.* Ryazan Oblast Clinical Hospital.

Savelli A., Bykov A. *Clinical Pharmacology as Scientific Basis for Formulary System Implementation.* Management Sciences for Health.

Savelli A., Bykov A., Zagorski A. *First Results of Cost-Effective Drug Selection on Regional Level.* Management Sciences for Health.

Shlygin S., Bogatin A. *Formulary System Implementation Strategy in Pskov Oblast.* Pskov Oblast Health Administration.

Sonin D. *Specifics of Rational Pharmaceutical Management in Dermatology.* Ryazan Oblast Dermatology Clinic.

Stepanova L., Voronkov D. *Drug Formulary Manual Development in Ryazan Oblast Clinical Hospital.* Ryazan Oblast Clinical Hospital.

Zakharov A., Ivanova N. *Drug Utilization Review Program as Main Component of Rational Drug Use.* Pskov City Hospital.

Fifth Russian National Man and Drugs Congress, 1998

Artemieva G., Tolstov N., et al. *Formulary System and Quality Assurance Problems.* Ryazan Mandatory Medical Insurance Fund.

Egorova S. *Experience in Oblast Formulary Manual Development.* Novgorod Oblast Health Administration Drug Information Center.

Kim M. *Development and Implementation of Oblast Target Drug Supply Programs.* SE Pharmacia, Novgorod Oblast.

Kolotvinov S., Yastrebov A., et al. *Some Aspects of Formulary System Implementation.* The Urals Medical Academy, Yekaterinburg.

Makarova V., Semenchenko M., et al. *Ryazan Medical University Educational Programs Based on Rational Pharmaceutical Management Project.* Ryazan Medical University.

Medik V. *On Some Outcomes of Rational Pharmaceutical Management Project in Novgorod Oblast.* Novgorod Oblast Health Administration.

Minashkina L., Voronkov D., et al. *Drug Formulary as Means of Drug Management in Hospital Setting.* Ryazan Oblast Clinical Hospital.

Savelli A., Zagorski A., Ushkalova E. *Rational Pharmaceutical Management Project: Four Years of Experience in Russia.* Management Sciences for Health.

Stepanova L., Garmash V., et al. *Drug Utilization Review: Treatment of Ischemic Insults in Hypertensive Patients in Intensive Care Setting.* Ryazan Oblast Clinical Hospital.

Svistunova T. *Oblast Drug Legislation Development: Novgorod Oblast Law On Drug Supply.* Novgorod Oblast Health Administration.

Tolstov N., Artemieva G. *Role of Formulary System in Drug Supply within Mandatory Medical Insurance System.* Ryazan Oblast Mandatory Medical Insurance Fund.

Ushkalova E., Savelli A., Zagorski A. *Rational Drug Selection and Formulary Development.* Management Sciences for Health.

Voronkov D., Minashkina L., et al. *The Role of Formulary-Therapeutics Committee in Hospital Drug Supply Activities.* Ryazan Oblast Clinical Hospital.

Zaitsev A., Karpov O. *Clinical and Economical Aspects of Drug Formulary.* Saint Petersburg Medical University.

Other Publications

Belousov, Yuri (Russian State Medical Univerity). "Formularies as the Basis of Rational Drug Therapy," *Pharmacia Journal*, volume 3, 1996.

Bykov A., Zagorski A. "Clinical and Economic Aspects of Rational Drug Use," *Pharmaceutical Gazette*, #8: 1996.

Bykov A., Belousov Y., Olbinskaya I. (The Presidium of the Clinical Pharmacologists and Pharmacotherapists Society). "Clinical and Economic Aspects of the Rational Drug Use," *Pharmacia Journal*, volume 1: 1997.

Bykov A., Zagorski A. "Drug Formulary as the Basis of Rational Pharmaceutical Management," *Pharmaceutical Gazette*, #9: 1996.

Bykov A., Zagorski A. "Rational Pharmaceutical Management," *Pharmaceutical Gazette*, #5 (6): 1996.

Makarova V., Savelli A., Semenchenko M. "Rational Drug Use, Drug Formulary Development: Methodological Recommendations for Physicians," *Ryazan Medical University Papers*: 1996

Sapovsky M.M. "Organizational Aspects of Rational Drug Use on the Basis of Regional Formulary System." Ph.D. diss. abstract, Military-Medical School at the Russian Medical Academy of Post-Graduate Education, 1996.

Shashkova G., Ushkalova E. "Drug Formulary System Development in Russia," *Pharmacia Journal*, # 5: 1998.

"USAID-MOH Health Projects: Rational Pharmaceutical Management Project." *Pharmaceutical Gazette*, #4 (8): 1996.

Voronkov Dmitri V. (Chief Physician of Ryazan Oblast Clinical Hospital). "New Approaches to Rational Use of Drugs (Implementation of Rational Pharmaceutical Management Project in Ryazan Oblast), *Chief Physician Journal*, #3: 1996.

RPM Key Materials and Products Disseminated in Russia

Armstrong, E.P., A. Bykov, and A.V. Savelli. *Introducing Formulary Drug Selection in Russia.* AJHP 1996; 53:426-8.

Callender, D. *The Diagnosis and Treatment of Tuberculosis in Five Russian TB Hospitals.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1998.

Duzey, O.M., and H.B. Desai. *Guide to Successful Management of Community Pharmacies.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, January 1997 (draft).

Management Sciences for Health/Rational Pharmaceutical Management Project. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1995 (Russian edition).

Moore, T.M., A. Bykov, A.V. Savelli, and A. Zagorski. *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals.* Arlington, VA. Rational Pharmaceutical Management Project/Management Sciences for Health, September 1996.

Moore, T.M. *Drug Utilization Review Workshop Proceedings: Ryazan Oblast.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1996.

Moore, T.M. *Conference Proceedings: Novgorod and Pskov Oblasts Policy Options Workshop.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, March 1996.

Moore, T.M., A.V. Savelli, H.O. Schwarz, A. Zagorski, K. Burimski, and O. Solovieva. *Novgorod Oblast Pharmaceutical Sector Assessment.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, November 1995.

Moore, T.M., A.V. Savelli, H.O. Schwarz, A. Zagorski, K. Burimski, and O. Solovieva. *Pskov Oblast Pharmaceutical Sector Assessment.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, November 1995.

Sallet, J.P. *Formulary-R Software.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1995.

475

Savelli, A.V., H.O. Schwarz, A. Zagorski, and A. Bykov. *Manual for the Development and Maintenance of Hospital Drug Formulary Systems.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, February 1996 (Russian edition), April 1996 (English edition).

Savelli, A.V. *Conference Proceedings: Ryazan Oblast Policy Options Workshop.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, December 1994.

Savelli, A.V., J.P. Sallet, A. Zagorski, O. Duzey, and H. Haak. *Ryazan Oblast Pharmaceutical Sector Assessment.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, November 1994.

Schwarz, H.O., A.V. Savelli, and E.P. Armstrong. *Drug Formulary Development in the Newly Independent States.* Submitted to the Annals of Pharmacotherapy January 1997, in press.

Schwarz, H.O. *Proceedings for the Workshop on the Development and Maintenance of Hospital Drug Formularies, Khilovo.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, May 1996.

Schwarz, H.O. *Proceedings for the Workshop on the Development and Maintenance of Hospital Drug Formularies, Moscow.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, February 1996.

Zagorski, A. *Availability and Procurement Methods of First-Line Tuberculosis Drugs in Novgorod, Pskov, Ryazan, and Yaroslavl Oblasts.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 1998

Zagorski, A. *Availability and Procurement Methods of First-Line Tuberculosis Drugs in Four Russian Oblasts (short version for international donors).* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, October 1998.

Annex 3. Equipment Provided to Russian Counterparts

Annex 3.A. Equipment Provided to Pharmedinfo

MANAGEMENT SCIENCES FOR HEALTH
RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT
EQUIPMENT INVENTORY BY LOCATION
CA No. HRN-A-00-92-00059-13
CA No. HRN-0004-A-00-5002-00

5/22/98

PHARMEDINFO

INVENTORY NUMBER	ITEM	BRAND NAME	DESCRIPTION	DATE PURCHASED	SERIAL No.	MODEL	COST	DISPOSITION/ LOCATION	CONTRACT
161	FAX	CANON	PLAIN PAPER, INK JET. WARRANTY REPLACED WITH 292	1/27/95	MCV03257	HI1265 B200	1,198.00	PHARMEDINFO	3200
180	COMPUTER	GATEWAY 2000	PENTIUM	1/7/95	355923	BABY AT,P5-60	2,860.00	PHARMEDINFO	3200
181	PRINTER	H.P.	HP 4L	3/7/95	NLCC39-4711	SPLA93001	795.00	PHARMEDINFO	3200
251	COMPUTER TABLE	DIRECTOR	BLACK	7/17/95		CT800B	168.70	PHARMEDINFO	3200
252	CORNER UNIT	DIRECTOR	BLACK	7/17/95		CNT90BSP	94.95	PHARMEDINFO	3200
253	WRITING TABLE	DIRECTOR	BLACK	7/17/95		ST1500H	168.70	PHARMEDINFO	3200
254	TABLE DRAWER	DIRECTOR	BLACK	7/17/95		FP403B	112.75	PHARMEDINFO	3200
255	DESK CHAIR	DIRECTOR	BLACK	7/17/95		SG500H	114.45	PHARMEDINFO	3200
256	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB23B	152.59	PHARMEDINFO	3200

257	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB23B	152.59	PHARMEDINFO	3200
258	FILECABINET	DIRECTOR	BLACK	7/17/95		FD200 B BASE	245.00	PHARMEDINFO	3200
259	FILECABINET	DIRECTOR	BLACK	7/17/95		FD2008	245.00	PHARMEDINFO	3200
260	WRITING TABLE	DIRECTOR	BLACK	7/17/95		STI500B	168.70	PHARMEDINFO	3200
261	TABLE DRAWER	DIRECTOR	BLACK	7/17/95		FP403B	112.75	PHARMEDINFO	3200
262	DESK CHAIR	DIRECTOR	BLACK	7/17/95		SG500H	114.44	PHARMEDINFO	3200
263	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDH23B	152.59	PHARMEDINFO	3200
264	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDH23B	152.59	PHARMEDINFO	3200
265	FILE CABINET	DIRECTOR	BLACK	7/17/95		FD200 B BASE	245.00	PHARMEDINFO	3200
266	FILE CABINET	DIRECTOR	BLACK	7/17/95		FD200B	245.00	PHARMEDINFO	3200
267	WRITING TABLE	DIRECTOR	BLACK	7/17/95		ST1500B	168.70	PHARMEDINFO	3200
268	TABLE DRAWER	DIRECTOR	BLACK	7/17/95		SG500H	112.75	PHARMEDINFO	3200
270	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB21B	152.59	PHARMEDINFO	3200
271	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB21B	152.59	PHARMEDINFO	3200
272	FILE CABINET	DIRECTOR	BLACK	7/17/95		FD200 B BASE	245.00	PHARMEDINFO	3200
273	FILE CABINET	DIRECTOR	BLACK	7/17/95		FD200B	245.00	PHARMEDINFO	3200
274	COFERENCE TABLE	DIRECTOR	BLACK	7/17/95		CFT240B	322.99	PHARMEDINFO	3200
275	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
276	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
277	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
278	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
279	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
280	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
281	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200
282	CONFERENCE CHAIR	DIRECTOR	BLACK	7/17/95		SL225	100.03	PHARMEDINFO	3200

283	WRITING TABLE	DIRECTOR	BLACK	7/17/95		ST1500B	168.70	PHARMEDINFO	3200
284	TABLE DRAWER	DIRECTOR	BLACK	7/17/95		FP403B	112.75	PHARMEDINFO	3200
285	DESK CHAIR	DIRECTOR	BLACK	7/17/95		SG500H	114.44	PHARMEDINFO	3200
286	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB23B	152.59	PHARMEDINFO	3200
287	BOOK SHELF	DIRECTOR	BLACK	7/17/95		CSDB23B	152.59	PHARMEDINFO	3200
289	MONITOR	VIVITRON 1572	COLOR	3/7/95	8215017	CPD-15F13	0.00	PHARMEDINFO	3200
290	KEYBOARD	GATEWAY 2000	ANYKEY KEYBOARD	3/795	D732189001	2189013	0.00	PHARMEDINFO	3200
291	COFFEE MACHINE	ROWENTA	WHITE	7/17/95	495	FT200	47.52	PHARMEDINFO	3200
292	FAX MACHINE	CANON	WARRANTY REPLACED 161		MCV02059	11265	0.00	PHARMEDINFO	3200
269	DESK CHAIR	DIRECTOR	BLACK	7/17/95		SG500H	114.44	PHARMEDINFO	3200
294	MICROWAVE	SHARP	WHITE	9/28/95	950709774	R-2V56	148.42	PHARMEDINFO	3200
293	PHOTOCOPIER	XEROX	AUTO FEED, DOUBLE SIDED, AUTO SORT	8/21/95	3104749444	5332/2	8,021.74	PHARMEDINFO	3200
295	MODEM	ZYXEL	FAX/MODEM	9/6/95	S550220139	U-1496E	331.43	PHARMEDINFO	3200
296	OVERHEAD	GEHA	TOP VISION, SLOW FUSE	5/14/95	687544	U-1496E	1,340.00	PHARMEDINFO	3200
297	PRINTER	HP	LASERJET, L5	4/11/96	JPBW004198	L5	647.96	PHARMEDINFO	3200
298	UPS	UPS INTERNET	UPSC/300	12/5/97	AO 164530	USPSC/300	129.59	PHARMEDINFO	3104
344	SAFE	N/A	GRAY	7/17/95	N/A	N/A	200.00	PHARMEDINFO	3200
345	DOCUMENT BINDER	GENERAL BINDING CORP.	BINDING MACHINE/ IMAGE MAKER 2000	7/1/95	HG03911	IM2002-2	529.00	PHARMEDINFO	3200
346	MONITOR	GLOBAL USA	14" ULTRA SVGA COLOR	12/6/94	40309545	CAD 14RG	275.00	PHARMEDINFO	3200
						Total:	**$22,184.83**		

Annex 3.B. Equipment Provided to Pskov Pharmacia

MANAGEMENT SCIENCES FOR HEALTH

RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT

EQUIPMENT INVENTORY BY LOCATION

CA No. HRN-0004-A-00-5002-00

5/22/98

PSKOV PHARMACIA

INVENTORY NUMBER	ITEM	BRAND NAME	DESCRIPTION	DATE PURCHASED	SERIAL No.	MODEL	COST	DISPOSITION/ LOCATION	CONTRACT
299	PRINTER	HEWLETT PACKARD	LASERJET	3/28/97	CNYN427922	5L	599.02	PSKOV PHARMACIA	3200
300	COMPUTER	ATS	PENTIUM, 16MB, 1.28GB/HDD, VIDEO CARD,CD ROM, FAX MODEM, ACER MONITOR	3/29/97	0300350	ATS-2000	1,487.22	PSKOV PHARMACIA	3200
						Total:	**$ 2,086.24**		

Annex 3.C. Equipment Provided to Ryazan State Medical University Hospital

MANAGEMENT SCIENCES FOR HEALTH
RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT
EQUIPMENT INVENTORY BY LOCATION
CA No. HRN-A-00-92-00059-13
CA No. HRN-0004-A-00-5002-00
5/22/98

RYAZAN STATE MEDICAL UNIVERSITY

INVENTORY NUMBER	ITEM	BRAND NAME	DESCRIPTION	DATE PURCHASED	SERIAL No.	MODEL	COST	DISPOSITION/ LOCATION	CONTRACT
337	OVERHEAD	AMBASSADOR	PORTABLE MODEL	10/27/97	76636620 QC		686.70	RYAZAN MEDICAL UNIVERISTY	3200
148	COMPUTER	COMPAQ PRISRIO	850,DX250MT,270HD, 8RAM,CDROM	1/4/94	6115HHB32585	PRESARIO 850	2,647.05	RYAZAN MEDICAL UNIVERISTY	3102
						Total:	$3,333.75		

Annex 3.D. Equipment Provided to Ryazan Oblast Clinical Hospital

MANAGEMENT SCIENCES FOR HEALTH
RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT
EQUIPMENT INVENTORY BY LOCATION
CA No. HRN-A-00-92-00059-13
5/22/98

RYAZAN OBLAST CLINICAL HOSPITAL

INVENTORY NUMBER	ITEM	BRAND NAME	DESCRIPTION	DATE PURCHASED	SERIAL No.	MODEL	COST	DISPOSITION/ LOCATION	CONTRACT
158	COMPUTER	HPVECTRA	486DX,2/60340MG,8MG, CDROM,MODEM	2/3/94	3102A01750	D3138A	1,845.00	RYAZAN HOSPITAL	3102
159	UPS	APC	ON LINE 400 VA,220V	4/3/95	5.14114E+11	AP4001	330.00	RYAZAN HOSPITAL	3102
160	PRINTER	HP	220V	1/3/95	USBB977926	HPLJ4L	655.00	RYAZAN HOSPITAL	3102
						Total:	**$2,830.00**		

Annex 4. RPM-Related Conferences in December 1998

Annex 4.A. Clinical Pharmacology and Rational Pharmaceutical Management Conference, Ekaterinburg

First Regional School
CLINICAL PHARMACOLOGY AND RATIONAL PHARMACEUTICAL MANAGEMENT
December 2–4, 1998, Ekaterinburg

Wednesday, December 2		
Registration of Participants		9:00– 9:50
Regional School Opening Ceremony		10:00–10:30
Role of Professional Drug Information in Rational Use of Drugs	G.V. Shashkova, Pharmedinfo	10:30–11:10
Role and Perspectives for the Urals Region Drug Information Center	S.V. Kolotvinov, Director of the Urals DIC	11:10–11:30
Drug Formulary Options	A. Savelli, MSH/RPM	11:30–13:00
Lunch		13:00–13:45
Drug Utilization Review Programs	A. Savelli, MSH/RPM	13:45–15:15
Drug Information for Health Professionals	K. Johnson, USP	15:15–16:45
Principles of Drug Formulary Development in Intensive Care Settings	V.A. Rudnov, Urals Medical Academy, Ekaterinburg	16:45–17:15
Discussion		17:15–17:45

Thursday, December 3		
Drug Information for Patients	K. Johnson, USP	9:30–11:00
Methodological Approaches to Drug Formulary Development in Infectious Pediatric Ward	S.N. Kozlova, Urals Medical Academy, Ekaterinburg	11:00–11:30
Break		11:30–11:45
Eubiotics	N. Litusov, Center for Military–Technical Problems of Biological Defense, Ministry of Defense	11:45–13:00
Lunch		13:00–14:00
Clinical Pharmacology in Practical Medicine	V.G. Kukes, Research Institute of Traditional Medicine, MOH	14:00–15:00
Pharmacogenetics	S.B. Seredinin, Pharmacology Research Institute, MOH	15:00–16:00
Break		16:00–16:15
Drug Pharmacokinetics	Y.B. Belousov, Russian State Medical University, Moscow	16:15–17:15
Discussion		17:15–17:45

Friday, December 4

Chronopharmacology (Clinical Aspects)	L.P. Larionov, Urals Medical Academy, Ekaterinburg	9:30–10:30
Immunopharmacology	S. Kolotvinov, Urals Medical Academy DIC, Ekaterinburg	10:30–11:15
Break		11:15–12:00
Clinical Aspects of Use of Domestically Manufactured Immunomodulators	B.V. Pinegin, Institute of Immunology, MOH	12:00–13:00
Lunch		13:00–14:00
Drug Registration Problems in Russia: Regulations	V.V. Parin, RF MOH Pharmacological Committee	14:00–15:00
Rational Use of Antibiotics in Nosocomial Infections	A.A. Zaitsev, St. Petersburg Medical University	15:00–16:00
Break		*16:00–16:15*
Prospective of Antiaterosclerosys Therapy (medical, economical and ethical)	O.I. Karpov, St. Petersburg Medical University	16:15–17:15
Discussion, summing up		17:15–18:00

Annex 4.B. Drug Formulary Implementation in Russia Conference, Moscow

Scientific-Practical Conference
DRUG FORMULARY IMPLEMENTATION IN RUSSIA
December 7–8, 1998, Moscow

Organized by: Russian Federation Ministry of Health
Russian Center for Pharmaceutical and Medical-Technical Information of MOH (RC Pharmedinfo)
United States Agency for International Development (USAID)
United States Pharmacopeial Convention (USP)
Management Sciences for Health (MSH)

With support from: Boston University Legislative Initiatives Project

Monday, December 7

OPENING CEREMONY		10:00–10:30
PRESENTATIONS		
Drug Formulary System Development Strategies in Russia	G.V. Shashkova	10:30–11:00
Drug Formulary Implementation in Russia on Oblast Level	A. Savelli	11:00–11:30
Formulary System Development in Ryazan Oblast	A.E. Arhipov	11:30–12:00
Break		*12:00–12:20*
Provision of Unbiased Drug Information for Public Health Professionals	K. Johnson	12:20–12:50
Legal Basis for Pharmaceutical Information	E.A. Volskaya	12:50–13:10
Drug Formulary Options	A. Savelli	13:10–13:40
Lunch		*13:40–15:00*
Formulary System Implementation Impacts in Novgorod Oblast	V.A. Medik	15:00–15:25
Discussion, sharing experience		15:25–17:30
Presentation of Russian Edition of USP DI Drug Information for Health Professionals. Volume 4, Drugs Used in Gastroenterology		17:30–18:00

Tuesday, December 8

PRESENTATIONS		
Role of Formulary System in Standardizing Pskov Oblast Public Health System	A.M. Bogatin	10:00–10:30
Clinical Aspects of Drug Formulary Systems	Y.B. Belousov	10:30–11:00
Basic Principles of Drug Formulary Development	E.A. Ushkalova	11:00–11:30
Experience in Formulary List Development: Antibacterials	L.S. Strachunsky D.V. Galkin	11:30–12:00

485

Break		*12:00–12:20*
Approaches to Formulary System Development in Moscow Oblast	S.A. Bertash	12:20–12:40
Experience in Drug Formulary Development in Multi–Ward Hospital	S.V. Kolobov A.L. Vertkin	12:40–13:00
Methodological Approaches to Drug Formulary Development in Neonatology	A.V. Soloninina A.M. Ustyugova	13:00–13:20
Lunch		*13:20–15:00*
Discussion, sharing experience		15:00–16:00
Closing Ceremony		
Summing up, presentation of certificates to participants		16:00–17:00

During conference breaks, the electronic version of Russian edition of USP DI, drug databases, formulary manuals, and other materials will be demonstrated in the hall.

The Conference was held at the Russian Academy of Government Service, 84 Vernadskogo, Moscow.

Ukraine

Executive Summary

The Rational Pharmaceutical Management (RPM) project's involvement in Ukraine began with an assessment conducted in November 1993, following a World Bank request to USAID/Kyiv. The key findings included

- The public heath drug supply system was not financially sustainable.
- Pharmaceuticals were very inexpensive, but generally unavailable.
- Decentralization of drug procurement occurred de facto, with little preparation at local levels for this responsibility.
- Drug pricing mechanisms did not allow the recovery of drug costs.
- Drug information was rarely available.
- Treatment guidelines existed at the national level but were not being used.
- The exempt prescription program, an entitlement program for drug products for specific populations, was in place but drug products were often out of stock.

RPM recommended that the best approach to assist Ukraine in the area of pharmaceuticals would be a package combining credits for purchasing essential drugs with selected management reforms to promote financial sustainability at the oblast level. Because of various local circumstances, the World Bank follow-up activity was never launched and there was limited interest in RPM involvement by the USAID/Kyiv Mission. In 1996, renewed interest in developing an RPM/Ukraine program resulted in an RPM/Ukraine reconnaissance visit in November. At that time, the Europe and Newly Independent States Bureau selected Ukraine as the second of the Newly Independent States (NIS) for RPM involvement.

Because the problems in the pharmaceutical sector in Ukraine were well known by the Ministry of Health (MOH) and USAID/Kyiv, the Mission requested that RPM begin activities by attending an MOH conference on health-reform issues in Yalta, Ukraine, in May 1997. Heads of Oblast Health Administration from almost all 24 regions of Ukraine attended the meeting. RPM was invited to orient the participants to the concepts of rational pharmaceutical management and RPM's practical experience in Russia and other countries.

Following the Yalta meeting, RPM, in consultation with the Mission, proposed to implement a program that included

- Formulary system implementation workshops
- Lectures on clinical pharmacology
- Technical assistance to hospitals implementing formulary systems
- Distribution of RPM tools developed in Russia

Zhytomyr Oblast

RPM began working in Ukraine in 1997 when Zhytomyr Oblast was selected as a pilot region. The initial program of activities included workshops and technical assistance (TA) in formulary system development and implementation; a clinical pharmacology workshop; TA in harmonization of standard treatment guidelines (STGs); and TA in reviewing and revising accreditation standards for health care institutions related to drug selection, procurement, distribution, and rational use. In 1998, the Mission developed the new Ukraine Health Care Strategy, focused on primary health care, and sought RPM's input on drug management issues. RPM participated in health partner meetings in 1998 and 1999 and revised the RPM program to support new Mission objectives and work with collaborating organizations.

As a result of RPM's formulary system development work in Zhytomyr Oblast, local health officials began to update STGs for the oblast primary, secondary, and tertiary levels of health care. The draft STGs were completed in May 1999 with RPM technical assistance. The Ukrainian Institute of Public Health (UIPH) revised national STGs and published them in fall 1999. RPM sought to link the UIPH with Zhytomyr Oblast Health Administration (ZOHA) to ensure consistency of the Zhytomyr STGs with the national guidelines and, potentially, to provide a means for the UIPH to test selected guidelines. Zhytomyr administration published a formulary to assist physicians in their selection of cost-effective drug products; the *Zhytomyr Oblast Drug Formulary* was published in September and distributed to all 5,000 practicing physicians in the oblast.

City of Kyiv

Kyiv Municipal Health Department (KMHD) officials proposed a program in rational drug management in late 1997, based on RPM materials developed in Russia. Lacking TA, however, the program did not progress until RPM began rollout programming in Kyiv in April 1999. In spring 1999, the KMHD designated technical personnel to work as counterparts for RPM activities.

RPM conducted a formulary implementation workshop for approximately 200 health professionals in Kyiv in May 1999, followed by TA activities in three municipal hospitals. Under the new USAID Ukraine Health Care Strategy, RPM continued to work with the hospitals and also began to address drug management challenges in primary health care settings, including possible adaptation of the formulary system to the outpatient exempt prescription program. This work culminated in the Strategies for Improving Drug Selection and Use Workshop in Kyiv in July 2000, which included participants from hospital and ambulatory-care facilities and showcased achievements to date in Zhytomyr and Kyiv. Activities also included direct RPM support for participant attendance at the Russian Man and Drugs Congress in Moscow, as well as participation in the Pharmacoeconomics Short Course in South Africa.

RPM Program Objectives

There were five primary objectives of the RPM Ukraine program.

- Develop the capacity of pharmaceutical sector decision-makers in comprehensive and targeted pharmaceutical surveys
- Develop local capacity in formulary system implementation
- Increase the understanding at national level of accreditation standards and their evaluation for health care institutions in drug selection, procurement, distribution, dispensing, and rational use
- Develop the capacity to critically review the exempt prescription program and apply formulary concepts to its management at municipal level
- Develop linkages among Ukrainian institutions and with other partners to foster coordination of activities under the new USAID Ukraine Health Strategy

Implementation

The RPM project in Ukraine sought to increase efficiency in pharmaceutical product selection and use to improve treatment outcomes and enhance the rational allocation of resources in the health sector. In Zhytomyr Oblast, RPM provided technical assistance, training, and direct financial support to develop and implement revised STGs; to develop indicators to track STG implementation in health facilities; and to develop, implement, and publish an oblast formulary manual. In Kyiv, RPM provided training to personnel of all 52 municipal hospitals in formulary development, and direct technical assistance and specialized training to four municipal hospitals in drug selection and rational drug use. RPM also worked with the KMHD to adapt the formulary process to provide cost-effective drug treatment in the outpatient setting. RPM examined the current exempt prescription program for areas of potential improvement in the drug selection process, such as inclusion of cost-effectiveness and drug product quality in criteria for selection of covered products.

This stream of activity supported USAID's strategic objective SO3: Increased use of key child health and nutrition interventions. It also supported the goal of the new USAID Ukraine Health Strategy to reform primary health care and improve the capacity of health practitioners to effectively and efficiently provide community-based health services. RPM activities supported favorable outcomes of SO3.2b, as a part of its Intermediate Result 3.2b.1: Provision and utilization of primary health care services improved.

Program Achievements

The RPM Ukraine Country Program achieved all of its objectives through various activities. The objective of developing the capacity of pharmaceutical sector decision-makers in comprehensive and targeted pharmaceutical surveys was achieved in Zhytomyr Oblast and the City of Kyiv. The objective was achieved through collaboration with counterparts on the following surveys:

- The pharmaceutical sector assessment in 1993
- Analysis of drug consumption (ABC/VEN) and morbidity patterns in Zhytomyr Oblast in 1997
- A survey of drug prescribing patterns in Zhytomyr Oblast in 1998
- An analysis of drug consumption patterns (ABC/VEN) in Kyiv hospitals in 1999–2000
- An analysis of drug use in the exempt prescription program in the city of Kyiv in 2000

The objective of developing the capacity of local decision-makers to conduct pharmaceutical-sector surveys and use this information to guide decision-making was only partly achieved through the initial assessment. Counterparts with the National Medical University (NMU), and district and municipal health departments were generally cooperative and could have been expected to conduct focused repeat surveys with minimal assistance.

