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REVIEW OF USAID'S RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT

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The opinions expressed herein are those of the authors and do not necessarily reflect the views of TvT, Pragma, or USAID.

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Preface

This evaluation is, of course, the work of many whose names do not appear as authors. In this regard, the team appreciates the contributions of those countless individuals whose efforts to facilitate this evaluation were critical to its success. Several persons deserve special mention. Anthony Boni and Linda Sanei were tireless in planning and facilitating the evaluation. Their efforts were paralleled in Russia by Nikita Afanasiev and by Olga Alexinskaya, our extraordinary interpreter. Matthew Friedman and Janardan Lamichhane provided helpful support in Nepal. In Zambia, Mark Anthony White and his staff were invaluable, as was Armand Utshudi-Lumbu in Mozambique. Finally, the team is grateful to Jim Bates, Keith Johnson, Anthony Savelli, and the personnel of Management Sciences for Health (MSH) and United States Pharmacopeial Convention, Inc. (USP) for the quality of their briefing materials, their receptivity to our inquiries, and their openness and patience in response.

A few words are also warranted regarding the report's possible biases and limitations. During this evaluation, a lot of ground, literally and figuratively, was covered in a very short amount of time. Yet, the evaluation team's work, by its terms, remains a snapshot in time of the RPM project and does not fully reflect its geographical scope. The countries for site visits were chosen carefully and, the team believes, appropriately. Nonetheless, the team recognizes that there are lessons to be learned from the other countries in which the RPM project has been working. These other countries, and the lessons to be learned from the work therein, have not, and cannot be, fully represented in this report.

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Acronyms

AED	Academy for Educational Development
AIDS	Acquired Immune Deficiency Syndrome
AIHA	American International Health Alliance (Russia)
ARCH	Applied Research on Child Health (USAID Project)
ARI	Acute Respiratory Infection
ARV	Anti Retroviral
ASD	AIDS and Sexually Transmitted Diseases (WHO)
BASICS	Basic Support for Institutionalizing Child Survival (USAID Project)
CA	Cooperative Agreement, or Cooperating Agency
CAIDP	Central Asia Infectious Diseases Program
CBOH	Central Board of Health (Zambia)
CDC	Centers for Disease Control (Atlanta)
CDD	Control of Diarrheal Disease
CDP	Community Drug Program (Nepal)
CHD	Division of Child Health and Development (WHO)
CMS	Central Medical Store
CTO	Cognizant Technical Officer (USAID)
DAP	Action Programme on Essential Drugs (WHO)
DDA	Department of Drug Administration (Nepal)
DfID	Department for International Development (formerly Overseas Development Agency, U.K.)
DGIS	Dutch Aid Agency
DIC	Drug Information Center
DINoN	Drug Information Network of Nepal
DILSAT	District Level Self Assessment Tool (Zambia)
DUR	Drug Use Review
EDL	Essential Drug List
EDMSS	Essential Drug Medical Supply Store (Zambia)
EPI	Extended Programme on Immunization
EU	European Union
FDA	U.S. Food and Drug Administration
GTZ	Gesellschaft fur Technische Zusammenarbeit (German Aid Agency)
HFS	Health Financing and Sustainability Project (USAID Project)

