Improving Drug Management for Public Health:

Lessons From

The Rational Pharmaceutical Management Project

August 2001

Rational Pharmaceutical Management Project
C.A. No. HRN-A-00-92-00059-13
Center for Population, Health and Nutrition
Strategic objective number: SS02,SS03,SS04, SS05

Management Sciences for Health
1515 Wilson Boulevard, Suite 710
Arlington, VA 22209 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpm@msh.org

MANAGEMENT SCIENCES FOR HEALTH

U. S. AGENCY FOR INTERNATIONAL DEVELOPMENT

UNITED STATES PHARMACOPEIA

Management Sciences for Health, Inc.

Management Sciences for Health, Inc. (MSH), is a private, nonprofit educational and scientific organization working to close the gap between knowledge and action in public health.

MSH's commitment to improving public health is based on the premise that the quality of life and human productivity enjoyed by a community depend on many factors but none is more critical than good health. To develop and prosper, community members must have access to basic health services and must believe these will be sustained in the foreseeable future.

Since 1971, MSH has worked with decision makers to improve the management of and access to critical health services such as primary health care, child survival, maternal and child health, family planning, and reproductive health. Using innovative educational strategies, MSH creates opportunities to share our global experiences through technical assistance, training, applied research, publications, and fellowships. We are proud of our contributions to strengthening public health management and improving the delivery of low-cost, efficient, and equitable health services to those who need them the most.

In 1981, with support from the U.S. Agency for International Development (USAID), MSH published the landmark textbook *Managing Drug Supply.* In 1983, MSH established its Drug Management Program (DMP), which, in its nearly 20 years of continuous involvement as a private provider of drug management training and technical assistance, is recognized both as a leader in global initiatives and as the preeminent provider of practical technical assistance in drug management. In 2001, the DMP officially changed its name to the Center for Pharmaceutical Management.

United States Pharmacopeial Convention, Inc.

Since 1820, the United States Pharmacopeial Convention, Inc. (USP), has set standards for the medications used by the U.S. public. USP standards are recognized as legally enforceable by several U.S. federal and state statutes, including the federal Food, Drug and Cosmetic Act of 1938. In the 1970s, USP developed and, in collaboration with MICROMEDEX, continues to maintain the USP DI® drug information database, the most authoritative source of unbiased drug information for health care professionals and consumers. USP drug information has been widely used in Canada and by countries in Europe, Latin America, and Asia for many years.

For more information, contact—

Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, Virginia 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852 USA
Phone: 301-881-0666
Fax: 301-816-8148

U.S. Agency for International Development
g/phn/hn/hpsr
Ronald Reagan Building, 3.07-075M, 3rd Floor
Washington, D.C. 20523-3700 USA
Phone: (202) 712-4789
Fax: (202) 216-3702

Improving Drug Management for Public Health:
Lessons From
The Rational Pharmaceutical Management Project

August 2001

This publication was made possible through support provided by the U.S. Agency for International Development under the terms of cooperative agreement numbers HRN-A-00-92-00059-13, HRN-00-95-00002, and HRN-A-00-00-00016-00 (MSH) and HRN-A-00-95-00001 and HRN-A-00-92-00052 (USP). The opinions expressed herein are those of the authors and do not necessarily reflect the views of the U.S. Agency for International Development.

Recommended Citation

Management Sciences for Health, Inc., and the U.S. Pharmacopeial Convention, Inc. 2001. *Improving Drug Management for Public Health: Lessons from the Rational Pharmaceutical Management Project.* Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, VA: Management Sciences for Health.

Contents

Acronyms

ARDIN	All-Russia Drug Information Network
ARI	acute respiratory infection
BASICS	Basic Support for Institutionalizing Child Survival [USAID Project]
CA	cooperating agency or cooperative agreement
CMA	Christian Medical Association [Zambia]
DIC	drug information center
DINoN	Drug Information Network of Nepal
DMCI	Drug Management for Childhood Illness
DMIS	drug management information system
DOTS	Directly Observed Treatment, Short-course [WHO]
DUR	drug utilization review
EDL	essential drugs list
GMP	good manufacturing practices
HIV/AIDS	human immunodeficiency virus/acquired immune deficiency syndrome
IMCI	Integrated Management of Childhood Illness
INRUD	International Network for Rational Use of Drugs
MOH	Ministry of Health
MSH	Management Sciences for Health
MTP	management-training-planning [strategy]
NCDA	Nepal Chemists and Druggists Association
NDP	national drug policy
NGO	nongovernmental organization
PTC	pharmacy and therapeutics committee
RECPHEC	Resource Center for Primary Health Care
RPM	Rational Pharmaceutical Management [Project]
STG	standard treatment guideline
STI	sexually transmitted infection
TA	technical assistance
TB	tuberculosis
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USP	United States Pharmacopeial Convention, Inc.
USPDI	USP Dispensing Information
WHO	World Health Organization

Introduction

Why Is Drug Management Important?

Pharmaceutical products and vaccines have revolutionized health care in industrialized countries over the past 50 years. Unfortunately, only a portion of that progress is evident in developing countries, where hundreds of millions of people lack access to even basic essential drugs. Millions of adults and children die each year from conditions that could have been treated or prevented if effective and affordable drugs and vaccines had been available and properly used—where and when they were needed.

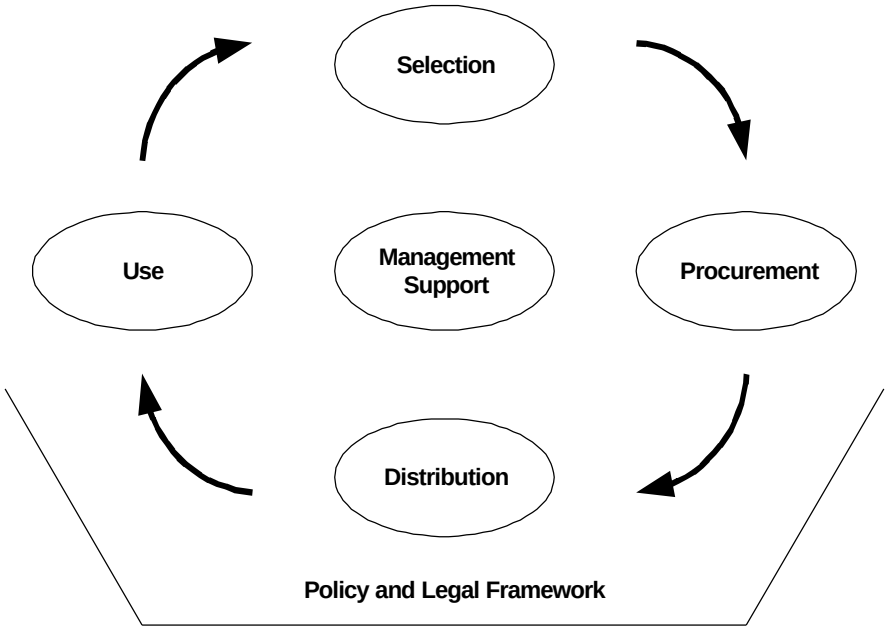
Adequate pharmaceutical supplies are necessary for the success of most health improvement strategies in developing countries. Too many health programs run into trouble because they have failed to address how the drugs essential to their goals will be supplied and managed in the health care system. Drug purchases also represent one of the largest expenditures in public-sector health systems, and drugs are usually the single greatest health-related share of foreign exchange. Because resources are seldom equal to needs, efficient management of pharmaceuticals and medical supplies is crucial.

What Is the Drug Management Cycle?

A useful way to understand the complex field of drug management is to think of it as a cycle. Drug management involves four basic functions—selection, procurement, distribution, and use—that are directly related to each other. Each function builds on the previous one and leads to the next. Problems in any part of the cycle can disrupt the entire drug management system. For example, if the drugs selected are not based on the population's needs, their procurement and distribution can be a waste of scarce resources, and the appropriate drugs will not be available for use by the patients who need them.

A core of management support systems sustains the drug management cycle: financial, human resources, and information management. These systems support the operation of the cycle as a whole, rather than as independent parts. The entire cycle rests on a policy and legal framework that establishes the mechanisms for the different functions and the basis on which they operate.