The development of capacity was much more evident following commencement of the RPM Ukraine program in 1997. Health administration officials from Zhytomyr Oblast and the KMHD quickly grasped the need to conduct surveys of current practices. In both sites, hospital personnel were trained in the methodology and demonstrated varying degrees of mastery of the analysis. It was particularly helpful in the city of Kyiv that KMHD designated a physician to work specifically with RPM. He quickly mastered the steps of ABC/VEN analysis and assisted formulary committees in the four pilot hospitals with their work; he also conducted the analysis for the exempt prescription program. Local personnel, through the analyses, were able to examine and document problems in drug consumption patterns including the use of outdated or unsafe products and products of dubious quality.

Using oblast-level personnel to conduct the survey of prescribing patterns was somewhat less successful in demonstrating local capacity to perform such a survey. Oblast-level personnel understood the process and the importance of conducting such a study, as well as how data that were currently available in hospitals could be used to provide feedback on the quality of prescribing. There were also challenges in having local personnel conduct the survey. These were primarily the time it took to complete the surveys and incomplete participation from *raion* hospitals. During the course of the study, there was a change in oblast administrative personnel, which caused data collection and transfer of the data to RPM to take longer than they would have had RPM contracted with the NMU or another organization to perform the data collection and analysis.

A combination of workshops to introduce concepts and TA at individual institutions has proven to be effective for implementation of learned material. Training of trainers and/or opinion leaders helps create credibility among the local health professionals because these individuals can describe their progress, problems encountered, and how to overcome challenges.
Through a series of training activities and technical assistance, Ukrainian counterparts increased their knowledge of all aspects of formulary systems, including methods of analyzing morbidity and drug consumption patterns, using this information to select priority therapeutics categories and appropriate cost-effective, quality drug products consistent with international standards; to provide feedback to prescribers on their prescribing patterns; and to maintain this system. They also developed practical skills in reviewing medical literature, finding objective drug information, performing ABC/VEN analyses, and then applying this information to decision-making.

During the life of the RPM/Ukraine program, approximately 600 physicians, pharmacists, and academic personnel were trained. Approximately one-half of those were in Kyiv and half in Zhytomyr Oblast. The full list of workshops and training appears in Annex 1.

Personnel from Zhytomyr Oblast and the city of Kyiv also demonstrated increased capacity to develop and implement formulary systems. In Zhytomyr Oblast, initially the ZOHA sought to have formulary committees in all 25 *raion*, two municipal, and oblast hospitals, but it chose instead to develop an oblastwide formulary that would be used for all institutions. Formulary committees were formed at oblast level and at the adult clinical and pediatric hospitals. These colleagues not only formed their own committees and developed formularies, but also sought input from *raion* hospital colleagues in forming the oblast-level formulary list. The group also revised existing STGs to provide continuity of care from primary through tertiary care in the oblast. Finally, an oblast drug formulary manual was published and distributed to all practicing physicians.

In Kyiv, personnel also exhibited an enhanced capacity for formulary development and implementation. KMHD support allowed dedicated personnel to work on developing necessary committees, collecting and analyzing data, and forming formulary lists in their institutions. Committee members presented their findings at the Strategies for Improving Drug Selection and Use Workshop. This workshop was particularly useful because committee members' experience provided credible evidence to colleagues that formulary development and implementation could be accomplished in Ukraine.

RPM provided technical assistance to the Accreditation Committee to review the proposed Accreditation Standards for Health Care Institutions in Ukraine. Activities helped increase the understanding at national level of accreditation standards and their evaluation for health care institutions in drug selection, procurement, distribution, dispensing, and rational use. Finally, all RPM suggestions for revisions in standards and in suggested means of objective evaluation of those standards were adopted.

Kyiv Municipal Health Department staff developed the capacity to critically review the exempt prescription program, meeting one-half of the RPM objective. The time that remained in the project did not allow further exploration of the data nor collection of additional data. The next

logical steps would have been additional data collection, and then development of a plan to apply formulary concepts to management of the prescription program at municipal level.

RPM was also successful in developing linkages among Ukrainian institutions and with other partners to foster coordination of activities under the new USAID Ukraine Health Strategy. RPM-sponsored training and workshops provided an avenue for colleagues to discuss technical issues in a nonthreatening environment and to explore new concepts on neutral ground. Most participants found this opportunity facilitated a greater understanding of rational drug use concepts and provided a reality check for how new concepts could be adapted in Ukraine.

Challenges

There were also challenges faced in implementing the RPM program of activities in Ukraine. They included changes of personnel; lack of current sources of drug and price information; a bureaucracy and authoritarian mind-set inherited from the Soviet system; unsustainable, generous entitlements to pharmaceuticals for sectors of the population, at least on paper; and an economy in transition, unable to finance the needs for outpatient or inpatient pharmaceuticals.

Next Steps

In the short term, there is unlikely to be an opportunity to increase the budget for drugs, or health care in general, in Ukraine. Therefore, the two remaining options of optimizing the current budget and finding mechanisms for cost recovery are the most likely ways of meeting the needs of the patients. Logical steps after the end of the RPM project would include activities that are an extension of formulary system and rational drug use activities completed under RPM, those that would support changes initiated under RPM, and several that would build on RPM accomplishments. In particular, there is a pressing need to identify incentives that influence physician prescribing under a situation where a severe imbalance exists between the public health budget and the demand for pharmaceuticals. The second area that would support development of primary health care in Ukraine would be development of a plan to analyze and reform the provision of outpatient drugs under the exempt prescription program. Successful implementation of a program to introduce management information systems, monitoring and evaluation components, and adaptation of the formulary to the exempt prescription program not only would have immediate benefits, but also would provide a working model for Ukraine, should it proceed to develop alternate means of financing inpatient and outpatient drug benefits.

Whereas initial funding for RPM Ukraine activities came from the NIS add-on to the RPM Worldwide cooperative agreement in August 1993, funding for the extension period (1999 through end of project) was through USAID/Kyiv field-support funds.

Acknowledgments

The RPM program in Ukraine evolved over time to meet identified needs that correspond to the government of Ukraine and USAID priorities. The accomplishments of the RPM program are due directly to the efforts of many individuals and organizations, for which the RPM program is profoundly grateful. The USAID/Kyiv project manager, Olena Radziyevska, consistently provided support, encouragement, and assistance in working in a country undergoing frequent changes in policy and administrative personnel, following Ukraine's transition to independence. Her efforts on behalf of our project, and, more importantly, the Ukrainian population, are greatly appreciated. Valentina Timofeyeva also deserves special recognition for her efforts well above and beyond that which was required as an interpreter. In the absence of an in-country presence, she often served as a logistics expert, facilitator, and conscience to keep things moving. Valentina exemplifies those individuals who strive to improve their own conditions, in her case, "for the good of Ukraine."

Although not listed by name, the support of chief district *(raion)* administrators, physicians, deputy physicians, and directors of pharmacy from the following districts and hospitals, was critical to the success of the RPM program:

Zhytomyr Oblast Raions (all 26)
Kyiv Municipal Hospital No. 12
Kyiv Municipal Hospital No. 17
Kyiv Municipal Hospital No. 3
Kyiv Municipal Hospital No. 7
Kyiv Central Hospital
Kyiv Zaliznychij Raion
Kyiv Kharkivskyj Raion

Because a country program is the product of the efforts of many, RPM would like to acknowledge the following persons for their support of the RPM/Ukraine program and activities and those who have significantly contributed to the program.

USAID

Susan Bacheller	JHU Fellow, USAID/ Washington
Anthony Boni	Cognizant Technical Officer, USAID/Washington
Catherine Fischer	Formerly USAID/Kyiv Senior Health Advisor
Pamela Mandel	Deputy Director, Office for Democracy and Social Transition (ODST), USAID/Kyiv
Eliot Pearlman	Senior Health Advisor, Kyiv
Olena Radziyevska	Project Manager, USAID, Kyiv, Ukraine
Marilynn Schmidt	Director, ODST, USAID/Kyiv

Ministry of Health

Inna Demchenko	Special Advisor to the Minister
Andrij Huk	Expert on Accreditation of Health Care Institutions Formerly ZdravReform Project/ Ukraine
Valentina Kozak	Pharmaceutical Department
Petro Sereda	Head, Pharmaceutical Department

Ukrainian Institute of Public Health

Viktor Ponomarenko	Director, UIPH
Antonina Nahornaya	Deputy Director

The Ukrainian Academy of Continuing Medical Education

Mychailo Ponomarenko	Department of Economics

The Parliament of Ukraine

Ella Kovzharova	Chief Consultant, Commission on Maternal and Child Health
Volodymyr Rudiy	Former Chief of Secretariat, Commission on Maternal and Child Health

City of Kyiv

Valentina Babiak	Deputy General Director, Kyiv Municipal Pharmatsiya
Maria Opanasenko	Deputy Head, Adult Medical Hospital Care, KMHD
Oleh Kosykh	RPM consultant, KMHD
Oleksandr Poladko	Chief, Primary Medical and Public Health Department, KMHD
Raisa Taran	Deputy Head, KMHD
Volodymyr Zahorodnij	First Deputy Head, KMHD

Zhytomyr Oblast

Vitalij Didyk	Deputy Head, ZOHA; Chief, Zhytomyr Oblast Pharmatsiya
Olexander Husak	Deputy Chief Physician, Zhytomyr Oblast Children's Hospital
Tetiana Kondratenko	Chief Physician, Zhytomyr Oblast Tuberculosis Hospital; former Deputy Head, ZOHA
Valentina Olijnyk	Deputy Chief Physician, Zhytomyr Oblast Clinical Hospital
Zinovij Paramonov	Head, ZOHA, Zhytomyr, Ukraine
Volodymyr Savchenko	Chief Physician, Zhytomyr Municipal Hospital No. 1; Former Deputy Chief Physician, Zhytomyr Oblast Clinical Hospital
Victor Shatylo	First Deputy Head, ZOHA

485

Management Sciences for Health

Inga Adams	Former Program Associate
James Bates	Former RPM Director
Dan Boesen	Senior Program Associate
Mehreen Butt	Senior Program Assistant
Maria Chomyszak	Former Program Associate
Olya M. Duzey	RPM/Ukraine Country Program Manager
Julie McFadyen	Senior Program Associate
Thomas Moore	Senior Program Associate
Chris Olson	Senior Program Associate
Anthony Savelli	Director, RPM
Marina Semenchenko	Senior Program Associate
Andrei Zagorski	Senior Program Associate

United States Pharmacopeia

Keith Johnson	Vice President, Drug Information Division
Kyrill Burimski	Russia/NIS Project Director, RPM/United States Pharmacopeia (USP)
Elena Ushkalova	USP Representative in Russia, All Russia Drug Information Network Coordinator

Other Collaborating Organizations and Individuals

Valentina Timofeyeva	Interpreter and Facilitator
David Mercer	Program for Appropriate Technology in Health (PATH)
Elena Kononova	Office Manager, PATH, Kyiv

Acronyms

ACME	Academy for Continuing Medical Education
ABC/VEN	Method of ranking and analyzing drug products according to the value of products used and the degree to which they are essential
ADR	adverse drug reaction
AIHA	Alliance for International Health
ARI	acute respiratory infection
DUR	drug use review
IHD	ischemic heart disease
JCAHO	Joint Commission on Accreditation of Health Care Organizations
JHU	Johns Hopkins University
KMHD	Kyiv Municipal Health Department
MOH	Ministry of Health
MSH	Management Sciences for Health
NIS	Newly Independent States
NMU	National Medical University
ODST	Office of Democracy and Social Transition
PATH	Program for Appropriate Technology in Health
RPM	Rational Pharmaceutical Management (project)
SO	Strategic Objective
STG	standard treatment guideline
TA	technical assistance
UIPH	Ukrainian Institute of Public Health [MOH]
USAID	U.S. Agency for International Development
USP	United States Pharmacopeia
ZOHA	Zhytomyr Oblast Health Administration

497

Program Overview

Background

The Rational Pharmaceutical Management (RPM) project's involvement in Ukraine began with an assessment conducted in November 1993, following a World Bank request to USAID/Kyiv. RPM focused on describing the system of drug selection, procurement, and distribution. A summary of the findings appears in the Program Accomplishments section, under Develop Capacity to Conduct Pharmaceutical Sector Surveys. Because of various local circumstances, however, the World Bank activity was never launched. In 1996, there was renewed USAID/Kyiv interest in developing an RPM program, and Ukraine was selected as the second of the Newly Independent States (NIS) for RPM involvement.

In September 1996, the Cabinet of Ministers of Ukraine passed Resolution no. 1071, which specified a list of drugs, domestic and imported, that could be purchased by institutions that are partly or fully funded through the budget (see Boesen, Duzey, Semenchenko, "The Exempt Prescription Program in Ukraine," Annex 2). Initially, this list contained approximately 80 products and was routinely ignored. In September 1997, the list was revised to include approximately 350 products (200 domestic and 150 foreign). The list was increased again in January 1999 to approximately 900 drug products.

Gaining Support at the National and Oblast Levels

At the initial stage of the project, RPM worked in close cooperation with key decision-makers to ensure that project goals and technical areas were well understood and accepted. By the end of 1996, the actual start of Ukraine program, RPM had gained significant experience in formulary system implementation from its program in Russia. Preliminary meetings with the Ministry of Health (MOH) in November 1996, along with results of the 1993 assessment, proved that many of the same conditions that had resulted in acceptance of RPM concepts in Russia appeared to exist in Ukraine, namely:

- An eroding public health budget
- Budget shortfalls throughout the drug supply system
- Devolution of public health decision-making authority from the national to the oblast level, and a subsequent managerial gap
- Increased responsibility for drug selection at the hospital level
- Lack of current, unbiased drug information
- Lack of training in clinical pharmacology for physicians
- A problematic system of providing drugs to exempt patients

Another event that led to wide acceptance of RPM in Ukraine and triggered development of the Zhytomyr Oblast demonstration site took place in May 1997, when RPM was invited to participate in the MOH Third Annual International Conference on Health Care Reform in Yalta, Ukraine. The audience consisted of key MOH officials, participants from almost all 24 oblasts and the Crimea, including representatives of oblast administration, hospitals, professional unions, insurance industry, domestic and foreign manufacturers, wholesalers, and academic institutions.

RPM made a presentation on current challenges in drug management and approaches RPM used to address these in Russia. As a result, various oblast officials, wholesalers, and MOH and other governmental representatives sought RPM input on various topics related to drug management, including policy considerations in accreditation and licensure of health care institutions, defining a package of pharmaceutical benefits, the development of standard treatment guidelines and formularies, manufacturer-wholesaler relations, and drug information.

On the basis of initial reconnaissance visits and participation in the May 1997 Conference on Health Care Reform in Yalta, RPM proposed to implement a program that included

- Formulary system implementation workshops
- Lectures on clinical pharmacology
- Technical assistance to hospitals implementing formulary systems
- Distribution of RPM tools developed in Russia
- Curricular reform at the National Medical University (NMU) of Ukraine
- Technical assistance to community pharmacies in procurement

In discussion with the Mission and counterparts, it became apparent that technical assistance in procurement to communities was premature in 1997. Similarly, it was felt that personnel from the NMU in Kyiv should be included to the extent possible in training and technical assistance activities, but that assistance in curricular reform would be most effective when Ukraine-specific experience was available.

Establishing a Demonstration Site

For the success of the RPM/Ukraine project, the choice of the demonstration site as the starting point for the project was very important. Given the large size of the country, it was decided that the RPM project begin by working in one oblast, an administrative unit corresponding most closely to a U.S. state, with the potential for rollout to additional regions.

The project site was chosen using established criteria after extensive discussion among RPM project staff, USAID/Kyiv, USAID/Washington, the MOH, and oblast officials. In the case of the pilot site, RPM wanted to work in an oblast that met the following criteria:

- Interest on the part of local officials and specialists in implementing pharmaceutical-sector reforms

- Logistics feasibility for bringing RPM consultants to the site

- Representative of a typical Ukrainian oblast
- Interest in serving as a model for other oblasts as the project expanded

Zhytomyr Oblast was selected in September 1997 as the RPM demonstration site. In 1997, Zhytomyr Oblast had a population of approximately 1.5 million residents; the city itself had a population of approximately 350,000. Between one-quarter and one-third of the population was registered to receive benefits, including free medical care, as having been affected by the Chernobyl nuclear disaster of 1986. In addition to this group, others such as veterans, young children, and persons with specific chronic health conditions were entitled to outpatient prescription drugs through the exempt prescription drug program.

There was no accepted written formulary list at the hospital, oblast, or national level. Severe budgetary constraints forced the Zhytomyr Oblast Clinical Hospital to be very conservative in selecting the number of drug products for patient use. This situation differed markedly from the situation in Ryazan, Russia, where a very large number of products was used in the hospital before implementation of the formulary system. A review of the list of drugs in stock showed no obvious duplication of drugs within therapeutic categories; the number of drugs was not excessive. Quantifying the actual availability of products was extremely difficult, given that families were required to purchase a substantial proportion of products use by inpatients, and the practice of holding a small reserve stock of each product. Neither the criteria for selection of products used at the hospital, nor that the final selection was the best choice, was clear.

The initial program of activities in Zhytomyr Oblast included workshops and technical assistance (TA) in formulary system development and implementation; a clinical pharmacology workshop; TA in harmonization of standard treatment guidelines (STGs); and TA in reviewing and revising accreditation standards for health care institutions related to drug selection, procurement, distribution, and rational use. In 1998, the Mission developed the new Ukraine Health Care Strategy, focused on primary health care, and sought RPM input on drug management issues. RPM participated in health partner meetings in 1998 and 1999, and revised the RPM program to support new Mission objectives and work with collaborating organizations.

As a result of RPM's formulary system development work in Zhytomyr Oblast, local health officials began to update STGs for the oblast primary, secondary, and tertiary levels of health care. The draft STGs were completed in May 1999 with RPM technical assistance. The Ukrainian Institute of Public Health (UIPH) revised national STGs and published them in fall 1999. RPM sought to link the UIPH with Zhytomyr Oblast Health Administration (ZOHA) to ensure consistency of the Zhytomyr STGs with the national guidelines and, potentially, to provide a means for the UIPH to test selected guidelines.

Zhytomyr Oblast provided a good location for start-up activities in Ukraine. The logistics of reaching the oblast, its population base, the supportive attitude of the oblast and hospital administrations, and the reforms already under way were indicative of a system that could serve as a successful model for other Ukrainian regions.

Rollout Activities

Kyiv Municipal Health Department (KMHD) officials proposed a program in rational drug management in late 1997, based on RPM materials developed in Russia. Lacking TA, however, the program did not progress until RPM began rollout programming in Kyiv in April 1999. In spring 1999, the KMHD designated technical personnel to work as counterparts for RPM activities. RPM conducted a formulary implementation workshop for approximately 200 health professionals in Kyiv in May 1999, followed by TA activities in three municipal hospitals. Requests for technical assistance were received from two additional hospitals. Under the new USAID Ukraine Health Care Strategy, RPM continued to work with the hospitals and also began to address drug management challenges in primary health care settings, including possible adaptation of the formulary system to the outpatient exempt prescription program. This work culminated in the Strategies for Improving Drug Selection and Use Workshop in Kyiv in July 2000, which included participants from hospital and ambulatory-care facilities. Many of the participants invited were identified together with USAID partner organizations. Activities also included direct RPM support for participant attendance at the Russian Man and Drugs Congress in Moscow, as well as participation in the Pharmacoeconomics Short Course in South Africa.

Objectives

Objectives of the RPM Ukraine program follow:

- Develop the capacity of pharmaceutical sector decision makers in comprehensive and targeted pharmaceutical surveys
- Develop local capacity in formulary system implementation
  - Develop and implement formulary systems at the hospital and oblast level
  - Harmonize oblast standard treatment guidelines from primary health care to tertiary level
  - Use formulary system tools, such as ABC/VEN or drug use review (DUR) analysis, to improve cost-effectiveness of drug selection and use
- Increase the understanding at national level of accreditation standards and their evaluation for health care institutions in drug selection, procurement, distribution, dispensing, and rational use
- Develop local capacity to critically review the exempt prescription program and apply formulary concepts to its management at municipal level
- Develop linkages among Ukrainian institutions and with other partners to foster coordination of activities under the new USAID Ukraine Health Strategy

501

Implementation Strategy and Major Activities

The RPM-Ukraine implementation strategy was developed on the basis of the assessment findings, by meeting local challenges and situations, and by building stakeholders at each level of the formulary system development. The objective was achieved through

- Gaining support at the national and oblast level
- Establishing a demonstration site
- Institutionalizing the formulary system in the oblast
- Training Ukrainian counterparts
- Developing formulary drug lists
- Developing standard treatment guidelines
- Developing the Zhytomyr Oblast formulary manual
- Disseminating information

The RPM project in Ukraine sought to increase efficiency in pharmaceutical product selection and use to improve treatment outcomes and enhance the rational allocation of resources in the health sector. In Zhytomyr Oblast, RPM provided technical assistance, training, and direct financial support to develop and implement revised STGs in the oblast, develop indicators to track STG implementation in health facilities; and to develop, implement, and publish an oblast formulary manual. In Kyiv, RPM provided training to personnel of all 52 municipal hospitals in formulary development and provided direct technical assistance and specialized training to four municipal hospitals in drug selection and rational drug use.

RPM worked with the KMHD to adapt the formulary process to provide cost-effective drug treatment in the outpatient setting. RPM examined the current exempt prescription program for areas of potential improvement in the drug selection process, such as inclusion of cost-effectiveness and drug product quality in criteria for selection of covered products. This stream of activity supported USAID's Strategic Objective SO3: Increased use of key child health and nutrition interventions. It also supported the goal of the new USAID Ukraine Health Strategy to reform primary health care and improve the capacity of health practitioners to effectively and efficiently provide community-based health services. RPM activities supported favorable outcomes of SO3.2b, as a part of its Intermediate Result 3.2b.1: Provision and utilization of primary health care services improved.

Whereas initial funding for RPM Ukraine activities came from the NIS add-on to the RPM Worldwide cooperative agreement in August 1993, funding for the extension period (1999 through end of project) was through USAID/Kyiv field-support funds.

Challenges Facing RPM Ukraine Implementation

The challenges faced in implementing the RPM program of activities in Ukraine were varied. They included the following: changes of personnel; lack of current sources of drug and price information; a bureaucracy and authoritarian mind-set inherited from the Soviet system; unsustainable, generous entitlements for pharmaceuticals to sectors of the population, at least on

paper; and an economy in transition, unable to finance the needs for outpatient or inpatient pharmaceuticals.

Below are some examples of these challenges.

- There was no medical school in Zhytomyr Oblast to provide technical assistance to the ZOHA in continuing education of medical personnel or in drug information. Little effort was expended to obtain drug information independently. In other countries, where RPM/United States Pharmacopeia also provided technical assistance in establishing drug information centers, that activity was synergistic with the drug management activities implemented by RPM.

- There was a sense of frustration, isolation, and not wanting "outsiders" to examine too closely what has been accomplished in Zhytomyr Oblast.

- The lack of financial resources for procurement of drug products made drug selection activities seem academic.

- Zhytomyr Oblast was a good initial choice because of administrative support and the presence of committed key counterparts, but changes of personnel made it difficult to proceed at the intended pace.

- Although statistical departments exist in hospitals and oblast administrative offices, and health personnel gather a variety of data, they are not accustomed to analyzing data locally, looking at them creatively, or using them to make decisions at a decentralized level.

- Institutions have in place structures whose function is nominally quality control of prescribing and medical care, but their effectiveness varies widely.

- The existence of the national "formulary" list made rational selection decisions more difficult. Whereas the initial list of 80 products was completely insufficient, inclusion of more than 800 drug products, many of them duplicates and products of dubious quality or effectiveness, made practitioners skeptical that a limited list of drug products could be enforced.

- There were many holdovers in traditional prescribing practices that had little to do with effectiveness.

Chronological Activity Timeline

Table 1. Activity Timeline

Date	Activity
November/December 1993	RPM Ukraine pharmaceutical sector assessment
November 1996	Ukraine reconnaissance trip
May 1997	MOH Health Reform Conference, Yalta
September/October 1997	Zhytomyr Oblast initial planning visit Hospital Accreditation Standards review
December 1997	Workshop on hospital formulary development (Zhytomyr Oblast)
May 1998	Clinical pharmacology workshop (Zhytomyr Oblast)
August 1998	Field-test prescribing assessment survey instrument and begin data collection (Zhytomyr)
October 1998	Partners' meeting (Kyiv); technical assistance (Zhytomyr)
January 1999	Visit Kyiv hospitals in preparation for rollout
April 1999	Collect data for ABC/VEN analysis (Kyiv)
June 1999	Formulary implementation workshop and TA (Kyiv)
September 1999	Partners' meeting (Kyiv) TA to Kyiv hospitals
November 1999	ABC and VEN analyses (Kyiv hospitals) Partners' meeting (Seattle)
March 2000	Preliminary assessment of the exempt prescription program (Kyiv) ABC and VEN analyses (exempt prescriptions, Kyiv) TA to Kyiv hospitals STG implementation workshop (Zhytomyr)
April 2000	Man and Drugs Congress (Moscow) Pharmacoeconomics short course (South Africa)
July 2000	Strategies for Improving Drug Selection and Use Workshop, Kyiv
September 2000	Formulary Manual, Zhytomyr Oblast

Program Accomplishments

Develop Capacity to Conduct Pharmaceutical Sector Surveys

Sustainable improvements in the pharmaceutical sector depend on the country's commitment to improvement, technically sound plans based on accurate situation assessment, and the technical and financial resources to implement proposed changes. Accurate systemic assessment is a prerequisite for planning changes in the pharmaceutical sector and, in particular, the drug supply system. Pharmaceutical-sector assessments can diagnose emergent problems in the system, guide intervention planning and implementation, and monitor changes. This objective was achieved through three activities:

1. The RPM Ukraine pharmaceutical sector assessment
2. The survey of prescribing patterns at the hospital level
3. Training and hands-on technical assistance in use of the RPM-developed tools

504

In Ukraine, RPM used a variety of implementation approaches including training, hands-on technical assistance, and use of local experts and RPM consultants. Assessment objectives were achieved through collection of background information, review of documents, structured interviews with key informants, collection of indicator data, and ABC/VEN analysis of drug procurement lists.

The RPM Ukraine Pharmaceutical Sector Assessment

The pharmaceutical sector assessment was conducted in Ukraine in November/December 1993, and the draft report on the findings was published in January 1994.

Assessment Objectives

The objective of the assessment was to provide a complete overview of how drugs were procured, stored, distributed, dispensed, and sold in Ukraine. The information was gathered for the purpose of supporting the World Bank and the government of Ukraine efforts to increase availability of drugs at least cost to the public.

Data Collection and Processing

The assessment data collection was performed in November–December 1993 by the RPM team with participation of experts from the national, regional (oblast), and district (*raion*) MOH, the city of Kyiv and Donetsk Oblast Pharmatsiyas, hospital and pharmacy administrators, and students from the National Medical University of Ukraine.

The team collected data in a convenience sample of 21 hospitals, 19 retail pharmacies, and two pharmatsiyas (pharmaceutical wholesalers) in Kyiv and Donetsk. Two tracer-drug lists were developed in collaboration with the MOH to collect drug-availability indicator data. The list for hospitals contained 30 drug products, and the list for retail pharmacies contained 32 drug products.

The assessment tools used in Ukraine included the following:

- Questionnaires to interview key informants at the national, oblast, municipal, and facility levels
- Drug availability and pricing data collection forms
- Electronic spreadsheets for qualitative and quantitative estimation of drug needs
- Spreadsheets for source-of-supply analysis

Key Assessment Findings and Recommendations

The key findings included the following:

- After the collapse of the Soviet Union, Ukraine could not ensure financial sustainability for the public health drug supply system.

Beginning in 1992, the stocks that were obtained while Ukraine was part of the Soviet Union were used and eventually depleted. Because funds were not available for stock procurement, severe shortages of drugs resulted in every category. Availability of tracer drug products was poor in both hospitals and community pharmacies. In hospital pharmacies, a mean of 49 percent of the 30 tracer products was available, with a range of 28 percent to 72 percent. In community pharmacies, a mean of only 29 percent of the tracer list was available, with a range of 13 percent to 56 percent.

- The existing centralized drug procurement system was not able to function in the new developing market economy. Therefore, decentralization of drug procurement occurred de facto, with little preparation at local levels for this responsibility.

Because there were no drug products or drug information provided through the public health system, pharmacies in hospitals and community pharmacies were forced to search for their own suppliers, a de facto decentralization. Little or no objective information was available about drug products, and pricing information varied from one supplier to another, with little opportunity for comparison. There were no wholesalers with a comprehensive line of pharmaceuticals. Procurement took place when funds were available from multiple small suppliers, rather than by making planned procurements. More important, the personnel nominally in charge of drug selection and procurement had little experience in doing so, and significant gaps existed in their knowledge of how to select drug products and procure them in a transparent and cost-effective manner.

- Drug-pricing mechanisms did not allow the recovery of drug costs.

According to law, when drug products were sold, their selling price was based on the acquisition cost, plus either a margin of up to 50 percent or a set schedule of tariffs. This system differs from other methods of drug pricing that allow repricing according to the most recent acquisition cost. Ukraine experienced six instances of hyperinflation (inflation of over 50 percent) in the second half of 1993. Overall in 1993, the inflation rate exceeded 10,000 percent. Therefore, if a product was purchased in the first half of the year, and sold several months later, the rate of inflation made cost recovery virtually impossible. Thus, the public and private sector were rapidly decapitalized.