Figure 1. Drug Management Cycle



Selection

Selection involves analyzing a country's health problems, identifying the best treatments for them, and choosing the specific drugs to provide health care. In addition, selection includes deciding which drugs and treatments will be available at different levels in the health system. Establishing and using a list of carefully selected essential drugs is perhaps the single most cost-effective action that any health care system can take to promote a regular supply of drugs. Essential drugs are those best suited to treat the most prevalent illnesses afflicting a population. Selecting the most useful drugs helps avoid wasting resources on unnecessary, unsafe, or ineffective drugs. Selecting the most appropriate drugs depends on current information about common illnesses, budget limits, and pharmaceutical advances. Many health systems can gain significant efficiencies by focusing on improving drug selection.

Procurement

Procurement includes quantifying drug needs; determining the best methods of purchasing; managing tenders and other methods; and writing contracts. Procurement also involves ensuring drug quality and enforcing adherence to contract terms. Drug availability and costs are tied to the effectiveness of a procurement system. Strong procurement processes help ensure that the right quantities of acceptable quality drugs are purchased at reasonable prices. Procurement strategies vary widely, but most models include the following critical activities: drug needs quantification, bid management, supplier selection, and drug quality assurance. By using proper procurement standards, countries can help ensure that selected drugs are made available for distribution to health centers.

Distribution

Distribution involves getting the drugs through customs and to warehouses and facilities where they can be dispensed to the patients. Effective distribution includes efficient clearing of drugs through customs, transporting them and making timely deliveries, keeping accurate records, maintaining adequate stock levels, and managing available stock. Distribution also includes stock control and management at all levels of the system. Storage managers monitor expiration dates, inventory levels, and storage conditions such as light, temperature, and sanitation. When distribution systems function well and are supported by good procurement practices, patients are more likely to receive necessary drugs on time and in good condition.

Use

Use is a critical function of the drug management cycle because it is the reason the entire cycle exists: to ensure that the correct drugs, in sufficient quantities, reach the patients who need them. Use involves diagnoses of illnesses and diseases, prescribing and dispensing of drugs, and proper consumption of drugs by the patient or administration by a health worker. To use drugs in the most effective, rational way, patients must receive the correct dosage of drugs that best treats their illness. Patients also need enough medication to take for an adequate time, at an affordable cost to themselves and/or to the health system. Labels with proper information and warnings help the patient use the drugs correctly and consistently.

Management Support

Management support, in terms of finance, information systems, and human resources, ensures that the drug management process functions as a cycle. This organizational infrastructure provides structure for the different parts of the cycle and helps to ensure communication among the various parts in the system. The goal of a drug management information system (DMIS) is to collect, process, report, and present the needed information in the most appropriate form for monitoring and evaluating drug management performance and for decision making. An effective DMIS offers useful feedback on how each level of the pharmaceutical system is functioning. The

entire drug management system relies on effectively integrating and managing finances and budgets, maintaining accurate and useful information systems, identifying and motivating capable staff, and instituting monitoring and evaluation systems. The expertise and organizational framework provided through management support are critical at each stage of the drug management cycle.

Policy and Legal Framework

A country's policy and legal framework defines the laws and regulations under which the drug management cycle operates and determines the general goals and parameters for effective drug management. Determining the authority and responsibilities of staff in the field of drug management helps ensure that the entire system works for the benefit of the public's health. Drug policies include allocating budgets, prioritizing research and development, promoting education initiatives, and defining the role of the public and private sectors in drug development. Through pharmaceutical laws and regulations, countries can determine drug quality standards, set price limits, require licensing of drug products, and establish production guidelines.

Rational Pharmaceutical Management Project

In 1992, the U.S. Agency for International Development (USAID) awarded initial five-year cooperative agreements to Management Sciences for Health (MSH) and the United States Pharmacopeial Convention, Inc. (USP). USAID teamed the two organizations because of MSH's long-standing dedication to drug management training and technical assistance and USP's reputation as an authoritative source of unbiased drug information for health care professionals and consumers. The two agreements composed the Rational Pharmaceutical Management (RPM) Project, which was extended and expanded for a total of eight years. MSH received $18.3 million for the RPM Project, plus an additional $2.37 million for work in Russia. USP received $2.4 million for the RPM Project.

The goal of the RPM Project was to improve the efficiency, equity, and quality of drug management in developing countries by promoting improvements in the allocation and use of resources in pharmaceutical systems. USAID designed RPM on the premise that significant improvements in drug availability and use, as well as substantial cost savings, could be realized through a systematic program of targeted short-term technical assistance. Following the project's initial country assessments, RPM focused on three revised priority technical areas of need:

1. Improving allocation, management, and use of resources
2. Promoting the rational use of drugs
3. Improving the level of drug information

Country Programs

Between 1992 and 2000, RPM endeavored to meet needs in its priority technical areas by developing and implementing programs in various countries around the world. Countries were selected based on the following criteria:

- Need for assistance in RPM priority technical areas, demonstrated by the findings of pharmaceutical assessments
- Ministry of Health (MOH) interest in having an RPM program
- USAID Mission receptivity to including an RPM program in its portfolio
- RPM judgment that reasonable progress was feasible

In all of the countries in which the RPM Project worked, health care reforms were ongoing. The systems-based drug management cycle provided a useful guide in determining how such changes were affecting drug supply and in what way technical assistance would be most beneficial. RPM established country programs in Bangladesh, Ecuador, Honduras, Hungary, Kazakhstan, Moldova, Mozambique, Nepal, the Organization of Eastern Caribbean States, Peru, Poland, Russia, Ukraine, and Zambia.

Central and Regional Activities

In addition to country programs, RPM managed a number of central- and regional-level activities supported by the USAID Global and regional bureaus. These activities included operations research and tools development to support USAID strategic objectives related to child survival, reproductive health, infectious diseases, and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). In undertaking these activities, RPM aimed to identify better ways to collect and use data in support of improved drug management practices and then to disseminate this information to USAID Missions, other cooperating agencies, international organizations, and other donors.

The Lessons

The eight lessons MSH and USP learned during the course of implementing the RPM Project follow. The first seven address technical issues of drug management and the last addresses project management issues specific to the RPM Project.

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

Highlight

Implementation of a Formulary System in Moldova

Moldova adopted a policy for establishing a national formulary system as part of an NDP to rationalize drug use. The Central Health Authority developed a formulary and distributed it to government facilities. The formulary was not well received by practitioners largely because they were not consulted during the development phase. RPM brought the various stakeholders together in a series of workshops, meetings, and lectures to understand their concerns and to offer them an orientation to the concept of formularies. Workshops were followed by on-site technical assistance and training. This approach, while more time consuming than the Central Health Authority's top-down approach, was more successful, resulting in acceptance of the national formulary and support for the development of subset formularies in all three of the demonstration-site hospitals.

Health policies, whether implicit or explicit, formal or informal, comprehensive or limited, are statements about the commitment of governments to certain values and goals regarding the health of the population, and drugs are necessarily implicated. Strategies to implement health policies can be complex. Such strategies often affect supporting systems such as those regulating drug supply. Implementation problems include poorly specified policies and strategies, unrealistic or inappropriate implementation plans, and failure to monitor the progress and impact of implementation on system performance.

Until recently, the standard approach to organizing public-sector pharmaceutical systems included centralized financing. Procurement and distribution of drugs occurred through a central medical stores, and the state owned and managed the entire system. All of the countries in which RPM worked underwent health reform that involved structural changes whereby the centralized approach was either completely or partially abandoned, from partial to complete devolution of responsibility to the facility level. In many cases, these changes were accompanied by efforts to integrate numerous vertical programs (such as malaria control and reproductive health) into the larger health and drug supply system.

As part of the health reform movement, the national drug policy (NDP) concept has taken hold in more than 60 countries over the past 20 years, due in large part to the efforts of the World Health Organization (WHO). National drug policies identify the goals and objectives for the public sector to ensure the availability of essential drugs. Many of the countries where RPM worked also have NDPs or key elements of NDPs, including Bangladesh, Ecuador, Kenya, Mozambique, and Nepal. The mere existence of policy, however, does not guarantee implementation. All of these countries continue to have serious problems with drug availability and use, resulting largely from lack of implementation of the NDP.

Implementation plans are frequently unrealistic or inappropriate. Policy makers may not take into account the need for a legal basis to support policies and strategies such as decentralization of health systems. Moreover, the time and political commitment needed to put laws into place are underestimated. Not uncommonly, health system reformers overestimate what can be achieved with existing resources and how quickly new programs can be implemented. In Zambia, for example, plans to establish a drug regulatory agency were unrealistic because decision makers did not adequately consider human resources or budgetary requirements.

For effective drug management activities to take place, some sort of authority and legitimacy must be established. For example, when RPM worked in Russia, no NDP existed, and a comprehensive “Law on Drugs” had been tied up in the federal legislature for several years. Therefore, no national policy basis existed for the activities RPM recommended in formulary development and drug procurement. In the absence of national-level policy, RPM sought *oblast* (state) support and legitimacy for recommended RPM activities by recommending that local health authorities include them in annual oblast health workplans. As a result, oblast authorities have been able to monitor the progress of the program through the annual workplans.

Working Solution: Managing the Implementation of Decentralization in Zambia

In the 1990s, following a national conference on National Health Policy, Zambia began one of the most dramatic health sector reform initiatives in Africa. The plan called for financial and management accountability at all levels, decentralization of procurement to the district level, and integration of vertical programs. The decentralization plan called for drug procurement to remain a central activity. The quantification of needs, however, was to be a new responsibility at the district level, and furthermore, district health services were also required to integrate 19 vertical programs.

When it was unclear to the Zambian government how many of the proposed changes would be implemented, it asked RPM to provide assistance. In some cases, in an environment of scarce resources and heavy donor dependence, the method of financing proposed reforms was not identified. Almost immediately, budgetary issues needed to be resolved. RPM conducted a study to estimate the drug, equipment, and supply costs to comply fully with proposed reproductive health guidelines. The study revealed that the costs would have exceeded the country's entire budget for drugs. Clearly, districts were submitting requests for drugs and supplies that were not accurately estimated because their staffs had not been trained in the basics of quantification, and they failed to include vertical programs.

RPM took the lead in coordinating varying input from the district and program staff, creating an integration plan, and providing technical assistance with implementation. More than 200 persons were trained in basic quantification during the first year. In the following budget cycle, all 10 priority health districts in Zambia submitted realistic requests for drug needs and medical supplies.

Although WHO has developed a set of indicators for monitoring the implementation of national drug policies at the national level, monitoring is rarely accomplished. Monitoring the implementation of policies is critical for ensuring that policies and plans achieve their desired outcomes and do not have unanticipated negative consequences. To address this need, RPM developed indicators for rapid assessment and conducted assessments in the Eastern Caribbean, Ecuador, El Salvador, Ghana, Mozambique, Nepal, Russia, and Ukraine.

An important sublesson relevant to technical issues of drug management took form as RPM worked to implement policy and strategies in support of drug supply: The specific needs of programs must be taken into consideration within the context of the overall drug supply system. Two widely known instances of adopting case management as a strategy in rationalizing care for common public health problems in the developing world illustrate this sublesson.

1. In 1992, WHO and the United Nations Children's Fund (UNICEF) developed the Integrated Management of Childhood Illness (IMCI) strategy for reducing childhood illness.

2. The Directly Observed Treatment, Short-course (DOTS) for the treatment of tuberculosis in selected sites presented different treatment schedules from those used in the past.

Highlight

Drug Management for IMCI

RPM, in collaboration with USAID, the Pan American Health Organization, and the Basic Support for Institutionalizing Child Survival (BASICS) Project, developed the Drug Management for Childhood Illness (DMCI) tool. The tool, based on the use of indicators, helps IMCI managers identify and address important drug management issues that could hinder IMCI implementation. The tool was first tested in Ecuador, where it identified weaknesses in need of attention for most aspects of drug supply: vitamin A, indicated for treatment of anemia, malnutrition, and measles, was not on the EDL; the information system was severely hampered by poor record keeping and inventory management practices; antibiotics were overprescribed for acute respiratory illnesses and nonbacterial diarrheal diseases; and a group of IMCI tracer drugs was available less than 50 percent of the time on average over a period of one year.

For these and similar case management strategies, the drugs recommended for use should be included on a country's essential drugs list (EDL), minimizing the possibility of such drugs being overlooked in procurement activities.

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

International development efforts have frequently focused on the public sector, relegating to secondary importance the private sector. This focus has prevailed for many reasons. The public sector may be the largest and most influential health care provider and payer and is often the only provider for important segments of the population. In addition, government-to-government agreements may dictate a public-sector focus. Interest has been increasing, however, in the potential role of the private sector to support public health goals.

Private drug sellers can and do influence consumer drug use behavior. They are often the first point of consumer contact with health services, and they may also have the only drug supply available. It is estimated that in many developing countries, the value of drugs issued by the private sector is five to ten times larger than that issued by the public sector. For these reasons, drug sellers represent a potential human resource for public health. However, these providers may be untrained or unknowledgeable, unable to ensure drug product quality, and more interested in business than public health.

Nongovernmental organizations (NGOs) also provide important health services to a significant proportion of the population in developing countries. An important opportunity to improve drug management exists in countries where the public sector is partnering with NGOs.

The private sector can be brought into drug management activities through professional associations. These associations can serve

Highlights

Improving the Public Sector through the Private Sector

The **Russian government**, as part of a policy to open the economy, allowed pharmacies to privatize with the hope that this step would lead to more efficiently filled public-sector client prescriptions. For this plan to work, it was essential that privatized pharmacies succeed as businesses. RPM worked with selected private pharmacies to develop business plans for operating more efficiently. These plans included learning new skills in pharmacy operations, human resource management, financial analysis and decision making, and marketing. The pharmacy managers themselves developed and implemented business plans. Their procedures were then adopted by the regional pharmacy licensing authority to develop and implement business turnaround plans for several failing public pharmacies. Benefits for both public and private pharmacies included an increased assortment of pharmacy goods, decreased prices of pharmaceuticals to patients, and an increase and improvement in pharmacy services.

Drug sellers in Nepal, who receive minimal formal training, account for a very high percentage of total drugs dispensed. Because of the concern about the misuse of antimicrobials in the country, interventions under USAID's Program for the Prevention and Control of Selected Infectious Diseases to Improve Drug Use targeted drug sellers. RPM solicited the support and involvement of the Nepal Chemists and Druggists Association (NCDA), which is a member of the Drug Information Network of Nepal (DINoN). NCDA, with 12,000 licensed private drug sellers in 12 chapters around the country, endorsed the study, and it supported training to improve drug sellers' practices. NCDA also participated in a national USP/RPM-sponsored workshop on using drug information to combat antimicrobial drug resistance. NCDA made a presentation on the ethics of drug marketing in a forum that also included drug regulators, doctors, and consumer advocates. Finally, NCDA distributed posters developed by another drug information center in Nepal to its drug retailer members. These posters contained messages to educate the public regarding proper use of drugs, by, for example, suggesting that consumers check the expiration date of the medicine they buy and look to see if their tablets are discolored and by encouraging users to keep medicines away from children and to consult their doctors about when and how often to take prescribed drugs.

as implementation partners and efficient vehicles to reach large numbers of influential physicians and pharmacists. Professional opinion leaders can be urged to participate in the development of national policies and guidelines that will influence professional practice in both the private and public sector, promoting a unified approach to drug use.

As countries develop and the private sector matures, increased opportunities exist for the private sector to carry out many public health drug management functions. In developed countries, the trend has been for the public sector to increase efficiencies by moving away from the role of a direct provider of services toward the role of payer and overseer of quality and cost issues.

With this trend in mind, MSH has been helping governments evaluate options for improving drug supply. In the Philippines, one option was to contract with a private-sector prime vendor to carry out procurement and distribution functions, with the government retaining responsibility for selection and quantification. As a result of the MSH assessment, the government decided that transportation of drugs from warehouses to health facilities could be contracted with the private sector. In Mexico, MSH helped the Social Security Institute to evaluate an unsolicited private-sector offer to provide drug distribution and presented various options for restructuring. After conducting an assessment of the drug supply system, however, MSH determined that more significant and immediate savings could be achieved by revising the country's drug list.

Highlights

Improving the Public Sector through the Private Sector

In **Zambia,** the Christian Medical Association (CMA) provides between 10 and 20 percent of Zambia's primary health services. CMA staff are well trained and therefore represent a valuable technical resource for the country. RPM facilitated CMA participation in project-sponsored national efforts to create standard treatment guidelines (STGs) and a formulary that would apply to all health services, public and private, in the country. In addition, RPM involved the Private Pharmaceutical Association of Zambia in development of national-level policies, formularies, and STGs.

In **Bangladesh,** NGOs provide a significant portion of basic health services. RPM trained NGO physicians from both rural and urban areas in rational prescribing and patient counseling and in methods to strengthen revolving drug funds.