- A considerable number of pharmaceuticals put on the request list for the World Bank loan were duplicative, of unproven efficacy, and of dubious quality.

The original list of drug products submitted in the request list for the World Bank loan included 627 drug names, many of which were duplicative, of unproven efficacy, and of dubious quality.

On the one hand, the list contained, for example, several antidotes for organophosphate poisoning, which alone exceeded the proposed loan amount. On the other hand, the list did not include products from several significant therapeutic groups, including antineoplastics.

RPM recommended that the best approach to assist Ukraine in the area of pharmaceuticals would be a package combining credits for purchasing essential drugs with selected management reforms to promote financial sustainability at the oblast level. Examples of interventions included implementation of competitive procurement procedures, installation of routines for more efficiently updating inventory value and prices, and development of price structures that would allow recovery of the real replacement costs of products sold.

Outcomes

The assessment findings were described in the report submitted to the USAID/Kyiv Mission and the World Bank (see Annex 2, Ministry of Health of Ukraine Rational Pharmaceutical Management Project, Ukraine Pharmaceutical Sector Assessment). As part of the assessment visit, the RPM team analyzed the list of drug products on the request list and suggested a revised list of 218 products. However, because of various local circumstances, the World Bank follow-up activity was never launched, and at that time, there was limited interest in RPM involvement by the USAID/Kyiv Mission. Curiously, however, the MOH in subsequent years published an Essential Drug List.

The objective of developing the capacity of local decision-makers to conduct pharmaceutical sector surveys and to use this information to guide decision-making was only partly achieved through the initial assessment. Counterparts with the NMU and district and municipal health departments were generally cooperative and could have been expected to conduct focused repeat surveys with minimal assistance. However, obtaining national-level data was more problematic. There was less interest from some national agencies, which were very much in a state of flux. However, even if these data were available, using them to guide decision-making required obtaining approval from multiple levels of the public health bureaucracy, something which was difficult to achieve at that time.

In 1996, there was renewed interest in developing an RPM/Ukraine program. The findings of the 1996 visit can be found in A. Savelli, Ukraine Reconnaissance Trip Report, in Annex 2. The findings of the 1993 assessment, coupled with RPM experience in the RPM/Russia program, were then used to plan the Ukraine program. On the basis of initial reconnaissance visits and participation in the May 1997 Conference on Health Care Reform in Yalta, RPM proposed to implement a program that included

- Formulary system implementation workshops
- Lectures on clinical pharmacology
- Technical assistance to hospitals implementing formulary systems
- Distribution of RPM tools developed in Russia
- Curricular reform at the National Medical University of Ukraine
- Technical assistance in procurement to community pharmacies

Survey of Prescribing Patterns at the Hospital Level

In August 1998, at the request of the Zhytomyr Oblast Health Administration, RPM provided technical assistance to Zhytomyr counterparts to conduct a limited survey of prescribing patterns in selected hospitals. The survey was to be used as a baseline for district hospitals prior to initiating activities on the development of standard treatment guidelines.

Survey Objectives

The survey objectives were the following:

- Demonstrate the methodology and develop local capacity in conducting a targeted prescribing survey
- Provide the oblast with survey information on prescribing patterns and recommendations on its use in STG development

Methodology

The conditions selected for the survey were determined by examining admissions data submitted by *raion* (district) hospitals for the previous year. It was decided that a limited number of conditions should be examined to simplify data collection and analysis. The top three illnesses that triggered admission to Zhytomyr *raion* hospitals were acute respiratory infections (ARIs), pneumonia, and ischemic heart disease (IHD). These three conditions alone accounted for over 20 percent of all admissions. To narrow down IHD, acute angina was selected as the third condition.

The survey instruments consisted of specially developed data collection forms and questionnaires for structured interviews. A procedure for randomly selecting cases was established. ZOHA personnel were trained how to select cases and fill out the forms and questionnaires. The data entries included a unique patient identification number; diagnosis by International Classification of Diseases, 9th edition; drugs prescribed; routes of administration; daily directions; duration of treatment; reasons for discontinuing or changing the drug; and patient out-of-pocket expenditures on drugs.

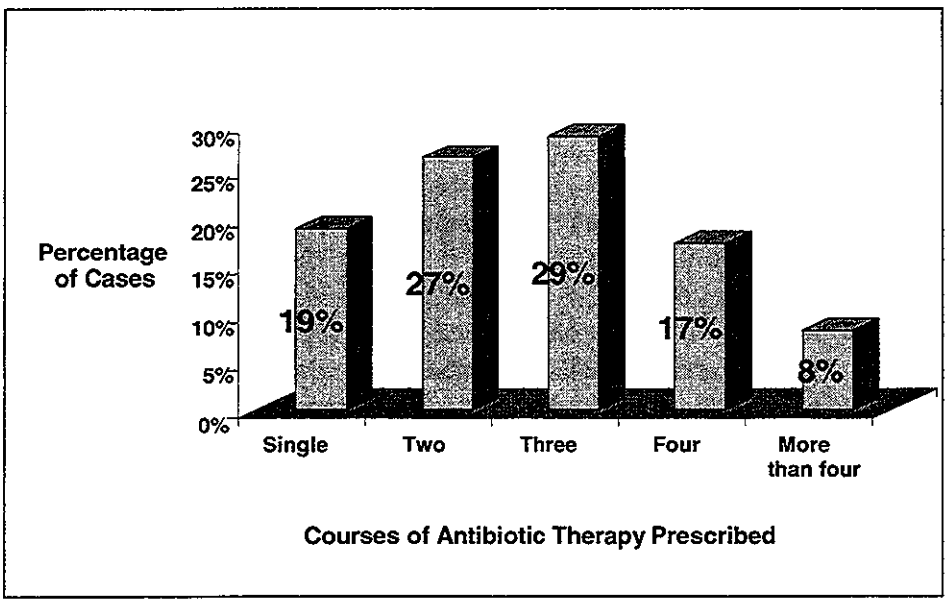
The RPM team interviewed physicians and administrators and studied hospital patient records while pilot-testing the data collection forms. At ZOHA insistence, further data collection was performed on-site by hospital staff. Five hospitals self-selected for inclusion in the survey. The patient sample included 133 pneumonia patients, 134 patients diagnosed with IHD, and 70 ARI pediatric patients.

Key Survey Findings

The study revealed a few significant prescribing and drug use problems in the treatment of these three conditions in oblast health facilities, including the following:

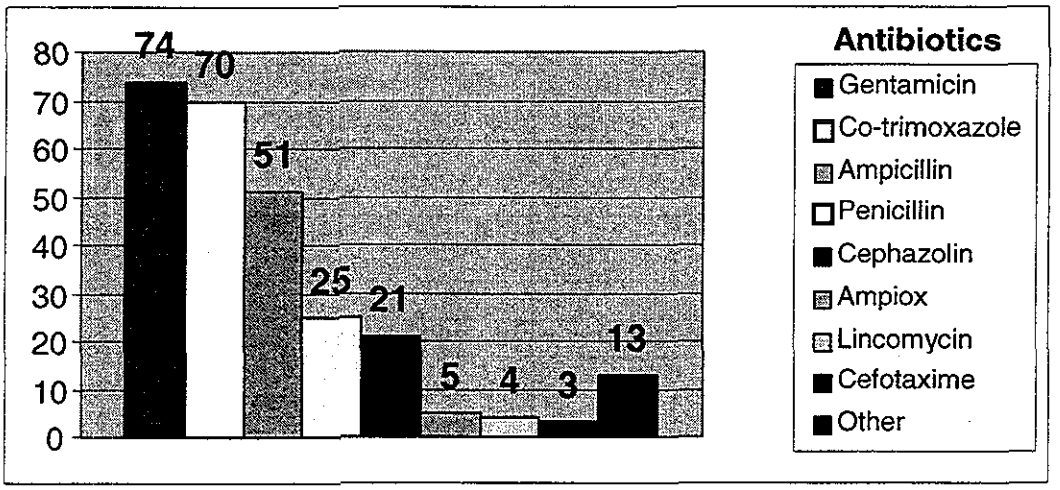
1. Overprescribing of antibacterial drugs was typical, which could potentially expose patients to unexpected side effects, contribute to antimicrobial resistance, and add unnecessary costs to treatment. Figure 1 indicates the number of courses of antibiotics that were prescribed either concurrently or sequentially for treatment of pneumonia. Only 19 percent of the cases used a single antibiotic; 54 percent of the cases received three or more courses of antibiotic therapy. These data do not distinguish between full and partial courses of therapy.

Figure 1. Courses of Antibiotic Therapy for the Treatment of Pneumonia



2. Drug therapy was idiosyncratic and did not comply with internationally accepted treatment guidelines and approaches. Figure 2 shows those antibiotics that were prescribed for the treatment of pneumonia. The antibiotic used most frequently was gentamicin, yet anecdotal discussions indicated that resistance to gentamicin was a serious problem in the oblast. Unfortunately, the hospitals did not have the laboratory supplies to allow routine cultures, nor reports of antibiograms. It was also a common practice to provide critical patients with the appropriate antibiotics from the inpatient pharmacy's stock (paid for through public health funds). However, once the patient was stabilized, the patient was required to pay for continuing antibiotic treatment; often the prescribed drug was changed to a lower-cost alternative.

Figure 2. Antibiotics Used for Treatment of Pneumonia



Other indicators suggest other potential prescribing problems. Injectables were prescribed in 52 percent of all encounters. Without additional information, however, it is not possible to conclude if this use was appropriate. Only 56 percent of prescribed drugs were prescribed by generic name. This indicator may be somewhat misleading, however, since the use of branded generic names is quite common in Ukraine.

3. Some important groups of drugs were underused in the treatment of ischemic heart disease.

   - ACE inhibitors, that can prevent cardiac failure, were rarely used.

   - Antiplatelet agents, which are recommended for secondary prevention of thrombotic, cerebrovascular, or cardiovascular disease, were underused.

   - Cardioselective β-adrenergic blockers, which are safer, were generally not used rather than nonselective β-blockers.

   The list of drug products prescribed for IHD included a category of drug products called "metabolic" drugs. These products accounted for almost 32 percent of all of the drugs prescribed for IHD (by frequency). If one considers the ranking by value, this percentage would be nearly double.

510

Table 2. Pharmacologic Agents Prescribed in Ischemic Heart Disease; Frequency of Use

Pharmacological Group	Frequency of Use	%
"Metabolic" drugs*	51	31.7
Nitrates	26	16.1
Potassium preparations	18	11.2
β-adrenergic blockers	14	8.7
Analgesics	9	5.6
Cardiac glycosides	8	5.0
Antiplatelet agents	7	4.3
Antihistamine agents	7	4.3
Calcium channel blockers	6	3.7
Diuretics	6	3.7
ACE inhibitors	5	3.1
Other	4	2.5
Total	**161**	**100.0**

*The group of "metabolic" drugs includes inosine, cocarboxilase, triphosadenin, actovegin, essentiale.

4. Polypharmacy, the use of multiple drug therapy, was typical. For example, the IHD patients received, on average, five drugs for treatment of the primary health condition. For all three conditions, 91 percent of all encounters result in four or more prescribed drugs.

5. Serious problems were identified with use of antibiotics to treat ARI, especially in children. These problems include overuse of antibiotics in ARI treatment (91% of patients were treated prophylactically with antibiotics with no confirmatory testing), unnecessary prescribing (20.4% of patients were prescribed two or more antibiotics), and misuse of antibiotics (prescribing gentamicin to children).

6. Cost was a significant factor associated with the selection of drug products in treatment. Approximately 90 percent of the products used by inpatients in surveyed hospitals were purchased outside of the hospital by patients' families. Often, drug therapy was shortened because of the cost of the products, or less effective and less expensive products were substituted for drugs of choice. The only exception to this practice was in the treatment of children. In the children's hospital, the public health budget covered 85 percent of the demand for pharmaceutical treatment of inpatients.

   For all pneumonia cases, the average treatment cost was approximately $57.00, with a range of $3.80 to $180, depending on the type of pneumonia. Considering that most workers did not receive their wages on a regular basis, and that wages were three to six months (sometimes longer) in arrears, this expense posed a significant economic hardship for patients' families.

Significance and Outcomes of the Survey

The results of the study clearly demonstrated to oblast health care officials that treatment patterns in the most common diseases were not adequate in many cases, selection of drugs was not rational, and standard treatment guidelines were not used in practice. The analysis of this study was reported and discussed at the RPM Formulary Implementation Workshop in Zhytomyr, March 2000. RPM staff presented the results of the pneumonia treatment survey at the International Conference on Antibiotics and Antibiotic Resistance at the Dawn of XXI Century held in Moscow in July 2000.

The results of the survey triggered oblast activities in revising existing STGs. It was known that the Ukrainian Institute of Public Health was preparing to publish national standard treatment guidelines in 1999, but the actual date of their release was unknown. Instead of waiting, the Zhytomyr Oblast Health Administration used these findings as a basis to develop a harmonized approach to treatment of conditions most frequently encountered in the 25 *raion* and two municipal hospitals. The chief oblast specialists were involved in drafting revised standard treatment guidelines and were responsible for overseeing their implementation in the 27 hospitals in the oblast. The ZOHA was willing to compare the oblast-developed STGs with national guidelines and committed to initiating contact with the UIPH for this purpose. The ZOHA also expressed interest in developing a system for tracking prescribing practices and providing feedback to the hospitals to improve the quality of prescribing and health outcomes.

Using oblast-level personnel to conduct the survey had some positive results and demonstrated at least partial achievement of the first RPM objective. In five hospitals, personnel became familiar with how to use the data collection forms, randomly select appropriate cases, and record the data. The process of collecting and analyzing the data created the impetus needed to proceed with revision of the oblast STGs. The results of the survey were shared with physicians from all 27 hospitals in the oblast at a one-day workshop. Oblast-level personnel understood how data that were currently available in hospitals could be used to provide feedback on the quality of prescribing. The survey was repeated for pneumonia patients in the Zhytomyr Oblast Hospital in the first quarter of 2000 without RPM technical assistance, and results were shared with colleagues at the Kyiv Strategies for Improving Drug Selection and Use Workshop in July 2000 (see Annex 1). The results suggested limited progress in improving prescribing practices, but findings could not be strictly compared with the first study because the Zhytomyr Oblast Clinical Hospital was not one of the sites in the original study.

There were also challenges in having local personnel conduct the survey. These were primarily the time it took to complete the surveys and incomplete participation from *raion* hospitals. During the course of the study, there was a change in oblast administrative personnel. This change meant that responsibility for RPM activities fell to the deputy chief physician of the Zhytomyr Oblast Hospital, who tried to fit in RPM activities with her normal duties. Unfortunately, this situation meant that data collection and transfer of the data to RPM did not happen within the time frame that would have been possible had RPM contracted with the NMU or another organization to perform the data collection and analysis.

512

The results of the survey were also disseminated outside Zhytomyr Oblast. The findings were shared at the Man and Drugs Congress in Moscow, Russia, in April 2000. RPM supported seven participants from Zhytomyr and Kyiv to attend this continuing education meeting in Moscow, the largest of its kind in the NIS. Two abstracts were accepted for the meeting; one was on the Zhytomyr prescribing survey and the other on formulary implementation in Kyiv. Ukrainian participation in this meeting was very useful, as there were many sessions on issues associated with formulary development and management. Information from the meeting provided support for exclusion of ineffective or duplicative drug products from the Zhytomyr Oblast Formulary.

Training of Ukrainian Counterparts

Training was an important component of the RPM/Ukraine implementation strategy. Many of the RPM-introduced activities, such as cost-effective drug selection, drug formulary management, and ABC/VEN analysis, were not previously practiced in Ukraine. Thus, RPM designed and conducted a series of training sessions and workshops to address the training needs at every level of project implementation. Training was provided through workshops, technical assistance, hands-on training, and specialized training. For a list of training and technical assistance activities, see Annex 1.

Workshops

Formal training was tailored to the needs of Ukrainian counterparts and consisted of workshops that covered broad aspects of formulary system implementation and maintenance, including development of policies and procedures, cost-effective drug selection and formulary list development, rational drug use, cost-containment strategies, pharmacoeconomics, and development of standard treatment guidelines. When Ukraine-specific data became available, these examples were incorporated into increasingly specialized workshops to implement formularies and encourage rational drug use. For a complete list of training materials, see Annex 2.

RPM conducted the first Formulary Systems Development Workshop in Zhytomyr Oblast in December 1997. Nearly 40 physicians and administrators from municipal, district (*raion*), and regional (oblast) hospitals and primary health care facilities attended the workshop. Participants attended lectures, group discussions, and participatory exercises on the formulary development process—a systematic approach for drug selection and use based on drug efficacy, safety, quality, and cost. Participants learned how to conduct an ABC/VEN analysis. During small-group activities, participants concluded that their approaches to treatment of commonly occurring conditions varied widely and that a consistent approach was desirable in the oblast. This buy-in was essential for their adoption of the standard treatment guidelines that were developed in 1999.

Approximately 200 physicians and pharmacists participated in the Formulary Implementation Workshop, held outside of Kyiv, Ukraine, on June 7–9, 1999. Participants represented approximately 50 hospitals and polyclinics in the Kyiv Municipal Health Department. Of these, few had previous exposure to RPM and formulary concepts, but several of the KMHD

administration staff had either attended educational sessions where formulary concepts were discussed or heard about the RPM experience in Russia. The three-day meeting was successful in applying both theoretical information about formulary concepts, with the practical examples from Ukraine and Russia, and practical application of formularies to drug selection, procurement, health insurance, and quality of care. Participants quickly grasped concepts when they were able to practice in small-group sessions.

In March 2000, approximately 150 physicians, pharmacists, and administrators participated in the STG implementation workshop in Zhytomyr. RPM presented the findings of the hospital prescribing survey, and ZOHA counterparts presented the progress on STGs and the draft formulary manual. Another component of the workshop was presentation of current treatment approaches to pneumonia, acute respiratory infections, and ischemic heart disease by faculty from the Academy for Continuing Medical Education (ACME) and the NMU.

RPM planned to conduct a workshop on drug management in primary health care in May 2000 as part of the new Ukraine Health Strategy. However, the KMHD requested that the conference be open to health personnel from both ambulatory-care and hospital facilities. RPM conducted the Strategies for Improving Drug Selection and Use workshop in Kyiv, July 10–13, 2000, in collaboration with Kyiv Municipal Health Department. Approximately 200 participants attended, representing the KMHD, Kyiv Pharmatsiya, chief physicians, deputy chief physicians, heads of departments, and pharmacists of city hospitals, ambulatory-care facilities, and the Zhytomyr Oblast Hospital. In support of the USAID Ukraine Health Strategy, many of the participants were also active in technical assistance activities through other USAID partner organizations.

The Strategies workshop's objectives were achieved through a variety of activities. The first two days of the workshop were designed to conduct two types of presentations, theoretical and practical. Presentations on different theoretical aspects of the problem of irrational drug use, and strategies for improving drug selection and use were delivered by RPM staff and consultants. Presentations on the current situation in drug supply, selection, and use in Ukraine, as well as RPM experience in formulary development in enrolled city hospitals, were delivered by local specialists. This dual approach of the theoretical and practical provided an information base, as well as understandable points of reference. The use of regional NIS specialists was cost-effective and well received by participants.

Small-group work was focused on practical aspects of improving drug selection and use. Topics included identifying obstacles to formulary implementation in Kyiv health care institutions, needs for effective implementation, and possible solutions; selecting drug use indicators for hospitals and ambulatory facilities; conducting ABC/VEN analysis; developing a DUR program for health care facilities; and studying practical aspects of rational prescribing. Participants quickly became very animated and developed rather extensive lists of potential problems in implementation, then suggested solutions to those problems. In one exercise, participants developed action plans for their own institutions for implementation of formularies, while others developed suggested indicators for tracking rational drug use. The Municipal Health Department plans to use these suggestions in revising the order for development and implementation of a program for rational selection and use of pharmaceuticals in the city of Kyiv, and in further implementation of formularies in Kyiv hospitals.

Hands-on Training by Visiting Experts

Formulary development in Zhytomyr Oblast was facilitated by direct technical assistance and hands-on training provided by RPM/Washington experts, specialists from RPM/Russia demonstration sites, as well as clinical and research personnel from the NMU, the MOH, the ACME, and the UIPH. This approach gave RPM the opportunity to rapidly identify training needs and develop appropriate educational materials and formal training courses for Zhytomyr Oblast and for the city of Kyiv.

Technical assistance was provided in various areas such as review and development of policy and regulations, as well as at all steps of the formulary process, including data analysis, group decision-making in the formulary committee, obtaining or evaluating drug information, reviewing or revising standard treatment guidelines, developing the formulary list, reviewing and revising drug management–related accreditation standards, and using formularies in third-party insurance systems. Hands-on training was also very effective in situations where counterparts needed to be familiarized with practical tools such as ABC/VEN analysis. For a full list of technical assistance activities, see Annex 1.

The first technical assistance visit to Zhytomyr Oblast, for example, oriented the key individuals responsible to drug selection and procurement in the Zhytomyr Oblast Clinical Hospital (the main referral hospital in the region) and Zhytomyr Oblast Children's Hospital. The RPM team visit also had a strong assessment component, as this was the first visit to the pilot site. The RPM project obtained strong support from both oblast and hospital administrations. The decision was made to coordinate activities at the oblast level and simultaneously develop formulary systems at several hospitals.

The technical assistance activities also built the capacity of RPM counterparts to assist colleagues in their own district or in other cities. In October 1997, RPM conducted preliminary technical assistance activities in two Zhytomyr oblast hospitals. Subsequently, Ukrainian counterparts from those two hospitals collected and analyzed their morbidity and drug consumption data for 1997—a crucial first step in the formulary development process. These counterparts presented their findings at the December workshop and provided practical advice to fellow participants on how to accomplish data collection and analysis in Ukrainian hospitals.

Specialized Training

Paralleling what RPM found in Russia, in Ukraine physicians lacked not only the clinical knowledge of drugs needed to approach drug comparison and selection scientifically, but also the required managerial skills to implement the formulary development process. Monitoring and evaluation of drug prescribing and use was rarely done. These problems were compounded by the fact that, over time, the Ukrainian market was flooded with drugs of questionable safety and effectiveness. In May 1998, RPM conducted a specialized training—a clinical pharmacology workshop in Zhytomyr—for approximately 200 Zhytomyr Oblast physicians and pharmacists; this step was the first by RPM in Ukraine to assist physicians and officials to address these issues

on a regional basis. The topics were so well received that RPM and ZOHA counterparts decided to include clinical pharmacology components in all subsequent workshops.

In April 2000, RPM supported seven Ukrainian participants to attend the Man and Drugs Congress in Moscow, Russia, where formulary issues were a primary topic of the conference. Two abstracts on the experience of Kyiv in implementing formularies and on the hospital prescribing survey were accepted for the congress. Another Ukrainian participant attended the Course in Pharmacoeconomics in South Africa in April 2000 as part of the primary health care activities. He later presented this information, adapting it to Ukrainian circumstances, to Kyiv colleagues at the July 2000 conference on Strategies for Improving Drug Selection and Use.

Outcomes

During the life of the RPM/Ukraine program, approximately 600 physicians, pharmacists, and academic personnel were trained. Approximately one-half of those were in Kyiv and half in Zhytomyr Oblast. The full list of workshops and training appears in Annex 1.

Through the training activities, Ukrainian counterparts increased their knowledge of all aspects of formulary systems, including methods of analyzing morbidity and drug consumption patterns, and using such information to select priority therapeutics categories, to select appropriate cost-effective quality drug products consistent with international standards, to provide feedback to prescribers on their prescribing patterns, and to maintain this system. They also developed practical skills in reviewing medical literature, finding objective drug information, performing ABC/VEN analyses, and then applying this information to decision-making.

Participants in the training also demonstrated its effectiveness by applying the skills learned in their own institutions. The best example of this was when hospitals in Zhytomyr Oblast and in the city of Kyiv conducted their own ABC/VEN analyses.

Develop Local Capacity in Formulary System Implementation

A formulary system includes a process whereby the medical staff of an institution, working through a Formulary and Therapeutics Committee, evaluates and selects drug products that are considered most efficacious, safe, and cost-effective. As such, the formulary system is a mechanism to optimize patient care, streamline procurement activities, and minimize costs.

The result of the drug selection process is a drug formulary list. The list contains all drugs approved for procurement and use in a given health facility. A drug formulary list is not synonymous with an essential drugs list in that formularies are restrictive, whereas essential drugs lists do not confine drug use and procurement to only the drugs contained on that list.

Institutionalization of the Formulary System

Zhytomyr Oblast

The desire to implement a formulary system may arise from either operation- or administrative-level personnel. Regardless of where this desire arises, successful implementation requires support from both the medical staff and administrators.

The need for establishing oblast hospital committees responsible for creating and maintaining lists of drugs approved for procurement and use was recognized by Ukrainian counterparts. After the December 1997 Workshop on Formulary Development in Zhytomyr Oblast, formulary committees were established in Zhytomyr Oblast Clinical Hospital, Zhytomyr Oblast Children's Hospital, and at the Zhytomyr Oblast Health Administration.

The first to have completed drug selection and a formulary was the Zhytomyr Oblast Children's Hospital. Although there was a competent team of physicians, who represented the major specialties in the hospital, the driving force was the deputy chief physician, who was responsible for drug management in the hospital and who served as the chair of the formulary committee. This hospital required minimal technical assistance in incorporating formulary principles into drug selection.

The Zhytomyr Oblast Clinical Hospital was involved in all aspects of formulary development in the hospital itself, as well as in the oblast. After the changeover in ZOHA personnel in 1999, the decision was made to approach formulary development as an oblastwide activity, rather than in the individual *raion* hospitals. The primary reason for this decision was that objective drug information was very scarce in *raion* hospitals, and the medical specialists, who would normally keep up with recent medical literature, were generally located at the Oblast Clinical Hospital. Although this approach was less participatory, there was general support for an oblastwide formulary from the *raion* hospitals. Therefore, the ZOHA issued a rule incorporating the formulary as the official guide for prescribing in the oblast.

Kyiv

In Kyiv, the situation developed somewhat differently. The Kyiv Municipal Health Administration was already supportive of the concept of formulary development in all Kyiv municipal hospitals at the time that RPM began rollout in the city of Kyiv. In 1997, the KMHD prepared an order to implement a program for rational drug use in the city of Kyiv, including formulary development and implementation. In March 2000, at a meeting of all Kyiv municipal hospital physicians, the group adopted a resolution to implement formularies in all 52 hospitals within the following year. Formulary committees were established in four hospitals, and RPM provided technical assistance to those committees in conducting ABC and VEN analyses and implementing the formulary process.

In another example of adoption of formulary concepts, colleagues at the NMU and the ACME discussed formulary concepts. The Academy created a computerized certification test program

for pharmacists-managers, which is currently awaiting MOH approval to be an official certification program for Ukraine. It includes 28 test items on formulary systems. These items are included in the continuing education curriculum for pharmacists and physicians. The NMU also began including formulary concepts in its curriculum and requested materials that had been developed for this purpose in the RPM/Russia program.

Development of Formulary Drug Lists

Zhytomyr Oblast

A drug formulary for Zhytomyr hospitals was developed following an ABC and VEN analysis, and an analysis of therapeutic drug classes following the steps outlined in the *Manual for Development and Implementation of a Formulary System in Hospitals* (see Annex 2, Training Materials). In addition to technical assistance from RPM, counterparts also used the United States Pharmacopeia Dispensing Information and other references provided by RPM to help in the decision-making process. The following table illustrates the results of the drug selection process for Zhytomyr Oblast.

Table 3. Drug Products before and after Formulary Development

Number of Drugs in Use before Selection	Number of Drugs Deleted	Number of Drugs Added	Number of Drugs in the Formulary List
728	170	40	598
100%	23.4%	5.5%	82%

Through the process of formulary development, the number of drugs in use was reduced by 18 percent to 598. This number is still relatively high, but it can be at least partly explained by the fact that it contains drugs for pediatric and adult use, it is meant to cover all medical specialties in the oblast, and it includes hospitals through the tertiary level. If the lists had been developed in each institution, the number probably would have been substantially lower.

Drugs Deleted from Use

As a result of formulary system development, 170 items were deleted from the initial list, accounting for 23.4 percent of the initial list. The majority of drugs was deleted from the formulary list because of low efficacy or safety. Examples include tissue metabolism stimulators of unproven clinical efficacy, herbal preparations, vitamins, fixed-dose combination products, and obsolete and unsafe cholinergic blockers. In addition, a significant number of duplicative, non-STG, and rarely used drugs were removed. Thirty-nine deleted products (23%) were herbal products of doubtful or low efficacy; 38 items (22%) were fixed-dose combinations. It is internationally accepted that the number of fixed-dose combination products that is included in the formulary should constitute a very small percentage of the total number of drug products.

These reductions are expected to improve clinical efficacy. In the reality of still-diminishing health and drug budgets, it is almost impossible to calculate the economic effect of the drug selection process. Even with funds saved by not procuring the deleted drugs, hospitals will still experience drug budget shortages. It may be safe to assume, though, that whatever small amount of funds Zhytomyr hospitals do use for drug purchases will be used to procure drugs of proven efficacy and safety. Also, if formulary drugs are purchased for inpatients, purchases are anticipated to be more rational.