In **Mozambique,** RPM's work on drug information planning involved the Mozambique Medical Association in a workshop on drug information in clinical decision making.

In **Hungary,** RPM worked with a national medical association to conduct a survey of prescribing practices of its general practitioner members.

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

Whereas donors and developing countries often devote the major portion of their health resources to improving primary care, patients often first seek care at hospitals, bypassing primary public health clinics. Lack of resources at the clinics and the perception of better quality services at hospitals are factors contributing to this behavior. In fact, hospitals often provide services that account for a significant portion of public health budgets. Hospital drug expenses are substantial, in part, because hospitals treat more serious and complicated conditions that necessitate access to a wider range of drugs; also, hospitals are essential for providing specialized drugs in public health to combat such problems as tuberculosis (TB) and HIV/AIDS.

The 1997 International Conference on Improving Use of Medicines, cosponsored by RPM, WHO, International Network for Rational Use of Drugs (INRUD), USP, and Applied Research for Child Health, recognized a gap in knowledge about hospitals in developing countries. A review of the existing literature revealed that most interventions to improve drug use in developing countries have focused on primary care. Subsequent to this review, understanding what interventions may work in hospitals to improve drug use was identified as a pressing research priority.

Highlight

The Cost-Estimate Strategy in Kenya

The Coast Provincial Hospital in Kenya needed information on the volumes and costs of drugs and supplies used for its maternity services in order to plan for expansion. MSH provided technical assistance in applying RPM's spreadsheet-based Cost-Estimate Strategy to help with this planning. The drugs and supplies required to treat 14 conditions according to standard treatment guidelines were identified and numbers of yearly cases were estimated. Medical records were reviewed and practitioners were surveyed to learn how the conditions were actually being treated. The exercise showed that more than 80 percent of the costs could be attributed to only four conditions. Of parallel importance, RPM's work revealed that two key drugs for these conditions were out of stock 83 percent of the time from the hospital storeroom and two others were out of stock 100 percent of the time, indicating a pressing need to identify the underlying causes of these stock-outs.

In some of the former Soviet Union countries (Russia, Ukraine, and Moldova), hospitals were seen as logical starting points for RPM because the health care systems were built around hospitals rather than primary care clinics. In addition, decentralization shifted decision-making

authority for selecting drugs from the national level to the individual hospital level. Nonhospital-based clinics did not have drug budgets. After discussions with the local authorities, RPM decided to focus on improving hospital drug selection and use within these countries.

The development of pharmacy and therapeutics committees (PTCs) is one strategy hospitals can use to address issues of drug selection and use. These committees typically develop policies and procedures on the use of medicines, develop and update the hospital drug formulary, and monitor and evaluate drug use. PTCs often have major responsibility for meeting the education and drug information needs of the professional staff. PTCs not only are a new concept for many countries, but they also present a new practice and management paradigm. Committee members need to be educated about what PTCs do as well as about how to carry out their responsibilities as a committee in a context of resource constraints and limited access to information. In Peru, RPM developed training modules to strengthen the PTC. These modules were used in 20 district-level hospitals. RPM also introduced the concept of PTCs and the use of formularies in Russian hospitals.

The PTC can be greatly facilitated by the establishment of accessible sources of reliable drug information, such as drug information centers (DICs) that disseminate information through bulletins, courses, and workshops about issues such as the use of unbiased information, new drug information, and drug side effects. DICs ideally respond to specific requests for information from physicians, pharmacists, and the public, and they can provide especially useful assistance to hospital committees involved in formulary development or drug utilization reviews, sometimes

Working Solution: Improving Drug Selection and Use in Russian Hospitals

In Russia, the collapse of the health care system established under the Soviet Union resulted in drug selection and procurement responsibilities being shifted directly to hospitals. Managers and clinicians were not prepared to take on these new tasks. Budget cuts and the plethora of drug products available on the newly liberalized market complicated the situation. In 1994, RPM and health administrators in Ryazan Oblast agreed to introduce the concepts of formulary systems and pharmacy and therapeutics committees.

With RPM assistance, the Ryazan Oblast Hospital formed a multidisciplinary committee to choose an official list of drugs approved for procurement and use in the hospital. First, the committee listed all 1,500 drugs then being used in the facility, including cost and volume of use information to determine how funds were being spent. Drugs on the list were then grouped by therapeutic category, and the committee, taking into consideration the following criteria, reviewed each group: cost, safety, efficacy, medical need, product quality, reliability of supply, and duplication. In preparation, RPM trained committee members how to objectively review drug information. The result was an official formulary list containing only 480 drugs. The hospital procurement department adopted the new formulary and reallocated approximately $51,000 from deleted drugs to formulary drugs during the first year. With RPM assistance, the committee produced a pocket-sized formulary manual containing basic drug information and prescribing guidelines and distributed copies to physicians, nurses, and pharmacists. The committee also began to regularly monitor prescribing and use of the most critical drugs on the formulary.

These initial results produced interest from other hospitals in the oblast. On the basis of the Ryazan Oblast Hospital experience, RPM and counterparts developed a manual on how to implement formulary systems. RPM began to work in Novgorod and Pskov oblasts and conducted a series of training courses for hospitals from all three oblasts. By mid-1997, 61 hospitals had developed formularies. The number of drugs used by participating hospitals decreased overall by 32 percent.

RPM and the participating oblasts reported on this work at four consecutive Man and Drugs Congresses in Moscow. This exposure generated considerable interest on the part of non-RPM oblasts. RPM responded by providing training materials and limited assistance to several oblasts, but many others began work on their own, based on the favorable reports at the congresses.

as the center of those processes. In Russia, for example, a representative of the DIC was always a member of formulary committees supported by RPM.

In addition to the clinical benefits of enhancing the role of PTCs, individual hospitals can realize financial gains by improving procurement of drugs or by organizing into buying groups with other hospitals to take advantage of bulk purchases. Distribution within most hospitals can also be improved. Many hospitals now rely on systems where a significant number of drugs are kept in bulk on the wards, and some drug orders are handled much the same way outpatient prescriptions are filled. Arriving at an optimal combination of these two systems and introducing "unit-dose" distribution where it is feasible can save funds and improve patient care.

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

Officials, prescribers, and pharmacists in every country where RPM worked expressed serious concerns about drug product quality. Markets that often lack technical capacity operate in these countries without sufficient efforts to ensure and monitor the quality of the products circulating. Furthermore, as responsibilities for drug procurement are decentralized, ensuring drug quality sometimes becomes the responsibility of inexperienced or unprepared staff who often lack adequate facilities to carry it out. Given this situation, it is not surprising that drugs can be found in the market that are falsely labeled, mislabeled, or of such poor quality that they are clinically ineffective or dangerous. In the private sector, the lack of effective regulation and the inability of sellers to spot problems also lead to the selling of drugs of dubious quality.

Working Solution: Structuring and Refining TB Tender Documents in Kazakhstan

In Kazakhstan, weak procurement practices in 1998 resulted in the purchase of low-quality TB drugs. The tablets crumbled, they were found to be subpotent, and the country of manufacture was uncertain. Procurement contracts allowed for no recourse or manufacturer penalty. Upon review, RPM found that the tender documents were inadequate and the adjudication process lacked transparency. In 1999, to support Kazakhstan's next national TB drug tender, RPM provided technical assistance to the MOH and the National TB Tender Committee to structure and refine TB tender documents. This assistance included the development of a standard bidding document with supplier instructions and clear drug specifications. RPM also conducted a workshop to train procurement specialists in good procurement methods practices, such as—

- Requiring a specified level of drug manufacturer experience, references from other purchasers, letters from banks confirming manufacturer reliability, good manufacturing practices (GMP) certification, proof of manufacturer and product registration in their country of origin, quality certification of every batch by an independent international laboratory, and drug samples with every bid
- Specifying in the contract the manufacturer's responsibility for drug recalls, fines in the event that poor quality drugs are received, packaging requirements to protect the product en route, labeling requirements, payment through a letter of credit so that payment can be withheld if drug products do not meet quality requirements, and delivery scheduling
- Following up to assess quality of drugs received and to record all problems for redress and for reference in future procurement actions

All companies that won tenders in 1999 provided documentation of compliance with GMP standards stipulating that all products met either British Pharmacopoeia or U.S. Pharmacopoeia standards. The next step will be to follow up on supplier performance to determine whether drug product quality actually improves. Processes are in place to do this through the national drug-testing laboratory.