Drugs Added

In the process of formulary list development, 40 drugs were added. It was reported that the main reason for addition was high efficacy. The majority of drugs included were cardiovascular drugs (45%), followed by anticoagulant drugs (12.5%) and central nervous system agents (7.5%).

Though most of the additions to the initial formulary list were justified, a limited number of drugs added can be considered less efficacious products and drugs with a narrow therapeutic index. The costs of drugs were not always considered before drugs were added to the list. Unfortunately, drugs of low or unproven efficacy are in common use in Ukraine because of entrenched traditions, outdated treatment practices, or lack of continuing education. Replacing unsafe and ineffective items with more cost-effective products requires education of the physicians on updated concepts in clinical pharmacology and internationally accepted standard treatment practices. This need was taken into account when planning RPM workshops. To sustain these changes, however, additional monitoring mechanisms and refresher courses will still be needed. The oblast formulary should be a good base for further improvement in drug selection and use.

The Zhytomyr Oblast formulary list was drafted in compliance with revised oblast STGs. Drugs were classified according to therapeutic application. This classification based on therapeutic usage was considered to be adequate for physicians, nurses, pharmacists, pharmacy technicians, and nonmedical staff involved in the drug management system. The Formulary Committee felt that using a therapeutic classification along with an alphabetical index would facilitate use of the manual.

At the request of the Zhytomyr Oblast Health Administration, RPM funded printing of 150 copies of the draft oblast formulary and conducted a formulary implementation workshop where the list was presented and disseminated to health professionals from throughout the oblast for review. The oblast formulary committee compiled all the suggestions from physicians and some revisions were made after discussion. Being accustomed to traditional prescribing habits, Zhytomyr physicians were initially resistant to deleting many obsolete or ineffective drugs. It was at this stage that RPM supported participation of Formulary Committee members in the Russian National Man and Drugs Congress, which was mostly devoted to formulary implementation in Russia. Participation in the conference was very beneficial and helped committee members to understand the concepts better. As a result, they agreed with many RPM recommendations for deletions in the formulary list and provided their colleagues with legitimate, objective reasons for doing so.

Development of Standard Treatment Guidelines

Although RPM activities in the oblast did not specifically target development or revision of existing treatment guidelines, shortly after the work on formularies started, the ZOHA used the opportunity to revise the standard treatment guidelines in the oblast from the primary health care level to the tertiary oblast clinical hospital. The guidelines were drafted and reviewed with RPM assistance. It was anticipated that this activity would result in publishing an oblast formulary with guidelines for common conditions.

In 1999, the Ukrainian Ministry of Health also published revised national standard treatment guidelines, developed by the Ukrainian Institute of Public Health. Because national STGs were approved by the MOH, the ZOHA decided against publishing oblast guidelines, though the oblast STGs were harmonized with the national guidelines and draft copies were available to the hospitals. It should be mentioned that the national guidelines did not contain treatment algorithms or identify specific drugs and dosage forms, although they did specify therapeutic categories of drugs and could be widely interpreted by physicians. National STGs were not found in Zhytomyr Oblast health facilities at the time of RPM activities, since they were only recently published and the MOH did not distribute them free of charge. Health facilities had to buy this rather expensive, by local standards, two-volume manual, and often local facilities had no funds to do this. STGs, therefore, were not strictly enforced or complied with. In that situation, the ZOHA decided that the oblast formulary, harmonized with oblast and national STGs, might be the most practical guide for rational drug selection and use in all the health facilities of the oblast. For this reason, the ZOHA decided to publish only the *Zhytomyr Oblast Formulary Manual.*

Publishing the Zhytomyr Oblast Drug Formulary

The Zhytomyr Oblast Formulary Committee developed and published a formulary manual. The manual contains three parts: (1) drugs of choice for adults, (2) drugs of choice for pediatric patients, and (3) a section with information about the Oblast Formulary Committee and policies and procedures. The formulary lists the drugs by disease, with sublevel of pharmacological groups for each disease. An alphabetical index was also included, making location of necessary information easier. The Formulary Committee also devised a system of asterisks to indicate at which health care level the drugs could be prescribed. This step was taken to restrict prescribing in the oblast of drug products that were very expensive, of a narrow therapeutic index, or otherwise known to be problematic. RPM supported the printing and dissemination of 5,000 copies to all practicing physicians in Zhytomyr Oblast in September 2000.

Formulary Development in Kyiv

As stated earlier, the Kyiv Municipal Health Department demonstrated an interest in implementing a formulary system in municipal hospitals relatively early in the RPM program. Although it was not selected as a demonstration site, primarily because Kyiv is the capital, RPM kept KMHD officials updated on RPM work in Zhytomyr Oblast. The administration requested

RPM assistance at least one year before work actually commenced in Kyiv. It was easier to get started in Kyiv because the administration demonstrated strong commitment to the concept of implementing formularies in all Kyiv municipal hospitals, RPM had gained hands-on experience in Zhytomyr, and the necessary materials had already been developed in Ukrainian.

In January 1999, an RPM team met with counterparts from the KMHD to discuss how RPM could support development and implementation of the formulary process in Kyiv, visited representatives of the Institute of Public Health to discuss the development of standard treatment guidelines, and evaluated the facilities that would be participating in the RPM/Ukraine rollout. The Mission and RPM decided that the next activity would be a formulary implementation workshop, to be held in spring 1999. In April, RPM visited two hospitals that had been identified as potential rollout sites in the city of Kyiv and worked with counterparts on compiling morbidity and drug consumption data in preparation for the workshop in June 1999.

In April 1999, RPM also conducted initial technical assistance visits to several additional Kyiv hospitals. Although several hospitals were identified on previous visits, follow-up meetings helped identify issues of greatest interest; the willingness to work independently to provide data needed for decision-making; and a somewhat subjective sense of where implementation of formularies would result in actual changes in selection, prescribing, or procurement activities. There were also opportunities to discuss KMHD priorities, as well as to discuss the options with the USAID Mission in Kyiv.

The KMHD and public health facilities faced a number of problems with drug selection, procurement, and use similar to those found in Zhytomyr, except that because Kyiv is the capital of Ukraine, the funding situation is considerably better. For example, in Kyiv the municipal public health budget was able to meet approximately 50 percent of the needs of inpatients, considerably higher than the 10 percent in Zhytomyr. Other facilitating factors in Kyiv included the presence of a number of academic institutions, including the Academy of Continuing Medical Education; many ACME departments maintained clinical sites at various municipal hospitals. Kyiv also provided the opportunity to collaborate with other USAID partners within the framework of the USAID Ukraine Health Strategy. Potential constraints included the fact that medical literature, although more readily available in Kyiv, was still inadequate. Also, Kyiv is the home of many national research institutes that are not necessarily well connected to practice of medicine.

Potential interventions that were suggested for Kyiv included technical assistance and/or training in the following:

- Development of policies and legislation pertaining to drug selection, procurement, and use
- Implementation of a drug formulary system for municipal inpatient and outpatient facilities
- Training in inventory control as well as management of selection and procurement at the facility level

521

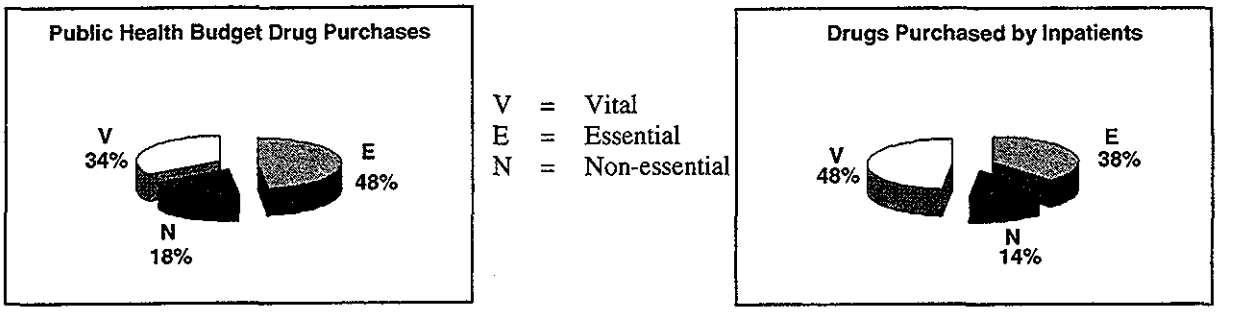
- Establishment of a pooled procurement mechanism for the city's public health facilities
- Quantification of drug needs
- Development and implementation of Drug Utilization Review programs
- Implementation of management information systems at the city and facility levels
- Development and dissemination of unbiased drug information

The areas that were jointly identified by the KMHD, the USAID/Kyiv Mission, and RPM were (1) support for development and implementation of a drug formulary system for hospitals; (2) assistance with revision or adoption of policies and regulations in support of formularies; (3) examination of the exempt prescription program, which funds drug products for specific subpopulations within Kyiv, for application of formulary concepts to this outpatient program; and (4) review of sections of the newly developed accreditation standards for Ukrainian hospitals pertaining to drug selection, procurement, storage, dispensing, and use. Information about the third and fourth areas appears in subsequent sections.

Because materials had already been developed in Ukrainian for Zhytomyr Oblast, training commenced in Kyiv for all 52 municipal hospitals in June 1999. Data from Zhytomyr and Kyiv were particularly helpful in illustrating morbidity and data consumption analyses (ABC/VEN). Approximately 200 physicians, pharmacists, and academicians attended this first training. Plans were made for future collaboration in Kyiv in four hospitals (Nos. 3, 7, 12, and 17).

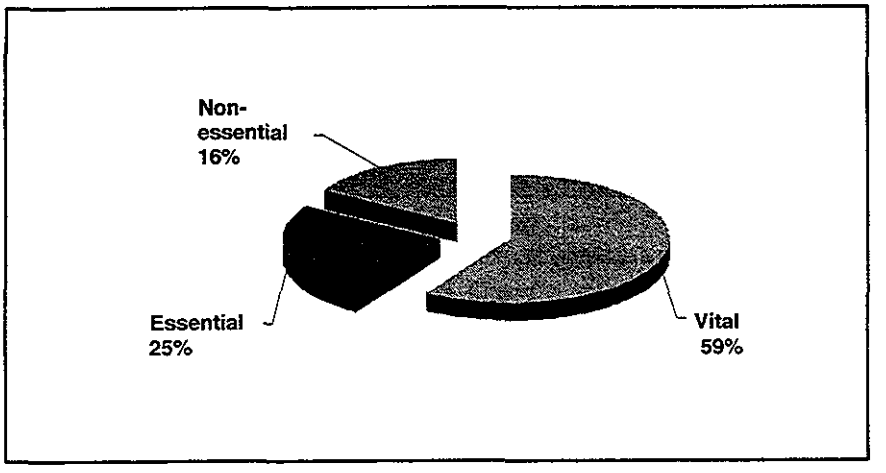
These four hospitals appointed formulary committees and began with ABC/VEN analyses of drug products consumed in their institutions. This work was facilitated by the addition to the staff of the KMHD of a physician who had demonstrated interest in pursuing formulary work and who was the primary author of the 1997 KMHD order on development and implementation of a rational drug use program in Kyiv. In addition, all four hospitals designated dedicated personnel for performing the ABC/VEN analyses and organizing the formulary committees. In one of the hospitals, the deputy chief physician quickly grasped the concepts and developed his own spreadsheets to analyze drug purchases in several ways. He also found a way to collect data on drugs that were purchased by families for inpatient use. Figures 3a and 3b show an interesting comparison between the categories of drugs purchased with hospital public health funds and those purchased by patients, with a greater percentage of vital drugs purchased by patients than those purchased by the hospital with public health funds.

Figures 3a & 3b. Drug Purchases in a Kyiv Hospital by VEN Category



For all four hospitals, the value of the drugs used in the hospital for the previous 12 months was calculated. The products accounting for 80 percent of drug expenditures (Class A) were then classified according to the VEN categories. The averaged VEN breakdown of drugs within Class A for all four hospitals is illustrated in Figure 4.

Figure 4. VEN Classification of Class A Drugs in Participating Kyiv Hospitals



The VEN classification of drugs procured individually by each of the four hospitals by value can be seen in Table 4.

Table 4. VEN Classification of Class A Drugs in Participating Kyiv Hospitals

Facility	# Drugs	Class A Drugs		
		V	E	N
		%	%	%
Hospital #3	91	73	12	15
Hospital #7	148	57	28	15
Hospital #12	138	34	48	18
Hospital #17	233	72	12	16
Average		**59**	**25**	**16**

523

Outcomes

The objective of developing the local capacity to implement formulary systems was largely achieved in both Zhytomyr Oblast and Kyiv. In Zhytomyr, personnel at the Zhytomyr Oblast Clinical Hospital, chief oblast specialists in various medical specialties, the personnel at the Zhytomyr Pharmatsiya, and some physicians at *raion* hospitals understood the objective of formulary systems and developed expertise in analyzing data already available in their institutions for this purpose.

In Zhytomyr, counterparts developed and implemented a comprehensive program that included the following:

- STGs were harmonized for all primary and secondary health institutions and were in line with the newly developed national guidelines of 1999.
- A formulary list was developed for the entire oblast that excluded 170 drug products and added 40 products, for a total of 598 drug names.
- The draft formulary was printed and distributed to 150 physicians, pharmacists, and administrators for review.
- The formulary was published and distributed to 5,000 practicing physicians in the oblast.
- The Zhytomyr Oblast Clinical Hospital staff understood how to conduct a prescribing survey and repeated it of their own accord to track their own progress.
- The Formulary Committee in Zhytomyr Oblast was still functional at end of project.

In Kyiv, the strong support of the KMHD and the chief physicians of the participating hospitals provided the appropriate impetus to focus on formulary development and implementation issues. This factor was critical, as without it, even the most motivated health professionals would not be allowed to pursue formulary implementation, or, more likely, not allowed to implement it.

All four hospitals have started selection of drugs for formularies primarily on the basis of the ABC/VEN analysis of drugs currently in use, and one hospital has compiled an initial formulary list. The proposed changes in Hospital No. 17's initial formulary list are demonstrated in Table 5. Similar changes are anticipated in the three other participating hospitals, as well as in other institutions.

Table 5. Proposed Changes in the Formulary List for Hospital No. 17

Number of Drugs on 1999 List	Number of Drugs in Draft Formulary	Number of Drugs Deleted	Number of Drugs Added
233	145	134	46

524

Formulary committees continue to function in all four hospitals in the city of Kyiv. It is anticipated that formulary committees will have been formed by December 2000 in the remaining hospitals. The KMHD expects that the four Kyiv pilot hospitals will provide technical assistance to their colleagues from other institutions.

The KMHD created a new position for the pharmacist RPM worked with, so that he would be able to work with hospitals and ambulatory-care institutions, as well as the exempt prescription program, to support implementation of formulary systems. In summer 2000, the KMHD was seeking separate funding for that position.

Increase the Understanding of Drug Management Accreditation Standards and Their Evaluation

Background

In fall 1997, the MOH had been working on development of accreditation standards for health care institutions with the assistance of consultants for over a year. According to the responsible department head, the impetus for development of the standards was to improve the quality of care for patients. An additional goal, however, may have been to reach a certain number of hospital beds by combining capacity of low-census institutions and closing some facilities. This plan was somewhat controversial, in that the Ukrainian Constitution of 1996 prohibited closing health care facilities and reduction of hospital beds. The method of financing hospitals provided a counterincentive to closing beds or embarking on cost-efficiencies, since the practical effect of these measures would be reduction of the overall budget of the hospital in future years. If, however, an institution did not meet accreditation standards, it could be allowed a provisional accreditation, with the threat of closure if the deficiencies were not addressed.

Standards Review

Before beginning its work, the Accreditation Committee became familiar with both Joint Commission on Accreditation of Health Care Organizations (JCAHO) and Canadian accreditation standards. Consultants from the Canadian accreditation body and the ZdravReform Project (Abt Associates) assisted in drafting the standards. An MOH member of the Accreditation Committee expressed concern that current evaluation methods are too subjective and requested RPM assistance in reviewing the proposed Standards for Accreditation of Ukrainian Health Care Institutions and their evaluation. RPM provided information on how JCAHO makes the process objective through the use of Interpretations of Intent and scoring parameters.

The RPM team reviewed with counterparts all draft standards related to medication selection, procurement, dispensing, and use. RPM provided recommendations for revisions and suggested methods for applying the standards in an objective manner as well as scoring them appropriately. Based on reviews of various records and observations in Zhytomyr hospitals, RPM illustrated,

525

through examples, how documentation currently available in Ukrainian hospitals may be used to support an objective evaluation process.

Outcomes

This activity provided an opportunity for collaboration between RPM and the ZdravReform Project. Because of RPM staff familiarity with the accreditation process and the familiarity with hospital records, Ukrainian counterparts understood how records already available in the hospitals can serve as objective documentation for drug management issues. All of the changes recommended by RPM have been incorporated into the proposed standards.

Develop Local Capacity to Critically Evaluate the Exempt Prescription Program

Background

In addition to application of cost-effective drug product selection and rational use in the inpatient setting, in response to health officials' interest, RPM began working with counterparts to apply these concepts to the publicly funded outpatient (exempt) prescription program. These steps were anticipated to allow counterparts to develop the necessary processes to transition from the current system to a mandatory health insurance model. Such steps would also support efforts by collaborating organizations in the area of primary health care.

The purpose of the report The Exempt Prescription Program in Ukraine: A Preliminary Assessment (see Annex 1) was to describe the current system of entitlements to drug benefits for outpatients, to describe preliminary data on drug consumption patterns within this program in 1999, and to suggest the next steps in a more detailed study of this system, including further data collection and analysis needs, and possible interventions to improve cost-effective drug selection and use for ambulatory patients. As the scope of activities and time to accomplish them was rather short, this report should be considered an initial descriptive report, rather than a conclusive one.

Review

Information about the exempt prescription program in Ukraine initially appeared in the Assessment of the Pharmaceutical Sector in Ukraine, December 1993. However, since that time, various changes have taken place, including a revision of the categories of patients entitled to receive outpatient prescription drug products at reduced or no cost, and the development and several revisions of the list of drug products that exempt patients are entitled to receive.

In September 1996, the Cabinet of Ministers of Ukraine passed Resolution no. 1071, which specified a list of drugs, domestic and imported, that could be purchased by institutions that are partly or fully funded through the budget. Initially, this list contained approximately 80 products, and it was routinely ignored. In September 1997, the list was revised to include approximately

350 products (200 domestic and 150 foreign). The list was increased again in January 1999 to approximately 800 drug products. The city of Kyiv, unlike many other cities in Ukraine, has additional financial resources as well as a special status as the capital of Ukraine. Therefore, a special committee reviews requests for additions to the list. In January 2000, the list of products that can be used by ambulatory patients in the exempt prescription program and city hospitals grew to approximately 1,200.

In March 2000, an RPM team visited the city of Kyiv and discussed the current program with officials from the Kyiv Municipal Health Department. The team visited several primary health care sites where administrators and physicians described the mechanics of the exempt prescription program, showed examples of documents, and described challenges in meeting patient needs in the current system. Documents obtained include the order that specifies procedures for the exempt prescription program in the city of Kyiv, the official list of patient populations that are eligible for prescription drug benefits, the list of diseases that are eligible for reduced patient fees, billing and summary documents, and the current and past list of reimbursable drugs.

The RPM team examined provisions of the exempt prescription program including the following:

- Eligibility
- Administration
- Physician prescribing (and its monitoring)
- Availability of data

The Kyiv Pharmatsiya, which owns all the pharmacies in the city of Kyiv that participate in the exempt prescription program, provided a list of drug products that were dispensed and billed to the Pharmatsiya by all pharmacies in 1999 for exempt patients. The physician designated by the KMHD to work with RPM on adapting the formulary system in the primary health care setting conducted an ABC/VEN analysis on the data with the assistance of RPM. Following the first analysis, the KMHD physician conducted an independent follow up ABC/VEN analysis on one month's worth of data in one Kyiv *raion*. The results of both are discussed below.

During 1999, according to a listing provided by the Kyiv Municipal Pharmatsiya, Kyiv pharmacies provided 278 unique single and combination drug products in the exempt prescription program. This number constitutes only 32 percent of the products on the official list in 1999.

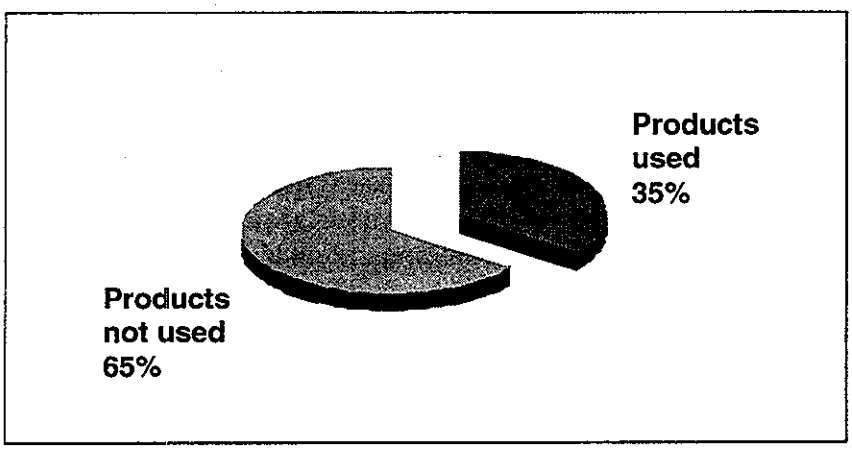
Four Kyiv hospitals also provided data on drugs purchased through public health budget funds: Hospitals No. 17, No. 12, No. 7, and No. 3. The names of the drugs they purchased were compiled into a single list, which contained 291 products. Of these, 241were on the official list; this number accounts for 27.5 percent of official list items. The Kyiv Pharmatsiya also provided a list of 120 drugs that Kyiv hospitals most often ordered from the Pharmatsiya; all 120 items appeared on the joint hospital list.

There were 50 products (17% of the 291 products) that did not appear on the official MOH or KMHD lists. There was no official explanation of this fact, although there are several possible

reasons. It is perfectly legal, for example, for hospitals to purchase products not on the KMHD or MOH lists, if they use non–public health budgetary funds for such purchases. It is also possible that the hospitals do not pay strict attention to the list, and purchase those products that they deem appropriate.

When all of the drug names from the exempt (ambulatory) program were combined with those from the hospitals, the total number of discrete products was 310. Out of 876 items on the official list, that accounted for 35 percent of the official list products, as seen in Figure 5.

Figure 5. Percentage of Official Drug Products Used in Kyiv Hospitals and Pharmacies



In a separate analysis, conducted by the KMHD counterpart in one *raion* (Zaliznichij) on data from the first quarter of 2000, only 130 of the 876 products were used. Given that this was a very short period, it is entirely likely that the list would grow if data were collected for a year, accounting for seasonal variation and other factors.

During the month of January 2000, Kyiv pharmacies dispensed 179 drug products to exempt patients. RPM counterparts performed an ABC/VEN analysis on this list. Group A comprised 48 drugs (80% of all expenditures), of which 23 were vital drugs (56% of class A expenditures), 16 were essential drugs, and 9 were considered non-essential. Non-essential drugs were responsible for 22 percent of class A expenditures. Table 6 lists the percentage of drugs that were purchased or dispensed in Kyiv health care institutions.

Table 6. Percentage of Official Drugs Used in Kyiv Health Care Institutions

Drug Products	Number of Drug Names	Percentage of Total
Total number on MOH list	876	100.00
Dispensed by municipal pharmacies (1999)	278	31.74
Purchased by Hospitals No. 17, 12, 7, and 3	241	27.51
Dispensed by polyclinic pharmacy Zaliznichij raion (first quarter 2000)	130	14.84
Dispensed by Kyiv pharmacies (January 2000)	179	20.43
Total number of products dispensed	310	35.39

When analyzing the products on the Resolution no. 1071 "official" list, RPM and counterparts made several observations:

- Many products are available from multiple sources and each of them appears separately on the list. For example, diclofenac was dispensed as diclofenac, Ortofen, and Dicloran.

- The official list contains only the drug name. Various drug dosage forms are dispensed with little guidance as to what may be acceptable. For example, the official list includes ascorbic acid; ascorbic acid was dispensed as injections, tablets, chewable tablets, and coated tablets.

- In some cases, pharmacies dispensed therapeutic substitutions for listed products, without clear guidance on how to do so.

Overall, the RPM team and KMHD counterparts found many opportunities for shortening the list of products dispensed to patients entitled to exempt prescription benefits. It also became clear that additional data are necessary to get a complete picture of the exempt prescription situation and to provide clear recommendations that would guide counterparts toward a system that could be incorporated as part of a mandatory social insurance program or other alternative financing program.

The RPM team made recommendations in several areas, including

- Coverage limitations
- Quantity controls
- Reimbursement
- Drug utilization review
- Purchasing
- Eligibility
- Auditing
- Additional data needs

In addition to the data on drug products, other administrative functions do not favor rational use of drug products, or accountability for drug products prescribed or dispensed. These include

- Patient-specific data are not available at a municipal level. Some patient-specific data are available at the district or polyclinic level, but such a system does not allow the development of any aggregate data, nor does it allow for auditing, checking eligibility, or DUR.

- There do not appear to be hard and fast rules about what drugs and dosage forms are appropriate for the covered patient. For example, it is possible for an 80-year-old veteran to obtain pediatric dosage forms, which could be used by other family members. There are no controls on such use.

- The current incentive is to dispense the most expensive not the least expensive product.

One of the commonsense recommendations to implement might be in the area of drugs covered, an area directly related to formulary development, in a stepwise approach. The current data suggest three distinct levels of utilization. Products rarely used (65% of those products in the list) should be relatively easy to eliminate from the list of approved products and should be the initial focus. The second level is products that have questionable safety and efficacy profiles. Although these may be harder to remove, if this effort were paired with education, such action should help pare down the list and eventually eliminate these products all together. The third level of products should make up the core of the desired formulary.

Increase in the use of technology should afford a greater opportunity to link prescription data to physician prescribing habits. Although standard treatment guidelines are generally understood and accepted, it is unclear just how they are currently being applied. RPM recommended that the KMHD consider implementing systems to accurately track not only polyclinic prescribing but also specific physician prescribing. Additional data in this regard would help to define future educational efforts and focus attention on those prescribing habits in greatest need of change.

Outcome

This objective was partially met. The ambulatory care department head of the KMHD was very interested in pursuing RPM recommendations. Unfortunately, he was taken ill and had to recuperate. It remains to be seen if this objective is pursued further by his department or if it will await his return.

Regardless of this outcome, RPM has developed a much greater understanding of how to approach exempt prescription program analysis. The report from this visit (see Annex 1) provides much food for thought, as well as recommendations for a systematic approach to collecting and analyzing data on outpatient drug benefits and how formularies can support rational drug use.

Develop Linkages among Ukrainian Institutions and Other Organizations

Background

One of the observations from the 1993 Pharmaceutical Sector Assessment of Ukraine was that after the fall of the Soviet Union, many governmental and private institutions did not necessarily communicate with and among each other on a regular basis. That situation remained true in 1997, when RPM began the RPM Ukraine Country Program.

Collaborations

As stated above, from the beginning stages of the project, RPM worked in close cooperation with key decision-makers to ensure that project goals and technical areas were well understood and

accepted. These included USAID, the MOH, Zhytomyr Oblast Health Administration, the Kyiv Municipal Health Department, the administration of the city of Kyiv, and others.

Collaborations occurred on several levels throughout the program:

- Ukrainian governmental institutions and administrative units at national, regional, and district level
- Hospitals among themselves
- Nongovernmental institutions in Ukraine and abroad
- Donor organizations

RPM collaborated with the Ministry of Health Committee on Adverse Drug Reactions, the Strazheska Institute of Cardiology, the National Institute for Continuing Medical Education, and the Institute of Folk Medicine in conducting a Clinical Pharmacology Course in May 1998.

During the September/October 1997 technical assistance visit, the RPM team collaborated with the ZdravReform Project in order to review and make recommendations for changes in the Proposed Standards for Accreditation of Ukrainian Health Care Institutions.

RPM participated in the USAID Primary Health Care Initiative Health Partner meetings in Kyiv, Ukraine, in August and October 1998, and in Seattle, Washington, in November 1998. The purpose of these meetings was to explore possible collaboration, particularly in light of the new Ukraine Health Strategy. Participants in these meetings included the following organizations:

- USAID/Kyiv
- USAID/Washington
- Abt Associates
- Alliance for International Health (AIHA)
- Centers for Disease Control and Prevention (CDC)
- The Futures Group/POLICY
- The Futures Group/SOMARC
- Family Health International (FHI)
- Health Resources and Services Administration (HRSA), Department of Health and Human Services
- Johns Hopkins University (JHU)/Population Communication Services (PCS)
- JHU/Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO)/Program for International Education and Training in Reproductive Health
- MSCI
- Program for Appropriate Technology in Health (PATH)
- Rational Pharmaceutical Management
- University of South Alabama

Other organizations taking part in the October 1998 Partners Workshop included

- Ministry of Health of Ukraine
- Kyiv Health Administration
- National Institute of Public Health
- National Medical University of Ukraine
- UN Development Program
- Canadian-Ukraine Partners Program
- World Health Organization (WHO)
- World Bank
- Soros Foundation
- Ukraine Family Planning Organization
- Family Planning Center
- Women's Health and Family Planning
- Women's Newly Independent States Consortium
- Counterpart International (CHAP)

As a result of the November 1998 Health Partner meeting in Seattle, RPM decided to consider partner objectives when selecting disease states for study. RPM may assist other partners when drug management issues arise. These organizations will share information regarding in-country contacts, as well as training and technical assistance schedules to facilitate coordination of efforts.