Poor drug quality can often be attributed to the lack of a drug registration system and poor drug procurement procedures. An effective drug registration system acts as an initial filter to prevent poor quality drugs from entering the market, allowing procurement organizations to focus on obtaining the right quantities of drugs at the best possible price and serving as the second line of

defense against quality problems. This situation, however, rarely exists in developing countries, where government efforts to ensure quality are often hampered by lack of financial and human resources. Some countries do not have a formal drug registration system in place and the absence of such a system may be a logical starting place for efforts at eliminating poor quality drugs from the marketplace.

RPM addressed drug product quality mainly by working with country staff to improve procurement practices to include quality assurance mechanisms. Although strengthening the procurement process alone will not ensure that products meet acceptable standards, it is an important step in the right direction. This effort is particularly necessary as programs experience increasing pressure to procure cheaper drugs. RPM recognized that increased attention is still required to improve the entire quality assurance process.

Lesson #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.

Decision makers at all levels of a health care system need reliable management information. Important health- and program-related decisions are frequently based on incomplete, inaccurate, outdated, or inappropriate information. Sometimes these decisions are made with little or no information at all. Even where useful information is available, the ability to use the information may be lacking. Many of RPM's activities involved helping decision makers generate, provide, and use management information to design and plan drug management activities. The systematic collection and analysis of data to assist decision makers in understanding the status of pharmaceutical systems, identify strengths and weakness, design interventions, and monitor change over time was the focus of the MSH rapid-assessment approach, the Drug Management for Childhood Illness tool, the Cost-Estimate Strategy for reproductive health commodities, ABC/VEN analysis software, and the Management-Training-Planning strategy.

Persuasive management information is essential for garnering the support of policy makers and influential clinicians and managers for important drug management reforms. Policy makers are often particularly receptive to financial arguments, such as when proposed reforms are clearly linked to cost savings. In the Central Asian Republics of Kazakhstan, Kyrgyzstan, and Uzbekistan, information presented by RPM and BASICS on the cost of irrational prescribing, including the potential for savings that would result from following treatment guidelines, influenced the federal MOHs to support IMCI in the region.

Given the complexity and interrelated nature of the drug management system, identifying the causes of system malfunctions is challenging, demanding an understanding of the entire system. In most places where RPM worked, little to no hard data existed about how the drug supply system was functioning. Anecdotal explanations were plentiful, but these provide a very weak basis for developing a program of activities to improve the system. A shortage of drugs on the shelf is not a problem per se, but rather a symptom of any number of potential failures in the system. In the absence of existing information, a comprehensive pharmaceutical sector assessment is an important starting point. Such an assessment can identify resource allocation problems, waste, and gaps and bottlenecks in the system. In addition, the exercise should provide baseline data against which impacts of interventions may be measured.

Although health reforms were universally taking place before the advent of the RPM Project, reforms had been implemented with an incomplete understanding of their potential impact on the drug management system. RPM conducted assessments in Ecuador, El Salvador, Ghana, Mozambique, Nepal, Russia, and Ukraine. Prior to the assessments, only anecdotal information was available about the status of drug management in those countries. The assessments supplied previously unavailable data on drug availability, prices, stock management, and usage.

Country-specific drug management information is essential for successful implementation of recent global initiatives such as IMCI and Roll Back Malaria at the country level, as well as for combating priority diseases such as TB and HIV/AIDS.

Management information that is available internationally often is not easily accessible to decision makers in developing countries. They may not know of important information resources that could be accessed free of charge, or they may not have the resources to purchase key commercial publications. RPM often played the role of information disseminator by providing secondary published information directly to decision makers and managers and by pointing them to previously unused but readily available resources.

In some countries, drug information centers can be extremely useful mechanisms for gathering, evaluating, and distributing drug information for use by clinicians, pharmacists, administrators, and the public. Led by USP, RPM established centers in Mozambique, Nepal, and Russia. RPM trained staff in these centers to identify sources of unbiased drug information, to evaluate research articles and data submitted by drug companies, and to present information to decision makers in a useful manner. USP provided the centers with drug information monographs, access to the Internet, and funds to purchase key publications. Assessments of these countries had found that unbiased, current drug information had been relatively unavailable and the information that existed was virtually inaccessible outside a few elite institutions.

Highlights

Focus on Information

TB Drug Assessments

RPM conducted two assessments of TB drug availability and use in Russia, where TB morbidity rates have doubled in the last decade. The first focused on drug availability and the methods used to procure first-line TB drugs. The findings showed that hospitals engaging in pooled procurement tended to have better drug availability, and those that used competitive tendering experienced lower TB drug costs.

The second assessment focused on TB diagnosis and treatment methods in hospitals in five regions. Findings showed that treatment was hampered by drug shortages and delays in sensitivity testing. The findings also revealed that treatment practices did not conform to international standards, causing significant clinical and cost implications.

DMCI Assessment

In May 1998, RPM assisted Bolivia in applying the Drug Management for Childhood Illness methodology and tool. The findings from the assessment were timely because the national health insurance plan, *Seguro Basico de Salud*, was about to include the IMCI drugs in the social security program. The DMCI assessment identified limited availability of IMCI products, poor stock management of drugs, irrational use of antibiotics, and weak dispensing practices in health facilities. Providing the findings 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 Basico de Salud.

Providing Information

MSH's annual *International Drug Price Indicator Guide,* presented in three languages, helps supply officers determine the probable cost of pharmaceutical products for their programs. The *Guide* can be used as a reference to compare current prices paid with those prices available on the international market. The *Guide* includes nonprofit suppliers and international procurement agencies, as well as actual prices obtained through international competitive bidding.

In all RPM countries, significant weaknesses were found in the ability of decision makers and managers to use data and information already available to them. In some cases, health facilities routinely collect large amounts of data. In systems that are more centralized, this information is sent to the central level where decisions are made. Many times, however, it was not clear that these data are used. In some instances, data may be collected without any idea why or how to use them, and, in others, key data may not be collected. For example, an MOH may not routinely calculate the per capita annual drug expenditure or the proportion of drug expenditure to the overall health budget; nonetheless, these simple calculations can tell a country a great deal about its spending and drug use patterns.

RPM found that efforts were required, and will be required for some time, to help decision makers and managers use information. To make the most use of information, knowledge must be combined with the skills to critically review information. This critical analysis includes identifying potential sources of bias, strength of argumentation, and level of evidence as well as understanding the relevance and relationship of information to other factors. If decision makers and managers are expected to make use of assessment information or make use of information obtained through system monitoring programs, these skills must be developed.

Working Solution: Making Use of Available Data in Ukraine

In Ukraine, data has long been collected on hospital patient days, reasons for hospital admission, mortality, and other patient-specific information. However, when RPM started working in Ukraine, the medical and pharmaceutical staff were not using these data to improve health services. With RPM assistance, district-level hospitals interested in harmonizing treatment approaches within their region decided to use data they were already collecting to help determine which conditions were most prevalent in the region. They learned that infectious diseases accounted for four of the six top reasons for admission. For example, acute respiratory infection (ARI) alone accounted for 13 percent of admissions. When staff cross-referenced the reason for admission with age groups, they found most ARI patients were children. Staff decided to make the availability of antibiotics a priority. Hospital staff also collected additional data on prescribing habits related to the top three reasons for admission, which together accounted for 20 percent of admissions. The analysis of this information formed the basis for developing standard treatment guidelines for the region, which are now being compared with the national STGs.

RPM also assisted staff to use data to help them understand the financial impact of different treatment practices. Before these efforts, staff did not consider the cost implications of their treatment decisions, particularly as they related to the financial viability of the hospital.

Lesson #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 remain a challenge.

In countries where RPM worked, unbiased information sources were limited and in most instances were not effectively used. Outside a few elite institutions, most information available to health care practitioners has come from the pharmaceutical industry. Drug companies have the resources to package and distribute information on their specific products to a wide audience; however, because dissemination of this information is intended to support product sales, it is seldom complete and has the potential for not being objective. RPM studies in Ghana, Mozambique, Nepal, Peru, Russia, and Zambia found numerous instances of misleading information in industry-sponsored publications, including questionable information on uses and dosing and lack of information on side effects and precautions.