Outcome

This objective was achieved. The discussion of formularies provided a forum for discussion among physicians from Zhytomyr Oblast and the Ukrainian Institute of Public Health, the MOH, the Academy of Continuing Medical Education, the National Medical University, and others. Although evidence is anecdotal, RPM counterparts readily volunteered that there had not been opportunities previously for them to collaborate or share ideas on a regular basis.

A similar sentiment was verbalized by physician counterparts and participants of workshops. RPM-sponsored training and workshops provided an avenue for colleagues to discuss technical issues in a nonthreatening environment and to explore new concepts on neutral ground. Most participants found this interaction facilitated a greater understanding of rational drug use concepts and provided a reality check for how new concepts could be adapted in Ukraine.

The emphasis the Kyiv Mission placed on collaboration provided an incentive for USAID partners to collaborate. Although opportunities to collaborate did not always present themselves, RPM made a concerted effort to discuss possible collaboration with other partners and to share information, documents, and experiences with other contractors. This activity was particularly important for RPM because the program did not have a resident office. The Kyiv Program for Appropriate Technology in Health office, in particular, was very helpful in providing logistical support, and RPM and PATH continued to look for opportunities to collaborate throughout the life of the project. Toward the end of the project, RPM was also able to coordinate efforts with the Kyiv Alliance for International Health office. RPM and AIHA traded documents, shared information about upcoming events, and sought input about how RPM activities could support the primary health care partnerships.

The administrative personnel in both Zhytomyr and Kyiv understood from the beginning that applying methods of cost-effective drug selection and rational drug use were paramount, given their severe lack of funding. They both provided consistent support for formulary activities, and provided the policy and regulatory backing that was necessary to implement formulary systems. Both have institutionalized formulary implementation and have officially included rational pharmaceutical management concepts in their plans of providing pharmaceutical care. Gaining administrative support is one of the core conditions for successful formulary system implementation.

Hospital and primary health care personnel recognized the need for establishing oblast or hospital committees responsible for creating and maintaining lists of drugs approved for procurement and use, as evidenced at the Strategies to Improve Drug Selection and Use workshop in July 2000. Participants produced 17 action plans for specific facilities for implementation of formularies and created 11 sets of suggested indicators for tracking rational drug use for ambulatory patients. These suggestions were submitted to Kyiv Municipal Health Department to use in revising the order for development and implementation of a program for rational selection and use of pharmaceuticals in the city of Kyiv.

Formulary committees were established in four Kyiv hospitals, written policies and procedures were approved, and the first steps in formulary development were made. This activity suggests that the committees will continue their role in hospital drug management after the end of the project. In addition, the Kyiv Municipal Health Department intended to implement formularies in all hospitals by the end of 2001. This intention is rather ambitious, but could be accomplished in time with some additional technical activities.

The Kyiv Municipal Health Department, which oversees both institutional and ambulatory care, decided to create a new position within its department to implement drug management activities in ambulatory settings. RPM has trained the physician who will fill this position to perform analyses of drug consumption and morbidity patterns as well as to use pharmaceutical indicators in pharmaceutical sector assessment to monitor progress in implementation of formularies and in rational drug use.

The Zhytomyr Oblast Formulary has been developed, and the manual has been published and provided free of charge to each practitioner within the oblast. After the formulary is distributed to all physicians, it will be a strong support for institutionalizing rational drug selection and use.

The Medical Academy of Continuing Education has included main RPM concepts in its curricula and in the certification tests for pharmacists. The academy stated that it would continue to promote the formulary system concept in postgraduate training after the end of the project.

The Ukrainian medical publishing agency Morion expressed interest in publishing RPM's *Manual for the Development and Maintenance of Hospital Drug Formularies* in the weekly newspaper *Apteka*. This publication will familiarize health professionals of other Ukrainian regions with the formulary concept.

Although these signs indicate that work begun under RPM will continue, funding continued participation, monitoring, and revising STGs or formularies may be difficult in Zhytomyr Oblast. The situation may be better in Kyiv, but limited activities in support of these efforts, particularly innovative ways of providing current clinical pharmacology information, would help ensure that they continue.

Activities Not Completed

It was anticipated that Zhytomyr Oblast would repeat the collection of prescribing data to evaluate changes that may have resulted from the introduction of the formulary and standard treatment guidelines. However, significant changes in personnel of the Zhytomyr Oblast Health Administration put RPM activities in Zhytomyr behind schedule. Therefore, a repeat assessment of prescribing patterns in those institutions where the baseline survey was taken was not possible before the end of the project.

Parallel with formulary development in Zhytomyr Oblast, ZOHA revised existing STGs from the primary health care level to tertiary level at the oblast clinical hospital. This activity was anticipated to result in publishing an oblast formulary with STGs for common conditions. Shortly after the Zhytomyr Oblast guidelines were completed, the Ukrainian Ministry of Health published revised national standard treatment guidelines in 1999. Although ZOHA harmonized Zhytomyr guidelines with the national ones, it decided against publishing them, since national guidelines were approved by the MOH for use Ukraine-wide.

The RPM Ukraine activities that RPM planned as part of the Primary Heath Care Initiative were based on the understanding that site selection for partnership sites would occur in September/October 1998. RPM took an active role in three meetings on how the health partners (those agencies funded by USAID to work in various sectors of health care in Ukraine) might collaborate. The PATH office in Kyiv provided support to RPM, and opportunities for collaboration with the AIHA project were explored. Unfortunately, primary health care site selection was delayed. RPM, jointly with USAID/Kyiv and USAID/Washington, decided to proceed with planned activities, rather than wait for site selection.

Likely Needs at End of Project

Given a limited and still diminishing health and drug budget that does not meet the needs of patients, the following ways may be employed to further deal with an imbalance of available funds and needs:

- Justify the need for an increase in the drug budget in the hope of getting approval for a budget increase

- Implement drug management strategies to optimize the budget (get the most out of the available funds)

- Find mechanisms and opportunities for cost recovery

In the short term, it is unlikely that there will be an opportunity to increase the budget for drugs, or health care in general, in Ukraine. Therefore, the two remaining options—optimizing the current budget and finding mechanisms for cost recovery—are the most likely ways of meeting the needs of the patients.

RPM initiated the implementation of a number of drug management strategies in Ukraine, which gained acceptance of local administrations and integrated successfully in local health care programs. It is anticipated that primary health care activities will gain in importance, and will remain a priority, because approximately 80 percent of patients seek care in ambulatory facilities.

Below are listed activities that are an extension of completed activities, those that would support changes initiated under RPM, and several that would build on RPM accomplishments.

Hospitals

Study potential incentives to change prescribing habits in the context of nearly nonexistent pharmaceutical budgets in health care institutions. Currently, on paper, citizens are entitled to free health care in hospitals. In fact, nearly 90 percent of drug use in hospitals is funded out-of-pocket. This situation undermines the enforcement of formularies or STGs, as physicians perceive, correctly, that their prescribing of nonbudgetary pharmaceuticals is not scrutinized.

City of Kyiv

- Support implementation of formularies in all hospitals of Kyiv according to the Kyiv Municipal Health Department plan; develop written policies and procedures. Disseminate the experience gained by four enrolled Kyiv hospitals.

- Provide technical assistance to develop workable mechanisms to monitor and enforce physician compliance with written formulary policies. Processes must also include continuing education to support changes in prescribing habits.

- In the reality of diminishing drug budgets and increasing use by patients of their own drugs (approximately 90% by value), provide technical assistance to develop mechanisms to track patient purchases, and establish policies to encourage the use of formulary drugs by the patients.

- Hospitals should take the next step in applying their formularies to drug procurement. Provide technical assistance to implement assessments of drug procurement and use in hospital sites to track changes in expenditures and outcomes, including the following:

- ABC/VEN analyses
- Indicator-based assessments proposed at the Strategies workshop
- DUR programs, primarily in facilities with clinical departments of medical academic institutions

- Introduction of drug use review concepts at the hospital level could be useful. After formulary systems are introduced, DUR provides the feedback to determine whether the products included in the formulary are being prescribed appropriately and whether they should continue to be included.

- Provide technical assistance to implement an adverse drug reaction (ADR) monitoring system to allow hospitals to more critically approach the drug selection process, reduce morbidity due to drug misadventures, and reduce expenditures on treating ADRs.

Zhytomyr Oblast

- Provide technical assistance to Zhytomyr counterparts to revise the existing formulary list in a year. Drugs of unproven efficacy should be deleted from the formulary as quickly as possible. Such drugs are in common use, in some cases, because of outdated treatment practices. Replacing them with more cost-effective products may require education of the physicians on updated concepts in clinical pharmacology and standard treatment practices. Throughout the drug formulary process, the standards for inclusion or deletion of a product must be explicitly defined; appropriate evidence should include well-documented clinical trials. Broader use of drug-product restrictions in the formulary should be considered, if appropriate, in order to improve clinical outcomes.

- Introduce ongoing monitoring of drug-related morbidity and adverse drug reactions. Implement an ADR monitoring system to allow hospitals to more critically approach the drug selection process, and reduce expenditures on treating ADR.

- Although counterparts will be collecting simple indicators of adherence to new standard treatment guidelines, a repeat of the prescribing practices assessment approximately one year after introduction would be desirable to assess physician compliance with the formulary and STGs, as well as actual impact on health outcomes.

Primary Health Care

- Conduct training and provide technical assistance to develop and implement drug management systems in primary health care, including a formulary list, regardless of whether products are provided by an in-house pharmacy or by contracting.

- Provide technical assistance and facilitate linkages with the Kyiv Municipal Health Department and/or Zhytomyr to the UIPH to develop primary health care STGs and publish a handbook for practitioners. Such a handbook could include common diagnoses; treatments of

first, second, or third choice and the basis for their inclusion in the handbook; and a formulary list of covered products. As the system of primary health care practitioners is implemented, collaboration with other institutions (donors or contractors) may be necessary to track drug expenditures by patient and/or condition to provide data on effectiveness of treatment approaches.

- Develop a management information system for tracking prescribing, patient and costing information, and outcomes for the exempt prescription program. The exempt prescription program can be used as a model for a prescription benefit for a mandatory national health insurance model.

- Develop a set of pharmaceutical indicators for ambulatory facilities to track changes in expenditures and outcomes. Incorporate the indicator data collection process into the existing system of drug prescribing and use. Use the indicators to initiate outcome and performance monitoring of drug procurement.

- Provide technical assistance to the KMHD to reduce the formulary list for exempt prescription patients to a reasonable size. A more limited list of drug products, which would be consistently available to patients, would result in better treatment outcomes, lower patient out-of-pocket expenses, and reallocation of city expenditures for drug products so that a greater number of patients would be served. When data are available, the program developed in Kyiv could be further discussed with the Ministry of Health for possible revisions of the national list and rollout into other areas.

- Support KMHD efforts to define clearly the issues of generic and therapeutic substitutions in the exempt prescription program, as well as in the formulary system.

- Improve drug procurement techniques in the KMHD with the Kyiv Municipal Pharmatsiya. Implement transparent, competitive tender practices to optimize the quality and cost-effectiveness of procurement primarily in procuring pharmaceuticals for targeted programs.

Training and Information

- Continue interaction with other organizations to strengthen rational drug management concepts, support development of materials, and integrate concepts into professional preservice and continuing education curricula. Possible counterparts include the Ukrainian Academy of Continuing Education and the medical and pharmacy schools of the Ukrainian National Medical University.

- Develop a regional course in Drug Management in Primary Health Care annually for the NIS and explore options for other donor support of participants in the course.

- Develop systems to facilitate and extend formulary and rational drug use concepts beyond the small circle of physician administrators. Management principles that support rational drug use must be taught at all levels of health care, including administrators, physicians of all

specialties, family (general) practitioners, pharmacists, and nurses. Training in quantification and procurement of pharmaceuticals for those who are responsible, as well as in rational drug selection and use for physicians, is especially important.

- Enable formulary committees to give more attention to educating medical staff about formulary system issues. Currently, formulary committees do not have the capacity to design and conduct on-site training of staff and need technical assistance. It is necessary to evaluate existing resources and options to get assistance from academic institutions and international projects.

- Establish drug information centers to support rational drug use. Assistance is needed in obtaining equipment and sources of unbiased medical information (drug and therapeutic reference manuals, computer databases, access to the Internet), and in training personnel in drug information development and use.

Other

- Conduct an assessment of the current mechanisms in place for funding pharmaceuticals in the hospital and ambulatory-care settings.

- Collaborate with other partners and provide technical assistance in drug management issues, including procurement of pharmaceuticals for targeted programs.

- Support the administrative measures that are needed to provide the regulatory and legal basis for rational drug management activities.

Lessons Learned

In Ukraine, drug selection is more tightly linked to STGs because limited budgetary resources do not allow purchases of a large number of products. Consequently, in Ukraine reduction of stockpiles of unnecessary or unsafe products is not generally the problem. Safety, cost-effectiveness, and availability of products in the pharmaceutical market (to the institutions as well as accessibility by cost to the patient) should be the primary criteria for selection.

Procurement in the NIS is still generally problematic. A fragmented wholesale market, inability to plan purchases to take advantage of quantity cost-efficiencies, lack of transparency in the process, totally inadequate funding of public institutions, as well as outdated treatment protocols and lack of access to current objective drug information contribute to ineffective procurement mechanisms. The fact that patients purchase such a large percentage of drug products used in the hospital can skew the analyses performed on drug consumption data, leading to questionable drug procurement decisions.

Drug use is theoretically monitored in hospitals and ambulatory clinics (polyclinics) by the deputy chief physician and a Commission on Rational Drug Use. Often, however, their comments refer to procedural/record-keeping functions rather than clinical decisions. The commission itself is not particularly active; most of the work is generally done by one individual. The concept and implementation of DUR is still gaining ground, even though the physicians intuitively understand the need for this process. There are still many holdovers in traditional, irrational prescribing practices that have little to do with effectiveness. In many cases, they can be traced back to the Soviet era, when drug choices were limited to mainly domestic, often outdated products. Treatment schemes, familiar to the prescribers, were built around these drugs. Changing prescribing habits requires time and effort.

RPM took an active part in reviewing and recommending changes and additions to the Accreditation Standards for Health Care Institutions in Ukraine. RPM also provided technical assistance to officials in Kyiv and Zhytomyr when they were drafting orders or regulations to support the use of formulary systems and other means of encouraging rational drug use. RPM also provided extensive documents to the Commission on Maternal and Child Health of the Parliament of Ukraine. Officials were more than happy to accept model documents and review policies, regulations, and procedures from other countries. However, the fact that most of the material is written in English was a limiting factor in its usefulness. Although a substantial number of people speak and read English, many of the decision-makers do not.

Although a lot of information is currently available regarding drug consumption, morbidity patterns, and drug use, it is unclear that hospital administrators know how to use this information for decision-making. It was difficult to evaluate prescribing practices, because a large but undefined portion of the prescribing and drug acquisition occurs outside of the normal hospital distribution system. RPM made efforts to compile and analyze the lists of drugs purchased by inpatients for their use in the hospitals according to special notes ("patient provided his/her own") in the charts. It is unknown, however, if these notations are made routinely.

A combination of workshops to introduce concepts and TA at individual institutions has proven effective for implementation of learned material. Training of trainers and/or opinion leaders helps to create credibility among the local health professionals because these individuals can describe their progress, the problems they encountered, and how to overcome challenges. When Ukrainian counterparts decided that they needed a clinical pharmacologist on staff, RPM support of the concept and assistance in helping clarify that new role meant that their support was validated. The use of Ukrainian-language materials was very well received, although virtually everyone speaks and reads Russian. This fact does not mean that the use of Russian language materials is acceptable; the MOH of Ukraine has specifically stated that it wishes training and materials used to be in the Ukrainian language. The language issue has been a barrier to participation in international meetings. Whereas RPM could have supported participants in several international meetings, such as the Drug Management in Primary Health Care workshop in Amsterdam, finding qualified candidates who spoke sufficiently good English to participate was problematic.

Financing is often a stumbling block in getting started. Administrators were so focused on when they would receive the next tranche of funds, that they gave up on short-term or medium-term

planning. Those who could get beyond this block have been able to apply various concepts in order to achieve incremental improvements. Staff physicians focused on how severe budgetary constraints have forced health facilities to purchase very limited number of drugs, which they considered the most important issue. In this situation, the implementation of drug management systems seemed academic to many physicians.

Having adequate current objective drug information is a necessary prerequisite to making rational decisions regarding drug selection, procurement, and use. Although there has been some increase in the availability of texts, handbooks, and references on issues related to pharmaceuticals, purchases of these books are totally inadequate to meet current needs. The absence of relatively low-cost access to the Internet in most of the hospitals and health care administration offices has made access to the wealth of information on the Internet relatively unavailable. When the program started in Zhytomyr, RPM and counterparts felt that the absence of a medical school in Zhytomyr Oblast would not pose a significant problem. However, this lack did turn out to be a problem, given the distance traveled to the nearest university and the communication cost; therefore, little effort was expended to obtain objective drug information independently.

Relative lack of access to the Internet also made continuous communication and feedback from the Ukrainian counterparts between RPM visits rather difficult. In many cases, it delayed receiving necessary information, making decisions, and conducting certain activities. This situation differs markedly from the situation in Russia, where computers were provided by the project, and drug information centers with Internet access were established in RPM sites.

Zhytomyr Oblast was a good initial choice for RPM activities because of administrative support, but several key staff and administrative changes within the Zhytomyr Oblast Health Administration and the major hospitals made it difficult to proceed at the intended pace. This problem points out the unintended effect that reliance on changes in a small group of people, rather than on systemic change, may have, especially when that small group is no longer available, is not in favor with the current administration, or is subject to other political pressures. RPM/Ukraine had the advantage of having RPM-trained consultants available in Russia and could facilitate a "north-to-north" exchange of information. However, the program still felt the lack of a person in-country to follow up on activities, detect potential challenges, and resolve them more quickly, particularly when the change in personnel occurred in Zhytomyr Oblast. Having a person in place also would have enhanced the facilitation of collaborative working relationships among Ukrainian institutions and with other USAID partner organizations.

Annex 1. RPM Ukraine Country Program List of Activities 1993–2000

Pharmaceutical Sector Surveys

1. Assessment November 1993
2. Ukraine Reconnaissance Trip Report, November 1996

Formulary System Implementation

- September 1997 (trip report)
  Result: Identified possibilities for data collection, delivered United States Pharmacopeia Dispensing Information (Russian), identified most likely sites as the Oblast Clinical Hospital and the Children's Hospital. Met with department chiefs at the Oblast Clinical Hospital. Made arrangements for a Formulary Development workshop to be held in December 1997.

- December 1997 (trip report, article/interview)
  Result: Oblast Clinical Hospital and Children's Hospital presented their ABC/VEN analyses, which they completed following September trip. These were very good for focusing the *raion* hospitals on the process and built support for continuing in the oblast. Oblast hospital and children's hospital issued orders forming formulary committees. Children's hospital has formulary list, due primarily to interest of strong nachmed.

- May 1998 (proceedings)
  Result: Clinical Pharmacology Workshop. All *raion* hospitals are in some stage of ABC/VEN analysis. RPM provided TA to work through problems. Participants identified need to harmonize STGs, so that treatment can be more predictable and standardized, with less antimicrobial resistance. The oblast administration accepted this need as a mandate to revise STGs for the top 50 conditions and selected three common conditions for study. Met with Kyiv Municipal Health Department.

- August 1998 (trip report, morbidity data in Excel, tables)
  Result: Found that data are available on patient hospital encounters. Oblast acting counterpart refused to have a team of data collectors gather the information. Instead, RPM will train oblast clinical hospital deputy chief physician in methodology, provide the data collection forms, and establish a date by which the data should be collected. Visited various facilities and found creative mechanisms for supplementing the hospital budget to provide for basic necessities. The budgetary situation for drugs has deteriorated.

- September/October 1998 (official proceedings, OMD presentation, Kyiv plan for collaboration)
  USAID Partners meeting. Introduction of the new USAID Ukraine Health Strategy, focusing on delivery of primary health care services, and discussion of how partners can integrate their work into the new strategy. Dissemination of information on RPM/Ukraine work. Plans for

another get together in November in Seattle, Washington (PATH). Met with Kyiv Municipal Health Department to discuss possible collaboration.

- January 1999
  Result: Site visits to Kyiv hospitals to select potential rollout sites for RPM.

- April 1999 (ABC/VEN report, trip report)
  Visit to Kyiv hospitals to evaluate morbidity and drug consumption patterns. The report on ABC/VEN analysis would be presented to the hospital when completed and used as an example for other institutions.

- June 1999 (proceedings, briefing)
  Result: This rollout activity was the first in Kyiv. The original counterpart was replaced by another higher-ranking official. The administration demonstrated strong commitment to the concept of implementing formularies in all Kyiv municipal hospitals. Data from Zhytomyr and Kyiv were particularly helpful in illustrating morbidity and data consumption analyses (ABC/VEN). Plans were made for future collaboration in Kyiv. In Zhytomyr, all of the hospitals had done the ABC/VEN analysis, but due to lack of objective information and knowledgeable personnel at *raion* level, the administration decided to focus its attention on revised STGs and an oblast formulary. Discussion with the UIPH on review of the Zhytomyr Oblast revised STGs in light of the MOH/UIPH's new STGs.

- October 1999 (official proceedings, briefing)
  USAID Partners meeting. Discussion with other cooperating agencies and the MOH on the RPM program. Further discussion with the UIPH and the Institute of Cardiology.

- November 1999 (trip report, article)
  Result: TA visit to Kyiv hospitals to work on implementation of the formulary, committee organizations, orders establishing the committee and the process. Article published in *Apteka* in December 1999 specifically about the process and benefits of formularies. *Apteka*'s readership is all pharmacies and hospitals in the country. Obtained final data in electronic form from Zhytomyr Oblast after much difficulty.

- March 2000 (trip report, STG draft, draft formulary, exempt prescription program report, official part of the plan for the city of Kyiv for the coming year at the plenary session for all hospitals)
  Result: Visited several primary health care sites to review drug management practices and collect data on drugs used in the exempt prescription program. There appear to be several steps that are relatively easy to implement (politically and technically) that would improve access to drugs for exempt patients within the current budget. There is a particular need among institutions for new information and treatment guidelines/protocols. In Zhytomyr, RPM obtained copies of the revised STGs and held a workshop on implementation of the new STGs. Distributed 150 copies of the draft oblast formulary for review and comment.

- April 2000 (Man and Drugs, trip report, revised draft formulary)
  Result: RPM counterparts participated in sessions devoted to formularies (2/3 of the

562

sessions). The clinical information and experience were particularly helpful in convincing Zhytomyr Oblast to exclude preparations that are of doubtful efficacy and safety from the final list. RPM obtained the list of drugs dispensed in the Kyiv exempt prescription program from the Kyiv Pharmatsiya for analysis.

- April 2000 (Pharmacoeconomics short course)
  Result: RPM supported one candidate for the course in South Africa, who would present the information at the primary health care conference and share the information with academic institutions.

- July 2000 (proceedings, final briefing, Zhytomyr Oblast repeat prescribing assessment)
  Result: The city of Kyiv wanted to involve participants from hospitals, clinics, and specialty institutions (pediatrics, OB/GYN). This time, Ukrainian presenters took a very active role in sharing their experiences with formulary development. RPM sites shared their data, and the prescribing data in Zhytomyr was also shared with participants to illustrate the use of indicators. Zhytomyr counterparts demonstrated that they had learned how to collect prescribing information by having conducted their own independent analysis of prescribing for pneumonia cases. Counterparts from Hospital No. 12 demonstrated a capacity for analysis of drug consumption patterns and showed how ABC/VEN data could be used as an indicator for appropriate drug procurement by the hospital. RPM conducted the final debriefing for the Mission.

Accreditation

September 1997, December 1997

Result: Reviewed accreditation standards and suggested changes and additions to correspond to appropriate drug management activities in the hospitals
Recommended criteria for objective evaluation of those standards
All recommendations were accepted and are now part of the national standards

Exempt Prescription Program

March 2000, April 2000 (Man and Drugs)

- Preliminary analysis of covered population groups
- List of drugs in program
- Sample data from pharmacies
- List of drugs dispensed through Pharmatsiya
- ABC/VEN analysis of drugs; only 35 percent of the approximately 800 names were used in 1999 (see charts for ABC/VEN information)

Linkages with Other Organizations/Dissemination

- Yalta May 1997
  - Result: Zhytomyr expressed an interest in working with RPM.
  - Result: City of Kyiv obtained RPM materials and started developing its own RPM program.

- October 1998, October 1999, November 1999 (Seattle), March 2000, July 2000
  - Result: PATH, with an in-country office, assisted with the logistics of the June 1999 Formulary Implementation Workshop.
  - Discussions with USAID and the new Alliance for International Health partnership program identified drug management areas that will need to be addressed for effective drug delivery at primary health care sites.
  - Articles in Zhytomyr Oblast publication *Health* in January 1998; articles in *Apteka* in December 1999 and July 2000; television interview in July 2000.

Annex 2. Materials Produced and Provided

List of Documents Produced

1. "Ministry of Health of Ukraine Rational Pharmaceutical Management Project, Ukraine Pharmaceutical Sector Assessment" (Draft), Rational Pharmaceutical Management Project, January 1994.
2. "Ukraine Reconnaissance Trip Report," Savelli, A., Rational Pharmaceutical Management Project, November 1996.
3. "Trip Report: Ukraine, May 22–31, 1997." Duzey, O., Rational Pharmaceutical Management Project, June 1997.
4. "Ukraine Trip Report: September 27–October 10, 1997," Duzey, O., and Olson, C., Rational Pharmaceutical Management Project, November 1997.
5. "Trip Report Ukraine and Proceedings of the Workshop of Hospital Formulary Development, December 15–23, 1997," Duzey, O., Rational Pharmaceutical Management Project, February 1998.
6. "The RPM Project: Russia, Ukraine, and the Central Asian Republics: 1993 through 1997," Briefing paper, Duzey, O., Savelli, A., Rational Pharmaceutical Management Project, January 1998.
7. "RPM Ukraine: April 1998 Update," Briefing paper, Duzey, O., Rational Pharmaceutical Management Project, April 1998.
8. "RPM Ukraine Trip Report and Clinical Pharmacology Course Proceedings: May 10–15, 1998," Duzey, O., Rational Pharmaceutical Management Project., June 1998.
9. "Trip Report Ukraine: August 2–20, 1998," Duzey, O., and Chomyszak, M., Rational Pharmaceutical Management Project, October 1998.
10. "RPM Ukraine 1997–98," Briefing paper, Duzey, O. Rational Pharmaceutical Management Project, August 1998.
11. "RPM Ukraine: October 1998 Update," Briefing paper, Duzey, O., Rational Pharmaceutical Management Project, October 1998.
12. "Ukraine Trip Report: October 25–November 1, 1998," Duzey, O., Rational Pharmaceutical Management Project, October 1998.
13. "RPM Ukraine: Summary of Activities January–December 1998," Duzey, O., Rational Pharmaceutical Management Project, January 1999.
14. "Drug Procurement and Distribution in the City of Kyiv Public Health Sector," Zagorski, A., Rational Pharmaceutical Management Project, May 1999.
15. "RPM Ukraine: Proceedings of the Formulary Development Workshop: June 7–9, 1999," Duzey, O., and Armstrong, E., Rational Pharmaceutical Management Project, August 1999.
16. "RPM Ukraine Trip Report: October 1–13, 1999," Armstrong, E., Rational Pharmaceutical Management Project, October 1999.
17. "RPM Ukraine Trip Report November 20–December 4, 1999," Semenchenko, M., Rational Pharmaceutical Management Project, January 2000.
18. "Treatment of Pneumonia in Zhytomyr Oblast: Survey Results" (Russian), Karpov, O., Rational Pharmaceutical Management Project, February 2000.

545

19. "A Survey of Drug Treatment of Patients with Ischemic Heart Disease in Zhytomyr Oblast" (Russian), Karpov., O., Rational Pharmaceutical Management Project, February 2000.
20. "The Use of Antimicrobials in the Treatment of Acute Viral Respiratory Infections in Zhytomyr Oblast" (Russian), Karpov., O., Rational Pharmaceutical Management Project, February 2000.
21. "Standard Treatment Guidelines for Zhytomyr Oblast" (First draft), Zhytomyr Oblast Health Administration, April 2000.
22. "RPM Ukraine Trip Report, March 5–25, 2000," Duzey, O., and Semenchenko, M., Rational Pharmaceutical Management Project, May 2000.
23. "The Man and Drugs Congress: A Report," Semenchenko, M., Rational Pharmaceutical Management Project, April 2000.
24. "RPM Ukraine: Strategies for Improving Drug Selection and Use, Workshop Proceedings and Trip Report, July 5–22, 2000," Duzey, O., and Semenchenko, M., Rational Pharmaceutical Management Project, August 2000.
25. "The Exempt Prescription Program in Ukraine: A Preliminary Assessment" (Draft), Boesen, D., Duzey, O., and Semenchenko, M., Rational Pharmaceutical Management Project, October 2000.
26. *Zhytomyr Oblast Drug Formulary* (Ukrainian), Zhytomyr Oblast Health Administration, Zhytomyr, Ukraine, September 2000.

Training Materials

1. *A Manual for the Development and Implementation of Formulary Systems in Hospitals* (Ukrainian), Savelli, A., Schwarz, H., Zagorski, A., and Bykov, A., Rational Pharmaceutical Management Project, Third Edition, March 1999.
2. *A Manual for Implementing Drug Use Review in Hospitals* (Ukrainian), Moore, T., Bykov, A., Savelli, A., Zagorski, A., Rational Pharmaceutical Management Project, Third Edition, March 1999.
3. "Stepwise Implementation of Formulary Systems, Strategies of Drug Procurement Utilizing Formulary Systems, Performing ABC/VEN Analysis, Rational Drug Use, Economic Aspects of Drug Selection, The History of Drug Formularies, Drug Utilization Review, Medical Misadventures, Formularies in Third Party Insurance Systems, Current Treatment of Angina, Current Treatment of Adult Pneumonia, Indicators in Drug Use Studies, The Exempt Prescription Program," Selected Audiovisual materials (Powerpoint), Rational Pharmaceutical Management Project, 1997–2000.
4. *Guide to Good Prescribing*, de Vries, T. P. G. M., Henning, R.H., Hogerzeil, H.V., Fresle, D. A. Geneva: World Health Organization, Action Programme on Essential Drugs.
5. *Antibacterial Therapy*. Practical manual (RPM-sponsored edition, Russian). Eds. Strachunskyi, L.S., Belousov, Yu. B., and Kozlov, S.N. Moscow, 2000.
6. *Rational Drug Use. Development of Drug Formularies*. Recommendations for practicals for residents and physicians. Ryazan Medical University, Ryazan, 1998.
7. Selected materials from the RPM Drug and Therapeutic Committees Training Course: Identifying Problems with Drug Utilization, Indicator-Based Assessments, DTC Activities.
8. Case Studies in Hypertension and Pneumonia, Armstrong, E., May 1998.

Key Sources of Information Provided to Ukrainian Counterparts

1. Management Sciences for Health (MSH). *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.* Boston, Mass.: MSH, 1997.
2. Management Sciences for Health. Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach.
3. United States Pharmacopeia Dispensing Information (Russian language copies), Volumes 1–6, Moscow: 1996–2000.
4. *Antibacterial Therapy.* Practical manual. Ed. Strachunskiy, L.S., Y.B. Belousov, and S.N. Kozlov, Moscow: 2000 (sponsored by RPM).
5. Proceedings, VII Russian National Congress Man and Drug, April 10–14, 2000.
6. Guidelines on Antimicrobial Prophylaxis in Surgery (ASHP).
7. Sidorenko, S.V., A.I. Sinopalnikov, and S.V. Yakovlev. *Antibacterial Therapy in Pneumonia. Recommendations for Prescribers.* Moscow, 2000.
8. Turusina, T.A. *Pharmacoeconomical Approach to Rational Antibioticotherapy in Community Acquired Pneumonia. Recommendations for Prescribers.* Moscow, 2000.

Annex 3. Documents Obtained

The following lists the main documents obtained by RPM while implementing the project in Ukraine.

1. "USAID Ukraine Health Strategy and Action Plan," Regional USAID Mission for Ukraine, Belarus, and Moldova, August 1998.
2. Copy of the National STGs, volumes 1 and 2, 1999.
3. Copy of draft Zhytomyr Oblast Drug Formulary, 2000.
4. Decisions of the Board of City of Kyiv Health Administration, March 6, 2000.
5. Order of Chief Physician of Kyiv Hospitals #3 "On Hospital Formulary Committee establishment" #79, from April 4, 2000.
6. Order of Chief Physician of Kyiv Hospitals #7 "On Hospital Formulary Committee establishment" #55, from March 3, 2000.
7. Order of Chief Physician of Kyiv Hospitals #11 "On Hospital Formulary Committee establishment" #79, from March 15, 2000.
8. Order of Chief Physician of Kyiv Hospitals #17 "On Hospital Formulary Committee establishment" #26, from April 5, 2000.
9. Copy of the "List of Domestic and Imported Drugs to be paid partly or wholly with federal or local budgets," Annex to the Order of Kyiv City Health Administration and "Pharmacia" #210/194, from June 9, 1999.
10. Questionnaire for studying the problems of Ukrainian drug market (Medical Academy of Continuing Education, Kyiv).
11. Tests for certification of Pharmacists (Medical Academy of Continuing Education, Kyiv).
12. RPM-related publications:
    - On the Benefits of Formulary System. Weekly newspaper *Apteka*, #49(220), from December 20, 1999 (available online at http://www.morion.kiev.ua/Apteka/Contribution/s_220_49_201299_014.asp).
    - Formulary Systems, their role in Rational Drug Use in Patients Care. Ponomarenko N., Babsky A., Vovk N. Proceedings: 5th National Meeting of Ukrainian Pharmacists, 1999.
    - Formulary System Implementation in Health Care Facilities of Kyiv. Makomela R., Zagorodnyi V., Opanasenko M., Taran R., Semenchenko M., Duzey O. Proceedings: 7th Russian National Congress on Man and Drug, Moscow, April 10–14, 2000.
    - Drug Formulary Implementation in Health Care of Zhytomyr Oblast. Paramonov Z., Shatylo V., Oleinyk V., Rudoi K., Semenchenko M., Duzey O. Proceedings: 7th Russian National Congress on Man and Drugs, Moscow, April 10–14, 2000
    - Analysis of Antibacterial Treatment in Pneumonia in the Hospitals of Zhytomyr Oblast. Semenchenko M., Duzey O., Karpov O. Proceedings of International Conference on Antibiotics and Antibioticoresistence at the Dawn of XXI Century, Moscow, June 6–8, 2000.

Zambia

Executive Summary

This is the closing report for the USAID-funded program in Zambia with the global Rational Pharmaceutical Management (RPM) project that ended November 30, 2000. This report shows results of the various program activities, which evolved from several visits in 1996 and 1997 by the RPM director and staff. During these visits, poor drug management skills of health professionals at district levels was identified as an important limiting factor for improving the drug supply system within health-sector reform.

The RPM activities actually began with collaboration of the Ministry of Health, Pharmacy Department, in 1995. With a core of international and local experts, RPM developed the first draft of the National Drug Policy and assisted in processing a World Bank pharmaceutical tender.

At the beginning of the project, RPM developed a framework for integrating supplies and other drug management functions in the medical stores and districts. By the time RPM support ended and a new private management firm took over the activities in the medical stores, a total of 18 vertical supply systems had been integrated into one national system with ongoing supervision by the districts, Central Board of Health (CBOH), and medical stores.

Strengthening capacity in the districts of Zambia's regions was a major area of focus for RPM and has led to significant improvement in drug management. RPM trained pharmacy personnel through a series of workshops and meetings. Participants in the courses became the core group and leaders in the strategy later employed for capacitating and training district staff. For example, since RPM began its technical and financial support to the CBOH pharmaceutical action plans in 1997 to the end of RPM, the number of health workers trained in drug management and particularly in quantification rose from 50 to 2,000 persons. Pharmacy managers and donors alike placed priority on monitoring drug budgets and consumption in the district. These data allowed for a better district health planning process and more accurate quantification of supplies at central level.

As part of program support, RPM provided financial assistance for the drug management activities. Funds were provided to purchase computers for the medical stores and for the CBOH directors who managed inventory systems and procurement of pharmaceuticals. RPM trained staff and installed INVEC-2, an inventory management software program, in several sites.

In 1998, RPM conducted several workshops with participants from the donor community and the districts and developed the first draft of the District Self-Assessment Tool (DILSAT). Using the CBOH core group trained by RPM, DILSAT was piloted in two districts. Implementation in the Lusaka health district began in mid-1998, and district facility staff members quickly adopted the tool to help improve their work. DILSAT provides key indicators to supervisors for pointing out weak management areas. Armed with this information, the pharmacy staff used DILSAT as a monitoring and evaluation tool. The tool was redesigned in 1999 in collaboration with the Family Planning Logistics Management (FPLM) project and Zambia Integrated Health Project (ZIHP) managers and, after redesign, was implemented in four districts.

Program Summary

Background

- Since 1991, the Zambian government has been engaged in a process of health reform.
- Three founding reform principles are leadership, accountability, and partnership. *New one added this year: affordability.*
- Objective of the reform process has been the development of district health systems providing basic health services to all parts of the country.
- Main objective is decentralisation of both financial and administrative powers to the district (and provincial) level hospitals and district health boards.
- Government of Republic of Zambia (GRZ) and donor funds are pooled to support the running costs of the districts and hospital management boards (the district basket).
- In 1995/1996, the operational role of the MOH was reduced.
- The CBOH was established in October 1996.
- In 1998, shift in strategy took place from systems development to services delivery.

Structure

- Zambia has 72 districts and nine provinces.
- Each province has one general or central hospital, and many, but not all, districts have one district hospital.
- Ownership of facilities is shared among MOH, the Churches Medical Association of Zambia (CMAZ), and industry (mostly mines).

National Health Profile

- Life expectancy at birth has come down to 47 years.
- Infant mortality rate has increased to 107 per 1,000.
- Under-five mortality rate has gone up to 197 per 1,000 (DHS, 1996).
- Maternal mortality ratio is officially recorded as 649 per 100,000 live births.
- HIV sero-prevalence over the past 3–4 years is at 29 percent in urban and 14 percent in rural settings.

Public Health Priorities

- Malaria–Zambia has embraced WHO's Roll Back Malaria initiative.
- HIV/AIDS
- Tuberculosis (TB)
- Sexually transmitted diseases (STDs)
- Sexual and reproductive health problems
- Child Health–Zambia has implemented the concept of Integrated Management of Child Illness (IMCI) in some districts.

- Immunization coverage
- Malnutrition
- Dysentery

Drugs and Medical Supplies

National Drug Policy

- National Drug Policy was officially launched in February 1999 and in the National Health Strategic Plan 1998–2000.
- New legislation has been drafted to meet the modern criteria for good quality drugs.

Procurement

- Public procurement in Zambia (Tender Board Act Number 30 ZNTB, 1982) gives power to the Zambia National Tender Board (ZNTB) to regulate, control, and consolidate the law relating to tenders generally on public procurement.
- In 1995, procurement units were being set up at the ministries.
- The MOH Procurement Unit (PU) has the official responsibility for procurement at the central level in the public health sector.
- MOH PU is understaffed and underequipped.
- Many of the procurement activities have been and still are being done by technical units at the central level, such as the CBOH Support Services.
- The end responsibility remains with the MOH PU (both for MOH and CBOH).
- Concerns about cost-effectiveness and transparency in procurement are justified.
- The current regulations, guidelines, and procedures are sound, but there have been examples where implementation has been questionable.
- Next step: Shift pharmaceutical and medical supplies procurement to the implementing agency, i.e. the CBOH.

Storage and Distribution

- Since October 1998, the management of Medical Stores Limited (EDMSS), has been contracted out to a private company for a period of five years.
- The procedure that led to this contract has not been transparent. Also, the contract has proved to be costly to the MOH.
- In 1996/1997, MOH together with other stakeholders took the decision to integrate all logistics.
- Nineteen vertical programs were integrated into one comprehensive Public Health Logistics System.
- Integration of drugs and medical supply systems is aimed at improving the storage and distribution of vital health supplies and their distribution to health facilities.

- District and hospital management boards have been ordering from one central store at Medical Stores Limited (MSL).
- Deliveries are made regularly following a well-developed transport schedule by MSL.
- In order to strengthen integration, 2,400 health workers have been trained in stores procedures for drugs and medical supplies. This activity was initiated in 1997 and completed in 1999.
- Training has also taken place in the selection and quantification of drugs and medical supplies at district and hospital levels.

Use and Selection

- Zambian National Formulary Committee (ZNFC) was established with a secretariat at CBOH. ZNFC has been working on the Essential Drugs List (EDL), the Zambia National Formulary (ZNF), and Standard Treatment Guidelines (STGs).
- Revision of the EDL and the production of the ZNF in 1999 are important achievements.
- Most district and hospital management boards have established Pharmacy and Therapeutics Committees (PTCs) that regularly meet to address drug use issues and promotion of the rational use of drugs. The ZNFC has developed guidelines.

Drugs Availability

- Most rural health centers receive reasonable supplies through the regular supply of rural health center kits (funded by the Dutch).
- Many rural districts, hospitals, and urban health centers have problems in procuring essential drugs that are not available at medical stores. Some reasons may be that the suppliers may not be based in their own locality, limited resources, and high prices.
- There was a critical shortage of drugs and medical supplies in many hospitals and urban health centers (e.g., the tuberculosis drugs in 1998 and early 1999).
- TB drugs were the subject of a bilateral agreement with the Netherlands that ended in 1995; however, they continued to procure TB drugs for the health institutions until 1998.
- Government input has been insufficient in 1998/1999 to meet the ever increasing need of these vital supplies for health facilities.
- World Bank tender stalled and did not receive a no objection from Washington, D.C.
- Late 1999, the British Department for International Development (DFID) procured TB drugs to cover a period of nine months.
- World Bank approved the tender in March 2000. Supplies will arrive in August and September.
- Canadian International Development Agency (CIDA) pledged additional support of several million Canadian dollars for the year 2000.
- Swedish International Development Agency (SIDA) suspended funding of the rural health kits for 1998/1999 (because of EDMSS issue).
- Dutch Directorate-General for Development Cooperation (DGIS) remains a major donor for rural health kits and DFID for contraceptive commodities.

Estimates for Annual Drug and Supplies Budget

- Approximately US$20 million (Zambian population is estimated to be at 10 million people).
- GRZ 2000 budget is Zambian Kwacha (ZK) 22.4 billion or US$8.3 million.
- Expenditure in ZK has increased from ZK 20.4 to 21.8 billion.
- Experience in Zambia has shown that annual per capita expenditure of approximately US$1.00 is insufficient.

RPM Contribution to Date

- Assisted in drafting the National Drug Policy and legislation for the establishment of a pharmaceutical regulatory authority.
- Assisted in developing curriculum for undergraduate training in pharmacy (future project) and pharmacy technicians at Evelyn Hone College.
- Assisted in establishing PTCs. Supported the ZNFC in developing the PTC guidelines.
- Assisted in the development of the ZNF, the EDL, and the STGs.
- Developed and rolled out DILSAT to three districts and collected baseline data.
- Conducted the first Zambian Workshop on Promoting Rational Drug Use. Trained 35 health workers (doctors, clinical officers, and pharmacist).
- Assisted in the development of the reproductive health strategies.
- Conducted a costing tool survey (CES) for an Integrated Reproductive Health Strategy.
- Conducted a Drug Management for Childhood Illness (DMCI) survey.
- Assisted in the development of the USAID/Sector Program Assistance.
- Developed manuals in stores procedures and quantification.
- Trained more than 2,000 health workers in stores procedures and quantification.
- Funded training in drug management of several participants (Amsterdam, Mombassa, Kampala, and East London).
- Developed the framework and assisted in the implementation for the integration of the logistics system.
- Developed and implemented procurement procedures at MOH and CBOH.
- Assisted the MOH and CBOH in processing several World Bank Tenders (1997/1998/1999).

- Equipped CBOH and EDMSS with computers and printers.
- Computerized inventory at EDMSS with INVEC-2.
- Collaborated closely with all donors and leveraged funds to conduct activities.
- Collaborated with local consultants.
- Attended all the donors/CBOH joint consultative meetings. Assisted in developing and drafting the chapters on pharmaceuticals in the National Health Strategies.

Drug Management Areas Needing Future Support

Procurement

1. Assist in establishing a Procurement Unit at CBOH and define the technical role of the Pharmaceutical Unit within the CBOH.
2. Draft comprehensive MOH/CBOH procurement procedures for pharmaceuticals and medical supplies.
3. Assist in procurement plans and include quantification and financial implications at all levels. Standardize tender conditions (international and local).

Storage and Distribution

1. Analyze cost of current contract management and prepare for the next contract.
2. Conduct training for better store management techniques at hospital, district, and health center levels.
3. Introduce gradual changes from the "push" system toward a "pull" system.
4. Collaborate with the Financial and Administrative Systems (FAMS) and Health Management Information System (HMIS) to include different procedures linked with storage, distribution, and use.

Finance

1. Assist in creating and operationalizing The Drug and Supply Fund (DSF). The Drug and Supply Fund is seen as a mechanism to solve problems of availability of funds in the context of a sectorwide approach.
2. Establish cost-recovery schemes.

5555

3. Find innovative and new funding mechanisms (Public Pharmacies, Community Pharmacies, Drug Revolving Funds, Bamako Initiative, Incentive-based performance, etc.).

Rational Use and Selection

1. Finalize the standards for drugs and supplies and the STGs as tools for rationalization for the use of drugs and supplies.

2. Update the EDL and ZNF (and include new drugs for the treatment of HIV/AIDS).

3. Review and finalize the STGs.

4. Establish that PTCs have to be fully implemented at all levels to promote rational use of drugs and supplies.

5. Conduct targeted (e.g., malaria, TB, STD) training in prescribing and dispensing.

Policy and Legislation

1. Assist the ZNF to review the NDP based on experience built up since 1996.

2. Assist in drafting legislation, now under study at MOH, has to be finalized and enacted.

3. Assist in drafting and implementing national donation procedures.

Drug Management Support

1. Improve access to drugs by improving drug management information systems at central level.

2. Improve public-private collaboration.

3. Collaborate with all stakeholders (including CMAZ, Evelyn Hone College, and donors) to improve availability and accessibility of drugs.

4. Conduct annual training in drug management at district level.

5. Conduct a national quantification exercise using available (from the district plans) and new data from the districts.

Concerns

- Procurement of drugs and medical supplies: There is a need to learn from past mistakes to avoid chronic or acute disruptions in supply pipelines.

- EDMSS (Medical Stores): EDMSS is a major partner and has to regain confidence of all stakeholders and work with the CBOH and others in improving the logistics and information systems of drugs and medical supplies.

- Budgets: MOF disburses budgets incompletely and irregularly.

- Rational Use of Drugs: Current activities in support of rational drug use are insufficient in order to produce visible and measurable results. Targeted interventions in the public and private sector are recommended.

- Human Resources: Innovative strategies are required for human resource development and management support. Technical assistance will be needed with the current staffing at CBOH (one pharmacist at CBOH).

Acknowledgments

RPM would like to acknowledge the following persons for their support of the RPM/Zambia activities as well as the many others who have contributed to the program. Although not everybody is listed by name, without the support of the district health managers and pharmacy managers, the RPM program would not have been successful.

USAID

Anthony Boni	Cognizant Technical Officer-Washington
Susan Bacheller	Child Survival Fellow Global Population, Health and Nutrition (G/PHN)-Washington

USAID/Zambia

Walter North	Mission Director
Robert Clay	Director, Population, Health & Nutrition
Peggy Chibuye	

MOH

Hon. David Mpamba	Minister of Health
Hon. Ernest Mwansa	Deputy Minister
Mr. Joshua Banda	Director, Procurement
Dr. Kashiwa Bulaya	Permanent Secretary
Mr. Davies Chifwembe	Health Economist
Mr. John Chimumbwa	National Malaria Co-ordinator
Ms. G Makayi	Donor Coordinator
Mr. A Malijani	Deputy PS
Mr. M Malukutu	National TB/Leprosy Co-ordinator
Mr. Vincent Musowe	Director of Planning and Development
Mrs. F C Mwale	Chief Paramedical Officer
Mr. Matheis Mwale	Medical Equipment Unit
Ms. J M Nyirenda	Child & Reproductive Health Specialist
M. Siome	Child Health

CBOH

Dr. Gavin Silwamba	Director General
Dr. M R Sunkuntu	Director – HSC
Ms. Peggy Fulilwa	Management Service Support (RPM counterpart)
Mr. John Chimumbwa	Malaria Coordinator
Dr. Ben Chirwa	Management Adviser
Mr. Bona Chitah	Manager, Contracting & Budgeting
Mrs. G C Kahenya	Laboratory Specialist
Dr. Eddie Limbambala	Director – Monitoring and Evaluation
Dr. M. Maboshe	Manager Service Quality and Performance Audit

Chikuta Mbewe	
Ms. Rose Andala	
Mr. Steve Mtonga	Finance Specialist
Ms. Jenny Nyirenda	Environmental Health Specialist
Mr. F. Nyirenda	Environmental Health Specialist
Dr. Moses Sichone	Public Health/Clinical Systems

LUSAKA DISTRICT

Dr. R. Kumwenda-Phiri	Director of Health, Lusaka Urban Health District
Dr. S. B. Malumo	Manager, Planning and Development, Lusaka District

Pharmacy & Poisons Board

Mr. Ceaser Mudondo	Chairman
Mrs. Patricia M Nalishuwa	Registrar

ZAMBIA MEDICAL COUNCIL

Mr. S. Banda	Registrar
Dr. Mukunyandela	

Zambia National Tender Board

Mr. Akolwa	Acting Board Secretary
Mr. Simwanza	Director Purchasing

CHURCHES MEDICAL ASSOCIATION OF ZAMBIA

Mr. Marlon Banda	Manager Pharmaceutical Services

ZAMBIA INTEGRATED HEALTH PROJECT

Mr. Yann Derriennic	Deputy Chief of Party, Health Finance Advisor
Mr. Peter Eerens	Chief of Party

CARE

Ms Michelle Munro	Health Sector Coordinator

MEDICAL STORES LIMITED (ESSENTIAL DRUGS AND MEDICAL SUPPLIES STORE)

Oliver Hazemba	(Former Managing Director)
David Storey	Managing Director
Clara Manuani	Warehouse Advisor
Salomon van Staden	General Manager

Cooperating Partners

ROYAL NETHERLANDS EMBASSY

Dr. Rik Peeperkorn	First Secretary – Health
Ms. Lidi Remmelzwaal	Counsellor

IRELAND HEALTH

Mr. Kevin Carroll	Programme Officer
Dr. Oliver Lulembo	Health Adviser
Finola Finnon	Former health and laboratory advisor

JAPAN INTERNATIONAL COOPERATION AGENCY

Ms. Naomi Toyoshi	Project Formulation Adviser

SWEDISH INTERNATIONAL DEVELOPMENT AGENCY

Mr. Per-Ola Mattsson	First Secretary
Ms. Mulenga Muleba	Social Development Officer
Dr. Anders Nordstrom	Former Senior Health Advisor

DANISH INTERNATIONAL DEVELOPMENT AGENCY

Mr. David Corder	Chief Technical Adviser

BRITISH HIGH COMMISSION/DEPARTMENT FOR INTERNATIONAL DEVELOPMENT

Mr. Anthony Daly	Health and Population Sector Coordinator
Ms. Tanya Kieslich	Programme Assistant

UNICEF

Dr Zephaniah Mkumbwa	Health Section Head
Ms Christine Rudert-Thorpe	Project Officer, Child Health

WORLD BANK

Bwalja Mumba	Procurement Analyst
Dr. Bert Voertberg	Health Adviser (Washington DC)
Julie Mclaughlin	Health Adviser (Washington DC)

WORLD HEALTH ORGANIZATION

UNAIDS

Dr. Paul Zeitz

Management Sciences for Health

Anthony Savelli	Director of global MSH/RPM project-Washington
Douglas Keene	Deputy Director of global MSH/RPM project-Washington
Elvira Beracochea	Former Deputy Director of MSH/RPM project-Washington
Maria Miralles	Senior Program Associate-Washington
Kara Suter	
Inga Adams	
Julie Mcfadyen	

United States Pharmacopeia

Nancy Blum

Acronyms

BASICS	Basic Support for Institutionalizing Child Survival (Project)
CBOH	Central Board of Health
CES	Cost-Estimate Strategy
CMAZ	Churches Medical Association of Zambia
DFID	Department for International Development [U.K.]
DGIS	Directorate-General for Development Cooperation [Dutch]
DHMT	District Health Management Team
DILSAT	District Logistics Self-Assessment Tool
DMCI	Drug Management for Childhood Illness
EDL	essential drugs list
EDMSS	Essential Drugs and Medical Supplies Store
EDP	Essential Drugs Programme
FAMS	Financial and Administrative Management System
FPLM	Family Planning Logistics Management (project)
GRZ	Government of the Republic of Zambia
HIV	human immunodeficiency virus
HMIS	Health Management Information System
ICB	international competitive bidding
IMCI	Integrated Management of Childhood Illness
INRUD	International Network for Rational Use of Drugs
JICA	Japan International Cooperation Agency
LUD	Lusaka Urban District
MOH	Ministry of Health
MSH	Management Sciences for Health
MSL	Medical Stores Limited
NDP	National Drug Policy
PRDU	promoting rational drug use
PTC	Pharmacy and Therapeutics Committee
PU	Procurement Unit
RDU	rational drug use
RPM	Rational Pharmaceutical Management (project)
SIDA	Swedish International Development Agency
SO	strategic objective
SPA	Sector Program Assistance
STD	sexually transmitted disease
STG	standard treatment guideline
TB	tuberculosis
TDRC	Tropical Disease Research Center
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
UTH	University Teaching Hospital
WB	World Bank
WHO	World Health Organization

ZIHP	Zambia Integrated Health Project
ZNF	Zambian National Formulary
ZNFC	Zambian National Formulary Committee
ZNTB	Zambia National Tender Board
ZK	Zambian Kwacha

Program Overview

Background

The Rational Pharmaceutical Management (RPM) project began receiving field support for work in Zambia in 1997. RPM collaborated with the Basic Support for Institutionalizing Child Survival (BASICS), the Family Planning Logistics Management (FPLM), and the Zambia Family Planning Services projects to develop a concept paper for strengthening public health logistics at the district level. Supply categories to be covered under the plan included drugs, family planning supplies, and laboratory supplies. The overall objective of the activity was to strengthen logistics management in support of USAID plans to build the capacity of health care providers and managers. Efforts were made to keep other donors directly informed of this activity and, where feasible, RPM actively collaborated with them. Irish Aid was an important collaborator.

Zambia Health-Sector Reforms

The Zambian health-sector reforms are described by many as one of the boldest and most radical reform efforts ever seen in sub-Saharan Africa. The major components of the reforms are decentralization, accountability, provision of essential health care packages, cost sharing, and increased community involvement and private-sector participation.

When RPM started work in Zambia in April 1997, the new district health boards had already been established and several administrative responsibilities decentralized. At the beginning of the program, RPM presented to the Central Board of Health (CBOH) of Zambia a concept paper on strategies to improve management of pharmaceuticals, contraceptives, vaccines, and laboratory and medical supplies at the district level. RPM's plan to focus interventions at the district levels fit well with the ongoing implementation of the health-sector reforms. RPM interventions in Zambia were planned jointly with the CBOH and were part of the National Drug Policy (NDP) action plan. The intervention activities included

- Developing stores management manuals and training staff of district and health centers
- Developing and piloting a District Logistics Self-Assessment tool (DILSAT)
- Training in rational drug use and developing formularies, standard treatment guidelines, and a national essential drug and supply list to support the new NDP
- Implementing the Cost-Estimate Strategy (CES), a cost-analysis tool to guide decision-making for improving the availability and management of reproductive health drugs and supplies, in 11 USAID priority districts in the Zambia Integrated Health Project (ZIHP)

Overall Strategy

At the request of the USAID Mission in Zambia, RPM conducted a reconnaissance visit in Zambia in 1997. On the basis of these visits, the Pharmaceutical Department of the Ministry of Health (MOH) asked for assistance in strengthening capacity of pharmacy and medical staffs, at both the national and district levels, in the areas of drug management and rational drug use. USAID/Zambia began funding the RPM program in Zambia in 1997.

In support of health-sector reform, RPM's plan was to assist the newly established CBOH to implement the action plans of the National Drug Policy. RPM's approach was to strengthen logistics systems at the district level by first conducting a district-level assessment to identify strengths and weaknesses in the system and, on the basis of those findings, to implement district-focused initiatives. In 1998, RPM began developing a district-based self-assessment tool modeled on the RPM rapid pharmaceutical assessment tool. By the end of the project, RPM, in collaboration with FPLM and ZIHP, had supported the implementation of DILSAT in four districts. The development and implementation of DILSAT were complemented by RPM training activities in quantification, procurement, and rational drug use.

In collaboration with the MOH and donors, RPM developed training materials and practical exercises in quantification, stores management, and rational drug use that incorporated the MOH national drug policy. RPM trained a group of national facilitators, who then led the training activities. By 1998, through collaborative financial support of RPM, BASICS, the Swedish International Development Agency (SIDA), the Dutch Directorate General for International Cooperation (DGIS), and the Danish International Development Agency, 162 pharmacy personnel were trained at central and district levels. RPM estimates that approximately $100,000 was leveraged from the donors for these training activities.

As part of program support, RPM provided financial assistance to the medical stores and CBOH to buy computers and printers, and provided technical assistance in procurement, rational drug use, and integration of the supply system. Funds were also provided to support several activities such as training and study tours for several MOH/CBOH staff members. CBOH staff also gained valuable experience during the process of developing the essential drug list, the national formulary, and the standard treatment guidelines (STGs). RPM also conducted two studies to assess different aspects of the drug management system in Zambia. The first was for reproductive health using the CES (1999) and the second was in support of the Integrated Management of Childhood Illness (IMCI) strategy using the Drug Management for Childhood Illness tool (2000).

Objectives

The RPM activities supported USAID's strategic objective SO2: Increased use of safe pregnancy, women's nutrition, family planning, and other key reproductive health interventions, and SO3: Increased use of key child health and nutrition interventions, and the Zambian Mission's program objectives.