Whenever possible, drug information issues need to be defined and addressed at the local level. In order to do this effectively, assessments of available resources must be completed at an early stage of the project. RPM baseline assessments found that locally specific information for health care providers was generally not available, nor was information targeted to patients and consumers. Not only was the information unavailable in local languages, but also it sometimes included dosage forms and amounts, brand names, precautions, and other information that would be primarily applicable only to products available in certain industrialized nations. Newly developed unbiased drug and therapeutics information directed at the health care provider must reflect local product availability and use recommendations following STGs. Information for patients and consumers must be locally developed to reflect cultural practices, social norms, and local health care policies and practices.

RPM-facilitated DICs in Mozambique, Nepal, and Russia were able to increase the availability of current, unbiased information. A discrete unit with specific goals and objectives provides a focal point for information development, communication, and education initiatives. In order to localize the information they would be dispersing, centers were provided with electronic versions of the USP DI® drug information database; however, transfer of such technology is not easy, and training and follow-up are essential. DIC staffs were trained to install and operate the database and to adapt the information for local needs. Most of the centers now produce and disseminate drug information in the form of newsletters, bulletins, books, workshops, newspaper articles, editorials, and radio or television programs. Using appropriate technology and providing necessary training have been key to achieving success in developing countries, where both physical resources and skilled human resources are often in short supply. Internet and E-mail communications to support drug information development and dissemination are central to the success of these programs.

Highlight

Focus on Nepal

The **Drug Information Network of Nepal (DINoN)** was established by five drug information centers representing governmental and private institutions in Kathmandu. RPM began its work in Nepal with a national workshop to raise awareness about the importance of unbiased drug information, then supported DINoN members with equipment, training, funds, provision of the USP DI® drug information database for adaptation, a CD-ROM version of the database adapted for Nepal, and other drug reference materials. Network members, with minimal support from RPM, expanded this work on their own initiative to meet the needs of their particular constituencies. Two additional organizations joined DINoN: British Nepal Medical Trust and United Hands to Nepal Poison Information Centre.

- The network held workshops for journalists and community leaders, such as teachers and local officials, on the importance of proper drug use.
- The Department of Drug Administration, MOH, housed a center that provided information to all of the public health clinics through a bulletin and assisted in the drug registration process.
- The Institute of Medicine, Tribhuvan University Teaching Hospital, the main teaching hospital in Nepal, housed a center that provided drug information to physicians and academics.
- The Resource Center for Primary Health Care (RECPHEC), a center run by a local nonprofit organization, provided information to primary health care workers by distributing an RPM-supported newsletter that included a column on proper drug use. With RPM support, this same center also worked to bring drug information to the public, developing educational posters for pharmacy outlets and working with a radio station to include drug information content in its broadcasts. RECPHEC began adapting USP pictograms designed for patient drug information for the Nepalese population.
- The Nepal Chemists and Druggists Association houses a center that publishes a newsletter for its 12,000 licensed private drug seller members. The association also facilitated RPM's study of private drug seller dispensing and counseling practices.

Building drug information initiatives on existing, well-established infrastructures is critical to increasing the likelihood of long-term success and sustainability. Recognizing and building on the work of local organizations already in place obviates the need to build a new infrastructure, saving time and resources. Personal interest and stakeholder status in any new activity are essential to success, and building on existing programs increases the probability of finding counterparts who have sincere interest in the work being done and in establishing new initiatives. In turn, these new initiatives are more likely to be seen as growing from existing programs rather than perceived as potentially competitive and threatening new programs. Finally, concepts of rational drug use and access to unbiased information may not be readily recognized by policy makers as critical components of rational pharmaceutical management. A greater likelihood of acceptance exists if such activities are established within the context of existing institutions, clearly linked to measurable outcomes such as improved drug access, cost savings, and better patient care.

Partnering with other organizations from both the public and private sectors is essential. Building local alliances and networks appears to be key to sustainability of drug information resources and broader dissemination of information within a country or region. In Russia and Nepal, RPM facilitated the linkage of drug information centers to form networks for greater dissemination of information and to maximize the use of available resources.

Loosely structured networks of diverse institutions are challenging to sustain, and such alliances are only effective if the goals of the network are clear and mutually agreed upon by all members. RPM found that professionally facilitated summits of organizational leaders could resolve obstacles presented by internal politics, organizational competition, and management styles that vary across cultures. For example, a summit for the leaders of the All-Russia Drug Information Network (ARDIN) was able to define the mission of the network, a vision for the future, impediments to ARDIN's development, objectives for the network's growth, as well as principles of interaction between the members, and designate the members of a coordinating body.

As RPM gained experience in the pharmaceutical and health care sectors in targeted countries, demand for an increased focus on the clinical application of drug information was noted. This encouraging outgrowth of the basic provision of drug and therapeutics information is indicative of potential impact on patient care. As the country became more market-oriented, physicians in provincial hospitals in Mozambique asked RPM for information on "new" drugs that were entering the market. Updated, condensed drug monographs in Portuguese were created and targeted to provincial physicians. In addition, RPM reached physicians directly through specialized training in drug and therapeutics information for new physicians and through continuing medical education programs. Of particular note was the success of physician training initiatives that used a problem-oriented approach.

Disease treatment guidelines present another opportunity for dissemination of objective drug information on a regular basis. Many developing countries have guidelines for the most common public health problems such as malaria, sexually transmitted infections (STIs), and diarrheal diseases, but few guidelines include practical drug information that can be updated to include treatment protocols and the drugs of choice for the country as well as drug-specific information including precautions, side effects, pharmacokinetics, and dosing for the patient populations being targeted. Because treatment guidelines are often widely distributed and sometimes created in various versions for different levels of the health care system, many more health care providers can be reached with current, accurate information.

RPM began providing information using a traditional public-sector approach but found the unavoidably slow movement of government bureaucracy was inefficient. Progress sometimes occurs more quickly using NGOs. This broadening of focus for RPM presented lessons to be applied to other countries privatizing their pharmaceutical sector; however, RPM had to be flexible in project implementation, working with local consultants and adding technical assistance in grassroots training program development.

RPM's target audience increased and diversified with each year of operation. Originally aiming primarily at pharmacists and drug regulators, RPM worked increasingly with primary care

physicians and pharmacologists and ultimately included private sector retailers, infectious disease specialists, and veterinarians. Considerable opportunity exists for further technical assistance in academic curriculum development and continuing education. Many countries have no requirements for routine relicensing based on continuing education credits. Continuing education is a logical way for health care practitioners to stay current with drug information and efforts should be made to work with professional bodies and regulatory agencies to develop continuing education requirements. However, RPM found that educational initiatives in academia must focus on "learning how to learn." The traditional system of learning by rote in many developing countries relies more on memorization of facts than on developing creative ways to apply knowledge. Educational programs that focused on problem solving and self-evaluation were the most successful.

Working Solution: Helping the Russian Health Care System Cope With a New Market Economy

The breakup of the Soviet Union had significant repercussions for the health care systems of the Newly Independent States. The economic crisis that ensued meant that Russia was less able to purchase drugs from Eastern Europe suppliers, who quickly searched for hard-currency clients. This situation resulted in drug shortages in Russia's public health system. In addition, the system was rapidly decentralized and decisions once made centrally for the selection and procurement of supplies and services were devolved to the oblast level. Simultaneously, Russian drug warehouse and outpatient pharmacies were permitted to privatize. Within months, the entire public health drug-supply system collapsed. The shortage of drugs was followed by an expansion of the market economy that allowed a flood of new products accompanied by liberal marketing methods to reach consumers and physicians with drug information that was often biased.

RPM stated working on issues of drug selection as hospitals and public health committees faced the challenge of procuring drugs in this chaotic market without the skills or information required to compare drug products. RPM filled the gap in capacity by training 820 hospital and oblast physicians and pharmacists in rational drug selection and drug use review through formulary committees. RPM also developed the capacity of 25 newly privatized pharmacies in business plan development, resulting in the financial turnaround of some failing businesses. RPM and local partners developed resources for drug information for managers and clinicians. RPM also developed the All-Russia Drug Information Network, 12 drug information centers linked from Moscow to Vladivostok to provide current, unbiased information on new and familiar products.

The activities of regional and hospital formulary committees were made mandatory by government decree through inclusion in official health plans and, in one case, by public health law. These efforts resulted in 61 hospital and 3 regional formularies eliminating unsafe and ineffective drugs and the reallocation of funds to purchase essential drugs. A survey of 32 hospitals showed that through implementing a formulary system, the number of drugs on the formulary in all the hospitals was reduced by an average of 34 percent. Committees were able to identify and eliminate drugs of unproven efficacy (such as bee milk), unsafe drugs (such as phenylbutazone), and high-cost drugs (such as cefuroxime).