The RPM Zambia program objectives were to

- Train a core group of national trainers in drug management and rational drug use
- Provide technical assistance to the MOH and CBOH
- Capacitate district health management teams in drug management techniques
- Support capacity building of district facility staffs, using RPM drug management tools
- Support the supervisory role of the CBOH pharmacist

Implementation Strategy and Major Activities

Major activities included the following:

- Developing a framework to implement the integration of logistics
- Developing drug management training materials, including a quantification manual and manuals in support of stores management
- Updating the Essential Drugs List (EDL), National Formulary, and STGs
- Training a core group of trainers at the CBOH
- Conducting training workshops for national and district staff
- Developing the district self-assessment tool (DILSAT)
- Providing technical assistance to the district health directors to implement drug management tools
- Providing technical support for training and supervision

Challenges Facing RPM Zambia Implementation

As RPM was beginning to work in Zambia in 1997, the pharmaceutical sector was entering a new era under the health-sector reforms. The position of the pharmacist was shifted from the MOH to the CBOH. Several meetings were conducted to document the extent of problems that had permeated the entire MOH system. As a result, RPM was asked to slow and in one case postpone planned activities from August to October 1997.

A new pharmacist was appointed to the CBOH to manage operations under the CBOH in September 1997. Because of other demands on this new counterpart and a change of political direction in 1999, RPM activities and workshops were either delayed or cancelled during 1999.

565

Chronological Activity Timeline

RPM activities in Zambia began in June 1996 with RPM participation in a consensus-building meeting. RPM received field support from 1997 to April 2000.

Table 1. Activity Timeline

Date	Activity
June 1996	RPM participated at the National Drug Policy consensus workshop in collaboration with Division of International Health of the Karolinska Institute of Stockholm.
August 1996	RPM systems coordinator assisted the Department of Pharmaceutical Services (DPS) in the analysis of the World Bank bids.
December 1996	RPM participated in a multiagency team of drug management experts from SIDA, DGIS, and the World Bank for the establishment of the Essential Drugs and Medical Supplies Stores (EDMSS).
March 1997	At the request of USAID/Zambia, RPM and John Snow, Inc./FPLM made a first joint visit to establish contacts with the Ministry of Health, Central Board of Health, and USAID Mission. The RPM director presented the RPM concept paper "Strengthening Public Health Logistics in Zambia."
April 1997	RPM was requested by the Board of Directors at EDMSS and USAID Mission in Zambia to look into the feasibility of installing INVEC-2 at EDMSS.
May 1997	Michael Gabra of RPM visited Zambia to start country program activities.
September 1997	The first quantification workshop was held.
October 1997	RPM participated in the Joint MOH/CBOH/Donor Health Sector Reform Technical Review Meeting in Lusaka. Drafted the Sector Program Assistance (SPA).
January 1998	First drafts of the Stores Manual were completed.
May 1998	First drafts of the Quantification Manual were completed.
May 1998	Collaboration between RPM and United States Pharmacopeia in Zambia began.
June 1998	Computerization of EDMSS with INVEC-2.
May–November 1998	Conducted drug management training at Evelyn Hone College.
August 1998	Facilitated the first Zambian Course on Promoting Rational Drug Use.
October 1998	Financed Zambia MOH staff attendance at the Management Sciences for Health (MSH)/International Dispensary Association Drug Management Course.
September–October 1998	Trained health workers to use the Quantification Manual and helped them prepare annual district plans. Funds leveraged from BASICS and SIDA.
December 1998	RPM assisted in developing the action plans and implementation strategies for reproductive health. Presented to the MOH the CES tool.
August 1998	RPM took lead in developing a conceptual framework for integration of all logistics supplies.
	RPM assisted the MOH in completing the adjudication of World Bank drug procurement in 1997, 1998, and 1999.
May 1999	Assisted the CBOH to quantify malaria drug requirements and participated in the Africa Research Agenda on Malaria Prevention and Control meetings in Lusaka, Zambia, and Harare, Zimbabwe.
March–June 1999	Drafted and reviewed the Essential Drugs List, National Formulary, and Standard Treatment Guidelines.
July 1999	CES assessment implemented in Zambia. The tool was applied in 11 USAID ZIHP districts following a training workshop. Data were collected locally and analyzed by RPM.
August 1999	Prepared drug needs and estimates for Japan International Cooperation Agency (JICA).
December–January 2000	Implemented the Drug Management for Childhood Illness (DMCI) assessment.

Table 1. Activity Timeline, continued

Date	Activity
January–March 2000	Final review of the World Bank bids and tenders.
February 2000	Second and final review of the Quantification Manual.
January–March 2000	Second draft of DILSAT piloted in four districts in collaboration with FPLM and ZIHP.

Program Accomplishments

National Drug Policy

RPM was involved in the development of the NDP since 1997. RPM reviewed documents, facilitated workshops, and reviewed the final drafts of the NDP in 1998. The NDP was officially launched in February 1999 and was included in the National Health Strategic Plan (NHSP) 1998–2000. After February 1999, new legislation was drafted and added to the NDP.

Procurement

Between 1997 and 2000, RPM assisted in the adjudication process of three World Bank (WB) tenders. Public procurement in Zambia (Tender Board Act Number 30 ZNTB, 1982) gives power to the Zambia National Tender Board (ZNTB) to regulate, control, and consolidate the law relating to tenders on public procurement. The MOH Procurement Unit (PU) has the official responsibility for procurement at the central level in the public health sector. However, the PU was understaffed and underequipped. As a result, many procurement activities were performed by central-level technical units such as the CBOH Support Services, while the final authority for approval remained with the PU (for both MOH as well as CBOH). Several donors expressed concerns about cost-effectiveness and transparency in procurement. Although the regulations, guidelines, and procedures exist, there were examples where procurement practices were viewed as questionable.

Storage and Distribution

RPM assisted Medical Stores Limited (MSL) (EDMSS) in developing standard operating procedures, computerizing inventory with INVEC-2, training staff, and purchasing computers. The process also included codifying all the products in the stores. In October 1998, the management of EDMSS was contracted to a private company for a period of five years. The procedure that led to this contract was transparent and the contract proved to be costly to the MOH. RPM activities at EDMSS slowed following this decision; however, RPM maintained a good working relationship with the new management at the stores level. Following is a summary of events and RPM storage and distribution activities.

- In 1996/1997, MOH, together with other stakeholders, made the decision to integrate all logistics.
- RPM supported the integration of 19 vertical programs into one comprehensive public health logistics system. Before, district and hospital management boards had been ordering from one central store at Medical Stores Limited.
- Integration of drugs and medical supply systems was aimed at improving the storage and distribution of vital health supplies to health facilities.
- Deliveries are made regularly following a well-developed transport schedule by MSL.
- In order to strengthen integration, RPM assisted in training 2,400 health workers in stores procedures for drugs and medical supplies; this activity was initiated in 1997 and completed in 1999.
- RPM also provided training in the selection and quantification of drugs and medical supplies at district and hospital levels.

First Quantification Workshop

The first quantification workshop was conducted in September 1997. In collaboration with BASICS, RPM trained 120 health workers at the workshop.

Zambia Sector Program Assistance (USAID): Drug and Medical Supplies Performance Conditionality

This paper was written to stimulate thinking and discussion about possible areas for performance for the MOH/CBOH-USAID Sector Program Assistance (SPA) in the area of drugs and medical supplies. The overarching goal was to increase the availability of and access to good-quality drugs for the population of Zambia, which would contribute to the strategic objectives of USAID. The five subareas included in this paper were developed through a collaborative process among the MOH, CBOH, and donors during the October 1997 Joint Ministry of Health/CBOH/Donor Health Sector Reform Technical Review Meeting in Lusaka.

Integration of Vertical Supply Systems

In 1996, the Ministry of Health made a policy decision to integrate all logistics previously done by the 19 vertical programs into one comprehensive public health logistics system. Integration of public health logistics systems came to mean the combining of diagnostic commodities, contraceptives, essential drugs, vaccines, and other medical supplies delivered by the different programs working in the Zambian health sector into one comprehensive logistics system. In March 1997, a Logistics Steering Committee was established to spearhead the integration of all logistics. In May 1997, the directors of the Central Board of Health requested RPM and

counterparts to examine integrating all public health supplies in the Medical Stores and to assist with the integration process.

The CBOH held a meeting to explain to several vertical program managers the problems with vertical programs and the advantages of integrating the supply system. The managers were asked to document their stocks, logistics operation procedures, and location of warehouses. These reports were submitted to CBOH and Medical Stores. The reports formed the basis for developing integration plans.

The Framework for Integration

In August 1999, at the request of CBOH, RPM took the lead in developing a conceptual framework for the integration in order to facilitate the process and clarify roles and responsibilities.

The strategy addressed the following:

- Procurement and financing
- Storage
- Distribution
- Supply use
- Managing information system

In September 1997, CBOH wrote to all program managers stating its vision for integration, namely "merge all supply systems and improve availability."

Impact of Supply Integration on Medical Stores

Districts and hospitals ordered from one place instead of 19 medical stores. This system helped ensure that deliveries were made at regular intervals and eased implementation with well-developed transport schedules. By coordinating their supply orders, the districts now saved time and money. At the central level, the CBOH was better informed of the stock levels at the Medical Stores.

For the vertical programs, handing over management of pharmaceutical supplies allowed them to focus on their technical work. This centralization also facilitated their work with the districts, reduced their costs, and cut waste from stock. However, the greater demands placed on district-level staff highlighted the need for training to build capacity at this level.

Storage and Distribution

Integration of the logistics management system called for pooling of resources, including storage and distribution. All public health commodities that were procured centrally in bulk were stored at one location, the Essential Drugs and Medical Supplies Store. Distribution has also been

integrated. This step proved to be cost-effective because it cut down on duplication of activities and because each district now had to send their vehicle only to and from Lusaka to collect supplies from one site, rather than from each vertical program storage site.

Constraints to Integration

- Difficult integration of staff
- Slow implementation of procedures for stores
- Indeterminate governance of EDMSS
- Delayed approval of the NDP, health financing policy, and medical laboratory policy
- Shortage of skilled staff at all levels
- Poor record-keeping at hospitals and heath centres stores
- Irregular monitoring and supervision

Quantification of Supplies as Part of District Planning and Training

Quantification Manual and National Training

Districts are required to estimate their own supply needs within a given budget as part of the decentralization of planning and budget activities. The shift from a push system (where supply needs are determined centrally) to a pull system (where supply needs are determined locally) requires districts to determine the quantities of essential supplies required to deliver the essential services within their budget allocation.

The needs will likely be greater than the allocated budget; it is therefore necessary to rationally adjust the quantification to within the allocated budget. RPM developed a quantification manual that describes the process for quantifying and reconciling supply needs to the budget.

Quantification of medical supplies is part of the planning process for the annual district action plans. It had to be integrated with quantification of contraceptives, drugs, laboratory supplies, vaccines, and other medical supply items by a working group of all concerned parties following the methods described in the quantification manual.

The following criteria guide the development of action plans:

- The most essential items required to deliver the appropriate package of care must be included.
- Each item should be quantified based on reliable data.
- The quantities should be adjusted for stock on hand and wastage.
- Programmatic changes and areas of emphasis should be considered.

- Items and quantities should be prioritized and adjusted to the budget allocation.
- Estimates should be validated.
- The quantification forms must be completed.

Joint Annual Consultative Meeting and Work Planning for the Pharmacy Department

Management Sciences for Health (MSH)/RPM staff participated in the Joint Annual Consultative Meetings held in 1997, 1998, and 1999. These meetings focus on the next year's action plans and donor collaboration.

District Planning and Guidelines

RPM assisted in drafting the district guidelines for 1997 and 1998 in collaboration with counterparts from the CBOH and technical and financial support from Irish Aid. The first of the 1998 district guidelines were ready in June 1998, several weeks before the second quantification and district planing training started.

Assisted HMIS to Integrate Drug Indicators

In fall 1997, the Health Management Information System (HMIS) unit drafted a template questionnaire to collect service indicator data. Initially, there was much resistance to integrating these simple indicators because it was felt that the health workers would be overloaded. Finally, some indicators were accepted. Unfortunately, these indicators did not measure important aspects of drug availability; however, they did provide a snapshot to assess a few critical aspects of pharmaceutical use in primary health care facilities as well as hospitals.

The three service indicators being used by the HMIS were

- A prescribing practice indicator to show whether there is irrational use of drugs
- An availability of essential drugs indicator focusing on a number of vital drugs, which should not be out of stock at any time
- An indicator to assess drug expiration to determine whether inventory procedures were being followed or essential items being ordered

Procurement Procedures

In August 1997, RPM assisted the CBOH in the quantification procedures for a World Bank tender. The National Tender Board processed the documents. Unfortunately, the World Bank

task manager did not approve of the process and an emergency procurement was put into motion instead. The suppliers delivered 82 percent of supplies from the 1996/1997 procurement. Of those, only 60 percent had been distributed to the districts by EDMSS and stocks were very low.

RPM agreed to retrain the procurement officer at the CBOH in the use of spreadsheets and INVEC-2. Unfortunately, this person was computer illiterate and showed no enthusiasm to learn about procurement procedures and the use of a computer. Several months later, RPM learned that this person was no longer with CBOH.

Stores Manual

The stores manual was completed in December 1997.The Financial and Administrative Management System (FAMS) was in charge of printing and distributing the manual to the districts. Due to lack of funds, FAMS printed a limited number of copies of the manual. SIDA promised the CBOH to fund the rest of the printing. The stores manual was originally intended for use at the district level, but the manual was produced in consultation with the committee preparing the manuals for the Polyvalent Health Provider at Health Centre level.

Quantification Manual

Computerization of EDMSS with INVEC-2 and Continued Technical Support

Two MSH staff persons came to Zambia for two weeks. They spent most of their time at EDMSS, training and troubleshooting the system. They also made a presentation on the capabilities of the system to stakeholders and visited installations at the Lusaka Urban District office, the University Teaching Hospital, the Central Board of Health, and the Churches Medical Association of Zambia. During a second visit, MSH staff members ensured that the hardware was adequate and the software program was properly installed and configured. They also checked the completeness and integrity of the program's databases.

Contractual Agreement to Run EDMSS

The Helling-Borda et al. report of 1996 reviewed four possible actions for MSL.

1. Restructure MSL and create a new separate EDMSS
2. Liquidate MSL and create a new separate EDMSS
3. Contract out all services (privatize MSL)
4. Restructure and delink MSL into an EDMSS with a separate fund

The consultants recommended option 4, because it laid a foundation for a viable EDMSS, excluded costly liquidation, included commercialization without privatization, and delinked the EDMSS from the government by creating an independent board of directors with separate

funding and entering into a contract with CBOH. However, in March 1998, MOH decided to contract out management to a private company.

Management was awarded for a period of five years to a company called GMR. GMR is to grant a loan to MSL to invest in the renovation of the warehouse and surrounding areas, as well as to refurbish the fleet and introduce modern, innovative technology and equipment for EDMSS. In turn, MOH is supposed to depreciate the investment and repay GMR for the total amount of the loans received within the contract period.

EDMSS (GMR) is to store and distribute a minimum specified quantity of products (procured and donated items) for a total turnover of US$10 million per year (although GMR was prepared to accept a minimum turnover of US$7.5 million). If the turnover is US$10 million, GMR will invoice MOH a stock management fee of 5 percent and a stock distribution fee of 10 percent. If annual turnover is greater than US$10 million and less than US$15 million, GMR will invoice MOH a stock management fee of 4 percent and a stock distribution fee of 9 percent. If the annual stock turnover is greater than US$15 million, GMR will invoice MOH a stock management fee equal to 2.5 percent and a stock distribution fee equal to 7.5 percent. A penalty of 2.5 percent per month or fraction of month of delay will apply on any payment that is effected later than 30 days after the date of the statement. In addition, GMR also charges 17.5 percent VAT on all invoices.

Collaboration with Evelyn Hone College

To train pharmacy technicians at Evelyn Hone College, RPM made three presentations to the second- and third-year students in 1997 on stores management, including a presentation of INVEC-2, Quantification and Procurement, and Rational Drug Use. These activities were coordinated with the principal tutor. He ended a three-year VSO assignment in Zambia in November 1997.

Tools Development

DILSAT (1997–2000): The District and Hospital Integrated Self-Assessment Tool for Improving Supervision and Management of Public Health Supplies

During the joint RPM/FPLM mission in February 1997, RPM presented for discussion a district-focused activities concept paper to the CBOH, Lusaka Urban District (LUD), and donors. The most important proposals that emerged in this paper are

- Focus on integrated public health logistics including drugs, family planning, medical and laboratory supplies, and vaccines
- Activities for which technical assistance would be supplied by RPM (drugs), FPLM (contraceptives), and Irish Aid (laboratory supplies)

573

This plan was effectively launched in January 1997 by staff of the three technical assistance providers and counterparts from the MOH Department of Pharmaceutical Services and the LUD Health Board. The first activity had been to develop an indicator-based approach to assess public health logistics at district level. This tool was tested in three health centers in LUD. The second phase will be to test the tool in three health centers in Petauke District.

What Is DILSAT?

DILSAT is an indicator-based tool that allows district health managers handling public health supplies to

- Self-assess management of public health supplies
- Supervise management of supplies at the district store and hospital and health center pharmacies
- Identify bottlenecks, gaps, and problems in the supply system
- Identify budgeting gaps and quantification needs
- Improve management, capacity building, and supervision
- Design specific interventions and training modules
- Promote rational use of drugs and good dispensing practices
- Contribute to improving drug availability
- Reduce costs and wastage

Background

The pharmacy technicians in the Zambian public health sector manage the public health supplies in the districts. Qualified pharmacists in the public health sector are often in senior management positions. In the new structure of the health reforms, the pharmacy technicians have more responsibilities than in the past. They are in charge of managing the whole cycle of public health supplies including inventory and storage, quantification, estimating budget requirements, and ordering and procurement. In some cases, they are also in charge of laboratory supplies and vaccines for children's immunizations. They are also in charge of promoting rational use and good dispensing practices for drugs and play a key role in the district therapeutic committees. They produce monthly reports with information on the stock level of supplies for the CBOH and District Health Management Team (DHMT), especially for supplies considered vital in treating communicable diseases, such as antituberculosis drugs.

The Problem

In the last few years, the private pharmaceutical sector in Zambia has grown substantially and has attracted to its ranks many pharmacy technician graduates. In the absence of qualified staff, the district pharmacies are sorely understaffed and responsibilities usually lie solely on the shoulders of one person. In addition, this category of health worker was not trained to take over such important responsibilities that were devolved to them in the context of decentralization of

the health sector. From information received, very few have had refresher training in managing public health supplies.

Development of DILSAT

Given all these elements, the USAID Mission in Zambia requested that RPM support the CBOH in strengthening district capacity in this area. When RPM started activities in Zambia in April 1997, the CBOH did not have enough information on the level of skills and training needs of the staff at the districts.

Initially, there were plans to conduct a rapid pharmaceutical assessment based on RPM's *Rapid Pharmaceutical Self-Assessment: An Indicator Manual.* It soon became clear that what Zambia really needed were district-focused interventions to improve management of public health supplies. Consequently, RPM in collaboration with the CBOH, Irish Aid, and John Snow, Inc./FPLM developed a tool that could identify strengths and weaknesses in managing an integrated supply system for drugs, contraceptives, medical laboratory supplies, and vaccines. Although the questions and indicators were inspired by RPM's manual, they were tailored to fit the needs of the Zambian district health managers.

The first draft was tested in two districts, one urban and one rural. After a two-day training of the district staff, the draft was tested in the field. Several modifications were made and a second draft was circulated to the CBOH for comments. The reaction was positive, and there are plans to pilot test DILSAT in six new districts in 1999.

Description of DILSAT

For convenience, DILSAT was divided in two manuals. Although complementary, they address different users. The first manual is called *DILSAT for DHMT* and the questions focus on data that can be found at the office of District Health Management Team, including the following areas:

- District Health Board financing and budgeting
- Stores management
- Quantification and resupply decisions
- Distribution
- Rational use

The second manual is called *DILSAT for District Facilities* and focuses on the daily operations in the facilities, including questions in the following areas:

- Proportion of users paying fees
- Health facility indicators
- Stores and pharmacy management
- Quantification and resupply decisions
- Distribution

- Rational use
- Dispensing practices

Current Use of DILSAT

As was mentioned earlier, DILSAT was tested in only two districts in Zambia. Since its inception, it has evolved to become a supervisory tool for the district health managers in the two districts where it was piloted. The pharmacy technicians are using it as a checklist during their monthly supervisions. The tool made it easier for them to identify problems in a standardized way and in some cases to provide solutions. Examples include storage cleanliness and inventory controls. This result was exactly what was expected from this tool. More complex problems were either referred to the regional pharmacist or the CBOH; examples of these include financing procedures, quantification, and rational use of drugs.

Future Plans with DILSAT

Following the first self-assessment with DILSAT, each district is expected to develop in-house monitoring, training, and planning interventions. Briefly, each district needs to (1) form a committee, (2) prioritize the problems that were found through DILSAT, and (3) discuss and plan how to solve the problems. The committee should meet once a month and plan strategies to solve the problems. Depending on their complexity, these strategies may require external interventions and training.

After solving the first problem, and pending verification by the committee, the next problem can be tackled, thus solving one problem per month. This method is similar to the one that has been used by RPM in Ecuador, which has proven to be very effective because it empowers the district staff to sort out its problems. RPM is planning to use the same methodology in Bangladesh and Mozambique. At the middle or the end of the cycle, a second self-assessment can be implemented with DILSAT to measure progress made to date while maintaining the tool for supervisory purposes.

As a first phase, RPM and the CBOH are preparing plans to roll out the tool to six more districts. There are also plans to document the problems that were found in the districts and to develop a handbook for basic skills with checklists, sample forms, planning and "how-to" tools for managing public health supplies.

Conclusion

In summary, DILSAT started in Zambia as a low-key intervention to help the district staff identify the problems in the supply system. Although DILSAT is still in a draft form, it is opening doors and interventions that were not tested before at district and central level. It is a new approach to supervision, efficient management, and improvement of quality of services and can be implemented in any setting. It deals with real problems in the field and is useful to central

and district hospital managers. It is hoped that it would prove to save time and money for the districts and would lead to the development of better monitoring, training, and planning systems in public health supplies management at all levels of the health system.

Collaboration with the United States Pharmacopeia in Zambia: AMR, May 1998

USAID has provided funding to RPM/United States Pharmacopeia to conduct technical reviews of antimicrobial drug information in six countries. Zambia is one of the countries selected to participate in the review. RPM facilitated the technical review of antimicrobial drug information in Zambia.

The purpose of the review will be to

- Catalogue and evaluate the range of information resources on antimicrobial agents available to health care providers in the target countries
- Identify information that is inaccurate, out-of-date, biased toward particular products or manufacturers, or information in one source that conflicts with that in another source
- Make recommendations for improving the availability of appropriate antimicrobial drug information for use in efforts to control infectious diseases including pneumonia, tuberculosis, malaria, STDs, and diarrheal diseases

Promoting Rational Drug Use

The assessment for Lusaka was completed and the results were presented during a workshop in October and November. Several students were asked to follow up during their internship on the status of antibiotic and injection use. The data collected from the districts will be used as examples and baseline studies in August.

Assuming that the patient has been diagnosed properly and prescribed the correct drugs, if the patient does not know how to take the drugs, then all the effort in prescribing, diagnosis, and purchase of the drugs is wasted. The patient will not take them properly, will not get better, and will return for more treatment, which again will not be taken properly, repeating the cycle. Ensuring that patients take their drugs as intended might alleviate some of the drug shortages—resources are wasted in handing out drugs that are not taken properly.

Various drug-use studies carried out in Zambia have found that many patients do not understand how to take their drugs. About 60 percent of patients understood some basic information about their drugs when they left the dispensary. They knew how many and how often to take the drugs they had been given. This statistic means that 40 percent did not even understand this basic information when they left the dispensary, not to mention a couple of days later.
The results of four different studies carried out by the students from the Pharmacy Section of Evelyn Hone College during 1997 and 1998 are summarized in Table 2.

Table 2. Results of Pharmacy Section Studies

Location	Date	% Patient Understanding
Promoting Rational Drug Use in Lusaka Urban District	August–November 1997	51
Health Centres in 9 Zambian towns	January–April 1998	59
Drug Use Study in 3 Lusaka Health Centres	January–April 1998	59
Drug Use Studies in Zambia	April–May 1997	65

These studies measure the basic indicator of whether patients understand how much and how often to take each of their drugs; the results are not encouraging. The studies do not look deeper into patient compliance issues, such as whether the patient understands to complete a course of an antibiotic or how to use eye drops.

At the beginning of the project, rational drug use (RDU) was chosen as one of the key areas of focus, since the MOH had seen from early discussions with RPM the necessity of doing so. In fact, the MOH national drug policy drafted about that time included wording supporting RDU.

Donor Collaboration

RPM started work in Zambia in March 1997. Prior to that date, however, RPM made several exploratory visits and technical missions and developed a work plan in support of the strategic objectives of the USAID Mission in child and maternal health. Initially, RPM focused on assisting the CBOH in developing and drafting the National Drug Policy, implementing quantification procedures at the districts, and introducing district-focused drug management. RPM was also involved in developing drug procurement procedures and assisted the MOH in completing the adjudication of World Bank drug procurement in 1997, 1998, and 1999.

In 1997, the first important initiatives of the health sector reforms were put in place. Accountability, decentralization, integration of services, and collaboration with all partners were the key messages. These messages shaped RPM's technical assistance. It is in this spirit and context of inclusiveness that RPM is working in Zambia.

Integration of Logistics System

The MOH/CBOH felt, at the time, that the integration of logistics of the supply systems was crucial to the success of their plans and asked RPM to take the lead in developing the framework for the integration of all vertical supply systems. RPM assisted the MOH/CBOH to organize a meeting with all the stakeholders in pharmaceuticals. With RPM assistance, the CBOH convinced UNICEF, Irish Aid, USAID, and other donors to fund and coordinate a technical mission to assist the CBOH in finding solutions to the system. A few weeks later, in August 1998, consultants from RPM and donors were in Zambia developing the blueprint for the integration of public health supplies.

Sector Program Assistance

In 1998 the USAID Mission was developing the action plans for the Sector Program Assistance. RPM played a very important role during this period. Following a mission in October 1998, RPM submitted a report about its views on what should be done in the pharmaceutical sector in Zambia. This report was very much appreciated by the Mission and other donors and has contributed (with other reports) to leveraging millions of dollars for Zambia under the SPA.

RPM and Irish Aid

RPM and Irish Aid collaborated closely in many areas and shared the expenses in conducting workshops and seminars and in hiring local and international consultants to assist the CBOH to meet deadlines. The outcome of this collaboration and leveraging of funds from Irish Aid produced the first drafts of the quantification and stores manuals and DILSAT.

In addition, the long-term collaboration between RPM and Irish Aid resulted in convincing the Zambian government to allocate funds within the national budget to purchase laboratory supplies (Irish Aid's main focus of interest) and to allocate a percentage of the 1997 WB drug procurement loan to purchase medical laboratory supplies.

The close collaboration in developing the quantification manual convinced Irish Aid officials to invest in the procurement of laboratory supplies and store the supplies in the medical stores.

RPM and SIDA

SIDA has always been supportive of all RPM activities in the pharmaceutical sector in Zambia. Leveraging funds from SIDA was a not an obstacle as long as the RPM activities coincided with the CBOH plans. The close collaboration among SIDA, CBOH, and RPM resulted in saving thousands of dollars in supplies by reviewing the contents of the rural health kits. SIDA committed itself to support CBOH to produce the EDL, the National Formulary, and the Standard Treatment Guidelines. These three manuals are technically reviewed by RPM and are under review by the Zambian National Formulary Committee. RPM is playing a crucial role in organizing, writing, and reviewing the production of these documents. RPM and SIDA also split the expenses of the first Rational Drug Use Workshop in 1998. See Annex 1 for a full report of the First Zambian Course on Promoting Rational Drug Use held August 17–27, 1998, in Siavonga district.

RPM and BASICS

RPM and BASICS collaborated closely on many issues surrounding Drug Management for Childhood Illness (DMCI). Several workshops, seminars, and transport cost within the country were supported by the BASICS projects. For example, the dissemination of the quantification manual in 1997 and in 1998, and training of more than 1,000 health workers were supported by BASICS.

Activities Not Completed

RPM was able to fully implement most of the activities in the action plans. In fact, several activities like the SPA, CES, and DMCI that were completed were not included in the original plans. Because of lack of funds and change of policy direction at the MOH, between January and September 1999, the two remaining activities that needed to be completed are the rollout of DILSAT to other districts and the final peer review and publication of the standard treatment guidelines.

Likely Needs at End of Project

To improve the drug supply system in Zambia, RPM recommends the following after the project has ended.

1. Financial and technical support is needed for ongoing continuing education of district staff in basic drug management and rational use procedures. The support should include technical and financial assistance for regular supervision and monitoring of pharmacy and medical directors in all districts, and the use of drug management indicator data such as DILSAT to identify problems and monitor improvements in drug delivery.

2. Technical and financial assistance will be needed by the CBOH to quantify national drug and supplies needs. The CBOH currently uses data from the annual district plans, which do not take stock-outs and expired drug quantities into account. The output would be a quantified list of national drug and supplies needs based on a study of consumption and morbidity data.

3. Building on the national quantification described in the preceding paragraph, the CBOH needs to promote the use of consumption data from districts. Drug information data will allow the CBOH to more accurately quantify future national drug needs. To accomplish this goal, the MOH will need financial and technical support for a combined manual/computerized information system for the central and district warehouses. Data from this system will be fed to the national procurement office at the MOH for more accurate purchasing of drug and supplies needs.

4. Additional support to publish and disseminate drug management procedures, as well as training in those procedures, is needed.

5. The drug and supplies cost-recovery scheme used in government health facilities needs improvement.

6. Zambia established a plan to gradually implement the Integrated Reproductive Health Strategies and to expand the IMCI scheme. Technical assistance will be needed for the drug management components of both strategies.

7. Technical assistance for selection, procurement, and proper use of drugs will be needed to comply with World Health Organization (WHO) treatment regimens in tuberculosis and malaria.

8. Technical assistance is needed to better focus and coordinate donor support to set achievable objectives for the pharmacy sector.

9. After many years, a new National Essential Drugs List and the Drug Formulary were published in January 2000 by the CBOH. Drugs in certain disease categories are missing, like HIV/AIDS and fixed-dose combination drugs for tuberculosis; therefore, a comprehensive technical review is needed. Technical and financial support is needed to upgrade the EDL and the formulary.

10. Technical assistance is needed for the Pharmacy Medicine and Poison Board to establish a comprehensive policy and service for registering new and currently used drugs.

Next Steps: The Future

According to information received from CBOH and donors in Zambia, RPM's interventions and collaboration are highly appreciated. RPM will continue working to provide technically sustainable assistance. RPM will strive to keep its activities aligned with the strategic objectives of the MOH, CBOH, and USAID.

The burden of disease is growing in Zambia and the need for an efficient, flexible, proactive management of pharmaceutical systems and supplies will be needed for some time. RPM is ready to support USAID/Zambia, the MOH, and the CBOH in this challenge.

What Does the Future Hold?

The commitment by the MOH, CBOH, and Medical Stores played a key role in implementing the integration process. A unique sense of collaboration with all stakeholders developed. This collaboration continued later in other areas of pharmaceutical management. The impact of integrating essential supplies was felt immediately at district and central levels. District pharmacists made orders from one or two sources instead of 18. Medical stores made sure that deliveries were made at regular intervals with well-developed transport schedules. In coordinating their orders, the districts saved time and money, and at the central level, the MOH and CBOH were better informed of the stock situation at the periphery.

As for the vertical programs, handing over management of pharmaceutical supplies allowed them to focus on their missions. It has also facilitated their work with the districts, reduced their

costs, avoided duplication of efforts, and reduced the levels of stock expiring in their offices and warehouses.

Lessons Learned

Adapting to Health Sector Reforms

Through several personal and public meetings and presentations to stakeholders handling and managing drug supplies, RPM convinced the CBOH to incorporate the strategies that were adopted by the National Drug Policy in the National Health Strategy. RPM interventions focused on improving district management and use of supplies and were in line with the strategic objectives of the reforms. RPM's patience and willingness to learn about the reform processes laid the foundation for excellent working relationships with the CBOH and the donors and paved the way for RPM work in Zambia.

Getting Involved in the Reform Process

At the beginning of the reforms, the CBOH and the donors invested little time in the overall issues of managing drug supplies. The restructuring at CBOH did not include the staff at the Pharmacy Department Services. This situation made it difficult for RPM to develop work plans and to communicate with the CBOH. To solve this problem, RPM put forward a proposal to the CBOH to hire a pharmacist. Less than a month later, a pharmacist was appointed to the CBOH and incorporated in the CBOH structure. RPM involvement facilitated the process and was well received by CBOH. From that point, RPM was invited regularly to the planning and strategy-development meetings of the reforms.

Listening and Responding to Demand

One of the most difficult problems in the pharmaceutical sector in Zambia is the shortage of staff. There is only one pharmacist at the CBOH managing the implementation of the national drug policy. This person is overloaded with work and RPM helped to alleviate some of the workload. In addition, RPM responded quickly to requests made by the CBOH and USAID. Examples include the evaluating bids and quantifying supplies, reviewing strategies for the SPA, and training pharmacy technicians at Evelyn Hone College. Accommodating CBOH and the donors about the real needs in the field paved the way for RPM to participate in a wider range of health activities in Zambia.

582

Political Commitment

The CBOH's political commitment facilitated the integration of supplies to the medical stores. Without such commitment, much of the work that was achieved in integrating the pharmaceutical supplies to the medical stores would not have happened. It has also helped to develop integrated training manuals. RPM has managed to convince the directors and the MOH to be involved in the process and asked the director to chair the first consensus meeting of the logistic steering committee. A similar commitment was received from the MOH in support of policies to promote the rational use of drugs.

Improving Procurement Procedures

Procurement is a complex process that involves many departments, agencies, and donors. Inefficiencies and delays become costly, and shortages of supplies erode trust of the clients in the health system. RPM technical assistance in this field included selection, quantification, preparing and evaluating bidding documents, and training staff. RPM purchased computers and installed a software program to assist in the evaluation of the bids. However, much remains to be done in this field. USAID does not purchase pharmaceutical supplies for Zambia, and although RPM technical assistance in this area was highly appreciated, RPM lacked the leverage that other donors had to change or influence certain procurement procedures.

Working in a Broad-Based and Collaborative Environment

The approach to health in Zambia is sectorwide. Collaboration and consensus building among all partners are the norm. The process may slow implementation of interventions, but overall RPM learned to negotiate and lobby early with all stakeholders and to make sure that everybody involved is informed. This broad-based participation proved to be essential during the development of the training manuals and training of district health workers. RPM coordinated these activities with eight different collaborators.

The Need for RPM Field Presence

RPM has learned that to make progress in the field, the physical presence of the program manager in the country is important. Despite the excellent support of the Zambian counterpart, the project needed constant monitoring and support. The physical presence on the ground of RPM was a motivating factor to counterparts and colleagues to accomplish many tasks. When RPM could not be in the country, a consultant with several years of Zambian field experience was hired to participate in three missions to monitor and follow up activities for RPM. Additionally, a local consultant is currently assisting the program manager to implement and monitor activities that were agreed upon with the CBOH. RPM has also funded per diem for several students and health workers who did excellent work as trainers and data collectors. These small incentives made a positive impact on morale and compensated local staff disseminating

important RPM training materials and information on managing drug supplies. Several dozens of the *Managing Drug Supply* book were disseminated in the country with their help.

The Essential Health Care Package

After an extensive study on the burden of diseases, the Health Reform Implementation Team summed up strategies and plans to tackle the following health problems: malaria, tuberculosis, acute respiratory infections, mother and child care, sexually transmitted diseases, HIV infections, water and sanitation, and malnutrition. The cost estimates for each category of disease were defined for each essential health package. Although RPM participation in this process came at a late stage, it has contributed in the selection of drugs and has learned about future financial schemes to sustain the essential packages of care.

Adapting to Change at the Medical Stores

The management requested RPM to assist in the organization and inventory control of the stores. RPM assisted the staff in the stores to develop plans to improve floor space and to harmonize code numbers of the stocks and encouraged the development of a standard operational procedures manual. At the request of the management, RPM installed inventory control software, INVEC-2, and trained five staff members in its use. RPM purchased two computers for the stores to pilot the software. Recently, the MOH decided to subcontract the management of the stores to a private company. RPM is learning to adapt to the new situation in the stores and will not miss the opportunity to learn about subcontracting management and to explore other innovative initiatives to manage a central medical stores.

DILSAT Proved Valuable as a Monitoring Tool

The drug management and rational drug use indicators introduced through DILSAT proved to be a useful tool for supervisors to understand problems in the drug sector of their district and to monitor the progress of their improvement efforts.

Decentralization

Decentralization requires planning, and written procedures should be provided for local staff to understand and follow. The quantification workshops provided such an environment in drug management.

Cooperative Agreement

The USAID Cooperative Agreement mechanism provided flexibility for RPM to meet USAID's goals in the area of drug management.

Annex 1. First Zambian National Course on Promoting Rational Drug Use

The first Zambian Course on Promoting Rational Drug Use (PRDU) was held in Siavonga, Zambia, from August 17–27 1998. The course brought together a wide range of participants from central and district health institutions throughout the country. This article describes the background and preparation of the course and draws on discussions, recommendations, and lessons learned for future work to improve the use of medicines in Zambia.

Background

In 1985, the World Health Organization (WHO) convened, in Nairobi, Kenya, a conference of experts on the rational use of drugs and defined the term rational use of drugs as follows:

> The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community.

Depending on the context, that definition can vary in each country. In sub-Saharan Africa, the most "rational" thing for Ministries of Health and Essential Drugs Programs to do was focus on the availability and accessibility of safe, good-quality, generic drugs. This situation is still true and a cause of major concern for many countries in the region. However, in spite of the problems on the supply side, the conference in Nairobi brought to the forefront the problem of drug use and, as a result, much has been done since 1985.

The Reasons for the Shortages of Medicines

In Zambia, shortages of drugs and medical supplies persist at different levels of the system. One study in Nigeria has shown that when drugs are not available the utilization rate for health facilities can fall by 50 to 75 percent. Inadequate or unreliable supply of essential drugs decreases the trust clients have in the provider and the health care system.

The participants of the course identified the following factors that are contributing to the shortages of drugs in Zambia:

- A low budget allocation for drugs
- Delays in disbursement of funds to the districts
- Complex procurement procedures by the ministry of health and donor agencies
- Inefficient distribution and storage systems
- Irrational use of drugs and medical supplies
- Overall lack of management and infrastructure

585

The Reforms and National Drug Policy

The health sector reforms recognize that the availability and accessibility of essential drugs and medical supplies by the majority of the population is a cornerstone to the success of reforms. In fact, the aim of the Zambian National Drug Policy is to ensure essential drugs and medical supplies be available and accessible to the majority of the population as close as possible to the family.

Strategic Planning

The steps of selection, procurement, and distribution are necessary precursors to the rational and good management of drugs and medical supplies. In the last year, the Central Board of Health (CBOH) worked in a collaborative manner with stakeholders on improving the management and logistics of pharmaceuticals, contraceptives, vaccines, and laboratory and medical supplies. In spite of the progress made in developing training materials and systems on storage and supply procedures, little has been done in the area of drug use. Given the impending health problems developing because of irrational use of drugs, and because resources will remain short of satisfying all needs, the Ministry of Health (MOH) and the CBOH recommended that the problem of irrational use of drugs be tackled as a priority.

Introduction: Rational Drug Use: A Priority for the MOH and CBOH

The course was held in Siavonga district, Zambia, which is situated approximately 150 km south of Lusaka on the shore of Lake Kariba.

The course opened with a welcoming speech by Dr. Eddie Limbambala, director at the CBOH. In his speech, he expressed his appreciation for the role the MOH had taken to bring about this course. He stressed the concerns of the CBOH on the inappropriate use of drugs and the impact it could have on the progress made so far in various areas of the health sector reforms. Following his intervention, Dr. Limbambala welcomed the Deputy Minister of Health and invited him to give his keynote speech.

In his speech, the deputy minister of health, the Honorable Enerst Mwansa, drew the attention of participants to the health and economic impact of shortages, inappropriate use, pilferage, and irrational drug use on the population. He urged the audience to rationalize use of drugs and medical supplies and condemned the use of drugs in the black market. The minister also said that even if Zambia had the drugs and the money, it would be irresponsible of the MOH to sustain such a system. He urged the participants to come up with resolutions and proposals to pave the way for rational use in Zambia in the next millennium.

In April 1998 the MOH endorsed the idea of conducting the PRDU course in Zambia and asked the CBOH, the operational body of the ministry, to conduct a national course instead of a regional PRDU course. Several reasons justified this approach. The concepts and training surrounding the rational use of drugs were neglected for several years in Zambia. Following a

small-scale study and workshop that was conducted in Lusaka in 1997, the organizers of the PRDU course felt that there was an urgent need to conduct the course at national level.

- The organizers hoped that training several health providers from each region with the appropriate skills and knowledge would have an immediate visible health and economic impact on the system.

- All parties involved, including the funding agencies, were of the same opinion that a national course would bring a national awareness to the problems of irrational use of drugs and would contribute to improving the quality of health services.

About the Course

Thirty-six policymakers, researchers, doctors, clinical officers, nurses, pharmacists, pharmacy technicians, and health managers from four health regions attended the PRDU course in Siavonga, Zambia. They represented the Ministry of Health, Central and District Boards, University Teaching Hospital (UTH), armed forces hospitals, nongovernmental organizations, and the pharmaceutical society and industry. Participants attended 14 sessions including field trips and evening and poster sessions.

The pharmacy managers at the CBOH and the medical stores organized the first Zambia National PRDU course. International sponsors included two USAID-funded projects, Management Sciences for Health/Rational Pharmaceutical Management (MSH/RPM) and Basic Support for Institutionalizing Child Survival, the Swedish Agency for International Development (SIDA), WHO's Action Programme on Essential Drugs, and the International Network for Rational Use of Drugs (INRUD). INRUD, together with the MSH/RPM Zambia program manager, prepared, planned, and presented the teaching sessions.

Objectives of the Course: Understanding Drug Use

The organizers of the course felt it was important to show the participants the problems facing Zambia in this field. They felt the message should follow the MOH vision in implementing the recommendations to bring visible impact in their work settings.

Course Contents

The course contents were based on the sessions developed in previous regional PRDU courses in Tanzania and Nepal, with slight modifications to some sessions. Two field trips were organized during the course to identify and collect data from the Siavonga district hospital, two health centers, and one mission hospital.

The organizers focused mainly on

- Identifying the magnitude and the nature of inappropriate drug utilization in their work settings
- Understanding the adverse effects and impacts of inappropriate use of drugs
- Describing and discussing the factors that influence the clinical and decision-making process in drug use
- Investigating behavior patterns of prescribers and dispensers
- Investigating drug use in their own setting through the field-trip sessions
- Assessing various interventions to effectively reduce irrational drug use
- Preparing intervention proposals

Guest Speakers

Three guest speakers were invited to the course. Dr. Remi Sogunro, chief of party of USAID/BASICS, talked about the impact training in Integrated Management of Child Illness (IMCI) has on improving counseling and use of drugs. He also presented the results of a two-year follow-up study obtained from eight health centers in Lusaka. Mr. Masauso Nzima, deputy director of USAID/Project Concern International presented preliminary results of a survey conducted in Lusaka on sexually transmitted disease (STD) drugs. The theme of his presentation was "Community Access to STD Drugs." In this presentation an interesting debate arose on the use of STD drugs, the treatment guidelines for these infections, and the role of the national drug authority in preventing the sale of STD drugs without a prescription. The third guest speaker was Mr. Michiel de Groeje from the International Dispensary Association in Amsterdam. His presentation focused on quality assurance, good procurement, and storage procedures.

Evening Session and Poster Presentations

Mr. Joseph Mthetwa, a researcher at the Tropical Disease Research Center (TDRC), made a very interesting presentation on the status of malaria in Zambia. He presented the center's research focus and objectives and then presented the center's recommended course of treatment for malaria in Zambia. Following his presentation, Mr. Mthetwa moderated a debate on the pros and cons of adding sulfadoxine pyrimethamine as a first-line drug in the rural health kits.

Two students from the Evelyn Hone College, representing the DF/96/d class of pharmacy technicians, made two poster presentations on the results of drug use studies they had conducted in nine towns during the third-year curriculum assignment. The results of the study showed that an average of 2.48 drugs are prescribed for each encounter, of which 9.8 percent were injections and 46.1 percent antibiotics. Only 31.8 percent of the 78.5 percent of drugs actually dispensed

were labeled properly. According to the same study, 59.1 percent of the clients understood the dosage and route of administration. Because of the success of this assignment, the teachers will include this type of work in the school's curricula.

Evaluation of the Course

The evaluation of the course exceeded expectations. On the technical aspects, the course received on average an 84 percent approval rating, and for the administration the average approval rating was 70 percent.

Outcomes

The PRDU course provided a unique opportunity for Zambian health providers from different backgrounds and institutions to discuss and collaborate on how to improve the use of medicine in their country. It also provided a chance for the participants to develop doable project proposals.

Following are listed the topics that were presented by the participants:

1. Determination of prescribing practices in the northwestern health region in Zambia
2. Promoting rational drug use in Lusaka Urban District and Chipata General Hospital
3. Improving the diagnosis skills of nurses and midwifes
4. Irrational use of antibiotics at UTH and Chainama Hospital
5. Pilot project for continuing education in promoting the rational use of drugs for dispensers in Churches Medical Association of Zambia (CMAZ) health facilities
6. Project proposal for the Defense Forces Medical Services
7. Control of unregistered drug outlets
8. Overprescribing of antibiotics in hospitals in outpatient department
9. Implementing guidelines for the management of uncomplicated malaria at health-center level
10. Investigating drug use in referral hospitals
11. A study on the use of antibiotics in the north central region of Zambia

Lessons Learned

A number of lessons were drawn from the discussions during the course, the presentation of the proposals, and the daily evaluation forms of the course. The participants expressed the need for more time for each session, in particular the session that discussed the statistical techniques in sampling data. The concepts were new for some participants and additional hands-on exercises may have facilitated better comprehension in this session. The participants also requested more role-play in smaller groups on issues such as management interventions, monitoring, auditing health centers, and development of feedback processes.

During the discussion the facilitator introduced a discussion topic on syndromic diagnoses in STD-related infections. This method is a pilot project and has yet to be officially endorsed by the

589

MOH. The discussion has led to a long debate on issues such as coordination of treatment guidelines with other donors and vertical programs, and case management of several important diseases in Zambia. The participants recommended that these topics be included in future PRDU courses.

Finally, the participants asked the CBOH to continue production of Zambian printed materials similar to the ones distributed during the course from Malawi, Uganda, and Zimbabwe.

Next Steps and Challenges for the Future

The CBOH was successful in its challenging attempt to organize the first Zambia National Course on PRDU. The course was successful at introducing the concepts and strategies for rational use of drugs and was a valuable opportunity to develop regional teams to implement the strategies. However, the success of the course will be measured by how effectively the project proposals, recommendations, strategies, and resolutions are implemented in the field.

In his closing speech, Dr. David Lee, MSH/INRUD, stressed that the fundamental goal of the course was to make health providers understand the framework of drug use practices in order to make drugs available, accessible, and used rationally to improve the quality of health. Michael Gabra, MSH/RPM Zambia Program Manager, closed the course by stressing that Zambia was not alone in this battle, and he urged the participants to keep the same team spirit that had developed during the course and implementation phase of the recommendations. The CBOH in collaboration with MSH/RPM will follow the implementation and funding by donors of the project proposals. The CBOH will continue promoting PRDU at central and regional levels and has plans to conduct a follow-up course in 1999.

Annex 2. Documents Produced or Assisted in Producing during the RPM Zambia Program

1. Integrated Reproductive Health in Zambia, Plan of Action, 1999–2004
2. Integrated Supply Management System, Framework and Plan of Action, October 1997
3. Tender Adjudication Assistance Report, May 1998
4. Discussion Paper: MOH/CBOH-USAID Zambia Drug and Medical Supplies Performance Conditionality, October 1997
5. Zambia Essential Drug List, 1999
6. Zambia National Formulary, 1999
7. Zambia Standard Treatment Guidelines, draft 1999
8. Drug Indicators in Health Centers, January–April 1998
9. DILSAT, October 2000 (final version)
10. FAMS Stores Procedures Training, CBOH, January–February 1998
11. Quantification Manual, first and second editions, 1998 & 2000
12. Manual on Stores Procedures, 1998 & 1999
13. Report on the PRDU Course, Siavonga, Zambia, August 1998
14. Cost-Estimate Strategies, Zambia, 1999
15. DMCI, Zambia report, October 2000

Annex 3. Proposal to Support Drug Management for Malarial Control

(Unfinished draft)

Prepared by Peggy Fulilwa, CBOH; Michael Gabra, RPM, NMRC, MOH; and USAID/Zambia, May 2000

Introduction

Malaria in Zambia is recognized as one of the leading causes of morbidity and mortality, especially among young children and pregnant women, and accounts for more outpatient and hospital admissions than any other disease. In 1994, more than 3 million cases of malaria were reported in Zambia at the rate of 356/1,000 population. Since 1990, the fatality rate among children less than 5 years of age has ranged from 21/1,000 to 48/1,000.

In line with the strategic health plan that has recognized malaria as a very important and urgent health burden, the Central Board of Health (CBOH) has prioritized specific areas in drug management to ensure availability and access to effective and quality malarial drugs for the population and to ensure their appropriate use.

In order to improve drug management, the following interventions are being implemented by the CBOH:

1. Integrating logistic systems
2. Developing National Formulary and Essential Drug List
3. Making available systems for selection and quantification of drugs and medical supplies
4. Promoting rational use of drugs
5. Developing legislation to support the implementation of the National Drug Policy

The provision of and improvement in the management of antimalarial drugs constitute very important components of initiatives aimed at containing the health burden caused by malaria. Antimalarial drugs are available to the public through different channels, both government and commercial.

Issues important in drug management for malaria include improved selection and quantification of antimalarial drugs, distribution, and appropriate use in line with developed therapeutic guidelines. Efforts need to be concentrated on providing adequate information about drugs, improving accessibility to appropriate treatment, and eventually regulating and controlling the drug trade.

There are concerted efforts to develop specific interventions aimed at improving the quantification and selection of antimalarial drugs to improve their availability to the population.

The CBOH in partnership with Management Sciences for Health (MSH) began addressing issues related to the selection and quantification of drugs and medical supplies through intensive national training aimed at building capacity in the management of vital supplies. All the 72 District Health Boards have been trained in selection and quantification of drugs and medical supplies. There has been a rekindled initiative to start training health workers in second-level and third-level hospitals to enhance their capacity in drug and medical supplies management.

In line with the National Drug Policy, which includes ensuring the availability of quality and efficacious essential antimalarial drugs to most of the population, much needs to be done to improve their distribution and use in health facilities.

Though the number of antimalarial drugs currently available in both private and public institutions does not constitute a large therapeutic group, their use patterns have not always been in conformity with developed guidelines. Deliberate measures are needed to ensure that there is adequate regulation for drugs to be used at different levels of health care in an attempt to control the spread of drug resistance. A reporting system that can provide more accurate patterns of demand for treatment needs to be developed that would in time allow for adequate adjustments of the distribution system.

Utilization of RPM Assistance

In line with the CBOH action plan, RPM assistance will be required to support the following interventions:

1. Improve selection and quantification of antimalarial drugs in district health boards and hospitals

2. Improve regulation and legislation of antimalarial drugs

3. Strengthen district Drug and Therapeutics Committees on rational use of antimalarial drugs

Drug Management Issues Related to ID Control Programs

Drug Policy and Regulation

National malarial and tuberculosis (TB) treatment policies exist within the context of the National Drug Policy, but there are no specific elements because no major policy changes have been made yet.

The public and private sector play an important role in the diagnosis and treatment of TB and malaria through the provision of diagnostic and treatment facilities, including provision of drugs and other critical medical supplies essential for management of TB and malaria. The public

sector also facilitates the implementation of specific interventions developed for the control of malaria and TB.

There is coordination between the Essential Drugs Programme (EDP) and malarial control and TB control programs, especially in areas of drug procurement, distribution, and use at different levels of health services. The EDP is represented adequately at all forums for malaria and TB control.

Drug Financing

It is imperative to underscore the fact that the funding for drugs in Zambia comes from a resource-based budget unlike a need-based budget. Therefore, prospects for long-term funding are dependent on the availability of resources. Funding for all essential drugs, including malarial and TB drugs, is derived from the following sources:

- Central Board of Health: Through the Drug Supply Fund, which depends on resources from the MOH.
- Cooperating partners: At the moment the Netherlands government is making available support to the government of Zambia for Rural Health Center Kits and Community Health Worker Kits that contain first-line antimalarial drugs.

The Canadian government through the Canadian International Development Agency supports procurement of essential drugs that include first-line and second-line antimalarial drugs.

Procurement by the government is usually through international competitive bidding (ICB) and prices are at least 40 percent more competitive than local or regional prices.

The government of Zambia has recognized the public health importance of TB to the community. In order to address the TB epidemic, treatment services for TB are free to the public. There are no cost-recovery programs for TB and malaria treatment. However, cost-sharing schemes have been introduced for other conditions including malaria, although there are general exemptions for children under the age of five.

Revenues generated for services under cost sharing go into a general fund for improvement of quality services.

Drug Management and Use

There is wide variation in the availability of TB drugs and antimalarial drugs. Generally, the availability ranges from 60 to 80 percent for both categories of drugs because of limited resources.

Under the health reform process, great strides have been made to improve accessibility to essential health services through decentralization of health services.

District Health Boards have been trained in consumption and morbidity methods for quantification of drugs and medical supplies through nationwide training undertaken with the support of MSH.

Drug suppliers are chosen through ICB and their performance verified through performance appraisal at the end of the contract.

The National TB and Malarial Control Program has made available proven effective and cost effective treatment guidelines for use at different levels of health services. Compliance with developed guidelines varies with the levels of general competencies of individual health workers. There has been yet a deliberate measure to regularly monitor and evaluate treatment guidelines for malaria. However, the TB program makes quarterly visits to District Health Boards to monitor and evaluate TB management.

There have been documented studies on the extent of resistance for TB and malaria drugs though the results have varied because of different methodologies used. However, the chloroquine falciparum resistance is estimated at about 30 percent. Except where there are adequate facilities for diagnosing malarial and TB resistance, drug selection has been more of clinical nature than resistance-data based. The newly introduced experimental drugs to contain resistance in malaria include artemisinin. The use has been restricted to TDRC and National Malaria Control Centre.

Drug Quality Assurance

Methods used for quality control for antimalarial drugs include thin-layer chromatography.

There have not been specific documented problems with the quality of products for TB and malaria. However, there was an incident when consumers for the combination of isoniazid and ethambutol complained of tablets melting when put in closed containers. This problem was attributed mainly to physical factors as it was a first combined formulation.

Some Specific Questions for National Malaria Programs

Access to second-line antimalarial drugs is controlled by restricting distribution of specific drugs to only those health facilities where competence for their use exists. However, in the private sector such control does not exist because of various limitations, including commercial interests.

The current registration system is not cumbersome, and where there is evidence that the introduced product is likely to offer health benefits to the population, the regulatory authority has the capacity to rationally support the registration process.

The impact of IMCI on the treatment of malaria has been described as positive. There has been a tremendous improvement in skills in diagnosing malaria and use of antimalarial drugs.
Drug selection for IMCI and malarial control is coordinated within CBOH.

Some Specific Questions for National TB Program

The advent of decentralization has ensured that as much integration as possible is achieved by moving away from the past vertical programs. Though the process is in transition, there has been tremendous effort toward integration of TB services into the health care package developed by the CBOH. The TB drugs are managed through the national essential drug programme.

Although information on exact drug expenditure on essential drugs compared to drugs used to treat side effects of TB treatment may not be readily available, it may be said that no deliberate procurement is made to purchase drugs to treat side effects of TB drugs. Thiacetazone, a drug renowned for life-threatening adverse effects in immunocompromised patients has since been withdrawn.

Annex 4. List of Documents Consulted

1. National Health Demographic Survey and Health Survey, Zambia, 1996.

2. National Health Strategic Plan 1998–2000. Ministry of Health Republic of Zambia.

3. Zambia Health Expenditure Review (2nd draft). Department of Economics, University of Zambia, and Swedish Institute for Health Economics, IHE, Lund. October 1996.

4. Technical Report I and II. Comprehensive Review of the Zambia Health Reforms, 1997.

5. HIV/AIDS in Zambia: Background, Projections, Impacts, Interventions, December 1997.

6. Integrated Supply Management System Framework and Plan of Action. Elvira Beracochea. RPM 1997.

7. Integration of Logistics "The Zambian Experience." O. Hazemba, Managing Director, Medical Stores; P. Fulilwa, Manager Service Support, CBOH; F. Finnan, Technical Expert, Laboratory Services, Irish Aid.

8. Report of the 2nd Mission to the Zambian Action Programme on Essential Drugs (ZAPED) 17–20 April 1995. Brian Stock, Imani Consultancy, Harare; Wilbert Bannenberg, CHD Consultancy Netherlands.

9. DILSAT – District Integrated Logistics Self-Assessment Tool for DHMT – CBOH.

10. Drug Use Studies in Zambia. Facility based study and community based study. Evelyn Hone College, Pharmacy Section Class DF 96/d and Martin Auton.

11. Pharmacy and Poisons Act.

12. Joint Procurement Review Mission between the Ministry of Health and the Central Board of Health and the Collaborating Partners. April 14–24, 1998, Lusaka, Zambia.

13. Minutes of the meeting between local pharmaceutical companies and Ministry of Health and Central Board of Health.

14. Designing and Operating Cost-Sharing Schemes for Health Care Guidelines for Health Centre Staff and Communities. August 1999.

15. Draft National Health Care – Financing Policy Ministry of Health 1998.

16. Final Report on the Establishment of the Essential Drug and Medical Supplies Store. Helling Borda, J. Bates, S. Capper, C. Lijdsman, and M. Mutukwa, March 1997.

17. National Drug Policy.

18. New Price Water House on the establishment of RPA.

19. Standards of Pharmaceutical Practice.

20. District Health Planning Guidelines CBOH Volume I and II 1998 – 1999.

21. Selection and quantification manual CBOH 1998.

22. Stores Procedures for District and Health Centre CBOH 1998.

23. 1998 Annual Health Review. MOH, CBOH.

24. Zambia Essential Drug List.