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

Building capacity in drug management through education and training is a critical need in developing countries. However, it cannot be assumed that after knowledge is gained and skills improved through training, drug management will automatically improve. Staff need more than knowledge and skills: They also need an enabling environment and the proper incentives to promote desired behavior. An enabling environment includes supportive policies, laws, procedures, systems, resources, and physical infrastructure. Staff can be trained in formulary development, for example, but if they are not supported with access to drug information, they may be unable to use their new skills. Further, because of the monetary value of drugs, those staff working in formulary development are vulnerable to situations that promote corruption, and they may require incentives to encourage them to make ethical decisions.

Staff need an enabling environment in which to apply their skills. An enabling environment to empower staff to implement change can involve something as simple as having stock cards and requisition forms available or something as complex as changing drug management policies or laws. Some of the problems typically seen include—

- **Selection.** Formulary committees often lack access to current drug information.
- **Procurement.** Agencies lack procedures that ensure transparency of tender bid preparation and adjudication.
- **Distribution.** Infrastructure for drug distribution, including roads, communications, and storage facilities may be poor.
- **Use.** STGs to promote rational drug use may not exist.

In many countries, the civil service system poses a significant barrier to sustained drug management improvement. In the absence of a threat to job security and positive reinforcement for high performance, civil servants have little incentive to do any more than what is minimally required. Some countries have begun to address this deficiency as part of their larger public-sector reforms. Restructured civil service systems in general can affect accountability in the health sector. For example, staff hired on finite contracts of one or two years can be held to performance criteria for increased salaries and contract renewal. When these types of changes occurred in overall public sector reforms, RPM observed increased counterpart accountability in drug management.

Although much is known about how to build capacity in drug management, much less is known about the best configuration of incentives to motivate people to strive for improvement. RPM noted that staff provided with proper training and tools did not always apply these in their work. In Russia, for example, physicians who were trained in drug utilization review (DUR) methodology and provided with the necessary informational resources did not, for the most part, implement DUR programs in their hospitals. Although the exact reasons for this failure are not

known, very likely the physicians perceived DUR as extra work rather than as an important activity to help improve the standard of care.

Hospital staff in Russia were, however, motivated by RPM's participatory style, by study tours to the United States, and by their own interest in learning the latest pharmaceutical techniques. A combination of skills, support, and motivation was successful in Russia even where motivation may have lagged due to limited funds. The RPM Project in Russia ensured that the information and support needed to successfully implement formulary systems was available. In Novgorod Oblast, for example, drug procurement must now be based on the formulary; reduced drug lists are available for exempt patients; and templates are provided for amending hospital charters so they can require formulary-based treatment.

Working Solution: Mozambique—Building Capacity in an Impoverished Environment

In 1992, after a 16-year civil war, Mozambique's health system was impoverished. Many expatriate health managers in key posts had fled the country, and roads and communication systems were destroyed. Minimally trained local staff managed health facilities. Soon thereafter, a policy of gradual decentralization of drug management responsibilities was adopted that placed additional burdens on ill-prepared local managers, without any formal implementation plan. RPM provided technical assistance to the local managers by introducing an adapted version of monitoring-training-planning (MTP), a capacity-building strategy that has been effective in decentralized health care systems with weak local-level drug management.

The strategy involves basic drug management training, planning and implementing systemic changes based on the training, regularly collecting data on system performance, decision making based on evidence, and monitoring change. Depending on the country situation, regular supervisory visits may be a critical part of the process. Systemic improvements are built into the strategy, creating an enabling environment. The MTP methodology involves the team approach to problem solving, including the formation of specialized bodies, such as drug management teams or drug and therapeutics committees. Improvements include creating or changing standard operating procedures, where appropriate. Staff collect and use information for feedback to monitor the impact of reforms on drug management.

Local managers with RPM input identified five MTP priority drug management topics in Mozambique: (1) storeroom management, (2) drug/supply procurement, (3) health facility requisitioning and distribution of drugs and supplies, (4) using information systems, and (5) rational drug use. Within one year, RPM trained managers on the five priority topics in 31 percent of the 152 hospitals and health centers in four provinces. Progress was observed as follows:

- Procedures for monitoring drug expiration dates were changed and the value of expired drugs decreased in three of four provinces.
- The use of stock cards for monitoring inventory movement increased.
- Prescription monitoring was initiated in three provinces.

Despite such rapid improvements, one year after the introduction of MTP, it appeared that without further resource inputs (from the MOH or donors), further improvements would not only be difficult to sustain, but also perhaps not even achievable.

Health workers and managers can also be motivated by recognition: A project can publicly recognize important staff contributions. For example, staff can be invited to attend conferences

and meetings where they can disseminate project results. Counterparts can also be motivated by the presence of on-the-ground RPM staff and can develop a coaching type of technical assistance. Russian doctors, accustomed to taking great pride in their national health care system, were motivated to learn more about and to apply modern principles of drug management once they understood the large gaps in their understanding and practices. In the end, it is not enough simply to state the incentives correctly. In order to respond to incentives, people need the appropriate infrastructure and skills. An ideal, perfectly thought-out incentive structure for drug procurement may not function if the communications systems are unreliable or if procedures are unclear or cumbersome.

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

Part of the experimental nature of the RPM Project was to determine whether drug supply systems could be improved with short-term technical assistance. With a long-term expatriate adviser resident for only one RPM country program (Ecuador), RPM's achievements described in this document were gained primarily through short-term technical assistance, using relatively few funds when compared with programs with long-term advisers.

Achieving country program results without a resident adviser is challenging and there are limits to what can be accomplished. Without a more constant presence, it is difficult to keep abreast of country developments as they occur. Responding quickly to USAID Mission requests is also difficult. Most of all, it is difficult to keep the momentum going for a program of activities that requires coordinated input from a wide variety of involved personnel.

RPM took various steps to compensate for the lack of an in-country presence. Programs with long-term advisers also employ many of the same steps. For RPM, each step presented considerable implementation challenges because managers were located in the MSH/Arlington, Virginia, office and USP Headquarters in Rockville, Maryland. Ultimately, the success of most RPM country and core programs depended on the appropriate combination of key strategies, such as—

- **Building stakeholders.** Building stakeholders was a priority for many RPM country programs. In Russia, RPM began by inviting local counterparts to participate early in the program, beginning with the baseline sector assessment. They were involved in designing the instrument, selecting indicators, collecting data, analyzing the results, and writing the assessment report. RPM then conducted a Policy Options Workshop where the Russian counterparts, together with RPM, used the assessment results to design the country program. As a result of this early stakeholder-building exercise, the program's design was acceptable to both policy- and operations-level counterparts, and broad ownership was ensured. In addition, counterparts developed a sound understanding of the system and the problems.

- **Conducting study tours.** For many topics, direct observation is a better learning technique than classroom teaching. For some country programs, it was particularly useful to coordinate study tours as part of the capacity-building effort. Drug managers and decision makers from Mozambique, Nepal, Poland, and Russia were invited to participate in various study tours and to collaborate on technical tasks. For example, the five high-ranking members of Mozambique's Drug Information Planning Committee came to the United States on an intensive study tour of drug information centers, research institutions, community hospitals, and managed-care providers. The committee then returned to Mozambique and facilitated workshops on the use of drug information for clinical decision making.

- **Employing local consultants.** RPM relied heavily on local consultants to maintain the momentum of country programs between RPM technical staff visits. RPM hired local consultants to carry out planned activities and monitor project progress in RPM's absence. In Kazakhstan, for example, a consultant was hired to manage logistics and to train data collectors for a study on drug use. In Zambia, a local consultant provided assistance in developing a manual for district-level quantification and rollout to six districts; in addition, a local pharmacy technician was supported to assist the Central Board of Health Pharmacy Director and to manage day-to-day activities for RPM.

- **Working with local organizations.** The capacity of local organizations to work in drug management was enhanced as a result of collaboration. For example, in Russia, RPM contracted with Pharmedinfo, a parastatal organization involved in the development and dissemination of drug information to help with logistics, organization of large conferences, and publication of RPM materials such as formulary manuals. Pharmedinfo also translated the USP DI® database, published it in five self-financing volumes (by therapeutic group), and disseminated them through ARDIN, the country's new network of 12 drug information centers. Elsewhere, local organizations were contracted to design and carry out drug use studies. In Nepal, for example, several professional and academic organizations, including the Nepal National Chemists and Druggists Association and the Nepalese chapter of INRUD were involved in various studies. Some of the results from these studies were used to design targeted training for prescribers and retail drug sellers.

- **Collaborating with other cooperating agencies.** RPM was able to successfully collaborate with other cooperating agencies on a variety of activities. For example, in Kazakhstan, RPM subcontracted with the Almaty office of the Academy for Educational Development to help RPM organize a drug procurement workshop. At this same workshop, a local staff member from the Abt Associates office in Almaty was a presenter. The same Abt staff member participated in follow-up technical assistance. RPM also worked extensively with BASICS in developing the DMCI tool for IMCI. BASICS provided funds for and participated in the DMCI field test in Ecuador. Similarly, RPM and MotherCare collaborated in the development and field-testing in Kenya of the Cost-Estimate Strategy tool for reproductive health commodities.

- **Using a regional approach.** RPM maximized opportunities to disseminate tools and information relevant for several countries by holding regional workshops, conferences, and training. An added benefit of this approach was the opportunity to cross-fertilize ideas and experiences among countries and regions. In Ecuador, RPM conducted a regional DMCI workshop to which representatives from four other countries (Bolivia, Honduras, Nicaragua, and Peru) were invited. The participants included IMCI coordinators and Essential Drugs representatives, among others. These representatives were able to learn about DMCI and use the tool to collect data as part of the workshop. For many of the participants, this was the first time that the IMCI coordinator and Essential Drugs representatives from the same country had an opportunity and reason to talk face-to-face about drug management issues common to both programs. As a result of the workshop, the Bolivian representative chose to use the tool in Bolivia with limited technical assistance from RPM. The Latin American experience was so successful that

RPM used the same process for introducing DMCI in Africa. RPM conducted a regional DMCI introduction workshop in Tanzania that included IMCI coordinators and Essential Drugs representatives from Uganda and Zambia. In Moldova, 10 Ukrainians joined Moldavians at a national drug information conference that was facilitated by representatives of ARDIN. In Africa, Regional Economic Development Services Office/East Africa asked RPM and the John Snow, Inc., Family Planning and Logistics Management Project to conduct a regional study on the availability of drugs, vaccines, and medical laboratory supplies. Following this activity, RPM was involved in conducting the Regional Logistics Initiative workshop, where the initiative to improve drug and medical supply management was introduced to six countries (Botswana, Kenya, Mozambique, Tanzania, Uganda, and Zambia).

In some circumstances, long-term technical assistance provided by a resident adviser may be essential even though fielding long-term expatriate resident advisers is expensive. Long-term presence may be more useful when a country program is particularly large and complex—for example, a program of five years' length with a large geographical scope, several areas of technical focus, or numerous institutional collaborators operating at different levels of the health care system. Often, there is a dearth of skilled local consultants or counterparts to manage and implement program activities in the absence of a long-term adviser. In the future, with the development of the Internet and the existence of more drug management tools and training materials, the optimal model could be small field offices staffed only by local experts who are visited periodically by expatriate staff and in frequent contact with a home office through the Internet.

Conclusion

The lessons and experiences discussed in this document point toward success in developing approaches in drug management and giving USAID a strong voice in drug management issues at the global level through a cooperating agreement built around short-term technical assistance. These lessons learned can now be applied to new challenges that are unfolding globally. RPM has shown that in any health care setting, it is useful and even necessary to understand the interrelated nature of drug selection, procurement distribution, and use; to arrive at solutions when drugs are unavailable or used improperly; and to use information as a requirement to arrive at the best solutions. Having good policies is not enough; the real challenge lies in implementation. In a world where the old, public-sector drug supply model no longer applies, the private sector cannot be ignored. After many years of focusing on primary care, renewed interest in improving the performance of hospitals presents many opportunities for drug management, particularly in improving the use of antimicrobials. Despite the fact that product quality can be addressed through registration, procurement, and formulary systems in a given country, widespread and ongoing problems indicate that quality needs to be addressed more directly. In order to succeed, the role of introducing proper incentives must be added to the current strategies of capacity building and creating an enabling environment.

Trends and Gaps

Trends

1. **Changes in epidemiology and demographics** are having, and will continue to have, an impact on drug management systems and, in particular, drug selection and finance systems. Such changes include—

   - The increased incidence and prevalence of chronic conditions such as HIV/AIDS and conditions present in aging populations, such as hypertension, cardiovascular disease, cancer, asthma, and diabetes

   - Changing and/or new treatment modalities for conditions such as malaria and TB

   - Emergence of resistance to antimicrobial drugs, and the need to rationally select antibiotics to curb antimicrobial resistance

   - The impact of war and migration on drug needs and consumption patterns

   Initiatives to address these problems will benefit from specialized drug management assessment tools and technical assistance.

2. **Health care reform initiatives** such as decentralization, integration of vertical programs, outsourcing, privatization, and health care financing schemes will continue. The trend in the pharmaceutical sector has been to make decisions without adequate information and to begin without adequate planning. Effective changes in pharmaceutical systems will require a thorough understanding of existing systems, options analysis, policy creation, implementation planning, and, finally, implementation itself. Governments will benefit from assistance in all of these areas.

3. **Cost-recovery** initiatives are likely to increase. MOHs in most developing countries are unable to satisfy their full drug needs through donor and existing MOH funds. Low gross national product growth and high population growth suggest that this problem will not decrease. Governments are increasingly deciding that they must find ways to share health care costs, including drug costs, through health insurance schemes, community health funds, revolving drug funds, or other mechanisms.

4. **Globalization of trade** promotes attempts at increasing a share of major international trade in pharmaceuticals and a corresponding effort by health agencies to regulate such trade to protect small private-sector providers and public health needs. The outcomes of these trends will have an impact on drug availability in developing countries—and possibly on quality assurance and drug research and development. For example, greater discussion will take place in many countries of what to do about parallel imports, especially now that World Trade Organization members have agreed to ban parallel imports. Also, countries especially hard hit by HIV/AIDS are increasingly aware of the benefits of compulsory licensing.

5. **Internet access** is growing rapidly: Countries that two years ago had virtually no Internet access are now online. Opportunities to use the Internet as an information dissemination, training, management, and idea exchange tool will increase in countries that have acquired a critical mass of technology and computer skills.

Gaps

1. **Drug information.** A tremendous need still exists for drug information and training in how to use that information. Some countries still have virtually no access to unbiased drug information. Confusion about generic names and generic drugs versus brand-name drugs is increasing in countries that are liberalizing their economies; here, the issue will be how unbiased drug information sources can stay current.

2. **Incentives.** Little is known about the role of incentives in drug management. Programs interested in strengthening drug management will have to understand and pay increased attention to the question of incentives. This issue will require a systematic approach to understanding what factors influence performance and how such an understanding can inform personnel management.

3. **Procurement.** The World Bank estimated that in sub-Saharan Africa, half a drug budget's value is typically lost through inefficiency, waste, and corruption by the time the procurement process is complete. The tremendous burden of disease in these countries, combined with growing donor pressure to increase transparency and efficiency, is leading to a much stronger interest among governments to improve procurement practices. With moves now in place to swap developing country debt for increased investment in health and other sectors, governments may have additional funds to devote to drug purchases—and an additional incentive to ensure that funds are used efficiently and transparently.

4. **Donor inputs.** With the dramatic impact of diseases such as HIV/AIDS, malaria, and TB on the ability of countries to become self-sufficient in financing drug supply, the need for planning and coordinating donor inputs is on the rise.

5. **Drug quality.** Improving and ensuring the quality of drugs used in developing countries health care systems will remain a critical need. Possible interventions include establishing or strengthening drug registration systems, improving procurement procedures to ensure that only reliable suppliers are used, and improving distribution systems. Improving testing capacity, possibly through use of effective, low-tech mechanisms such as the thin layer chromatography method, developed by the U.S. Food and Drug Administration, is also needed.

6. **Consumer education.** Drug companies will increasingly target consumers in developing countries, much as they are now being targeted in the United States, although probably with fewer governmental restrictions. When this happens, a need to educate the public to be discriminating consumers of available drug products will arise.

7. **Governmental planning.** Too often, RPM's role in country programs was to address the results of poor or no planning. Future assistance efforts should focus on helping governments think about timing of changes, training needs, infrastructure changes needed to support new polices, and setting up systems to monitor progress throughout the process.