IMCI	Integrated Management of Childhood Illnesses
INRUD	International Network for Rational Drug Use
JSI	John Snow International, Inc.
KfW	Kreditanstalt fur Wiederaufbau (Germany)
LMD	Logistics Management Division of the Nepal Ministry of Health
LMIS	Logistics Management Information System (Nepal)
LSIP	Logistics System Improvement Plan (Nepal)
MDS 2	MSH Publication, *Managing Drug Supply* (Second Edition)
MOH	Ministry of Health
MSL	Medical Stores Limited (Zambia)
MSH	Management Sciences for Health
NCDA	Nepal Chemists and Druggists Association
NDP	National Drug Policy
NGO	Nongovernmental Organization
NHRC	National Health Resources Council (Nepal)
NIS	Newly Independent States
NORAD	Norwegian Development Agency
OR	Operations Research
PAHO	Pan American Health Organization
PHC	Primary Health Care
QA	Quality Assurance
QC	Quality Control
RECPHEC	Resource Center for Primary Health Care (Nepal)
REDSO/ESA	Regional Economic Development Services Office for Eastern and Southern Africa
RFA	Request for Assistance
RH	Reproductive Health
RP	Results Package (USAID)
RPM	Rational Pharmaceutical Management
SDMD	Strengthening of Drug Management at the District Level (Nepal)
SIDA	Swedish International Development Agency
SO	Strategic Objective (USAID)
STD	Sexually Transmitted Disease
STG	Standard Treatment Guideline
TA	Technical Assistance
UNAIDS	United Nations Programme on AIDS
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USP	United States Pharmacopeial Convention, Inc.
USP DI	United States Pharmacopeial Convention Drug Information
WB	World Bank
WHO	World Health Organization

Executive Summary

This report is an evaluation of the Rational Pharmaceutical Management (RPM) components of the Health Financing and Sustainability project of the Center for Population, Health and Nutrition, of the Bureau for Global Programs, Field Support and Research of the United States Agency for International Development (USAID). Briefly stated, the evaluation was designed to achieve two objectives, the first retrospective and the second forward-looking: first, to provide an assessment of the degree to which Management Sciences for Health (MSH)and the United States Pharmacopeial Convention, Inc. (USP)[1] were able to complete the program descriptions contained in their respective cooperating agreements, and second, to provide guidance and recommendations regarding potential modifications to the USAID cooperative agreements that would address USAID's need for pharmaceutical-related expertise and support the Agency's strategic objectives.

USAID's Health Technical Services Project assembled a seven-member evaluation team that convened in Washington, DC, on June 16, 1997, for a series of meetings with personnel from USAID, the cooperating agencies, and collaborating institutions. Following these meetings, the team visited Russia, Nepal, Zambia, and Mozambique, countries where there are RPM activities — of varying maturity and complexity. The team also visited Geneva to discuss technical issues and areas of potential collaboration with the World Health Organization's (WHO's) Action Programme on Essential Drugs and other WHO programs. At the conclusion of the site visits, the team consulted again with project participants and collaborating institutions, and on November 6 and 7, 1997, the team reconvened in Washington to give USAID and the cooperating agencies a preliminary debriefing of its conclusions and recommendations.

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1 MSH is a Massachusetts-based nonprofit corporation founded in 1972. Its primary mission is to provide technical assistance to bridge the gap between what is known and what is done about improving health care for disadvantaged populations. MSH is a recognized leader in providing pharmaceutical management technical assistance.

USP, based in Rockville, Maryland, is an international leader in drug standards and the developer of the leading compendia of drug information in the United States.

A. TECHNICAL BACKGROUND

In most countries, pharmaceuticals account for the largest share of public health expenses other than salaries for personnel. Despite these large expenditures, the pharmaceutical sector in many countries — particularly in developing countries — is plagued by shortages of supply and, in some instances, the presence of drugs of questionable usefulness and/or quality. Also, pharmaceuticals are often prescribed and/or used ineffectively. Such "irrational use" of drugs not only wastes scarce resources, but also can compromise patients' health and present significant health concerns for the population by decreasing the overall effectiveness of drugs such as antimicrobials.

To address these problems, WHO took the seminal step of establishing a Model List of Essential Drugs in 1977. In 1981, WHO established the Action Programme on Essential Drugs to "ensure equity of access to essential drugs, rational use of drugs, and drug quality, within the context of the national health policy."* Other organizations have been active in supporting essential drugs programs and reform of the pharmaceutical sectors in developing countries, including multilateral institutions such as the World Bank and the United Nations Children's Fund (UNICEF) and the bilateral aid agencies of such countries as Denmark, France, Japan, Netherlands, Sweden, and the United Kingdom. Much of this donor support has consisted of actual provision of pharmaceutical supplies rather than technical assistance.

In 1992 USAID supplemented the funding for its Health Financing and Sustainability (HFS) Project to include a component on Rational Pharmaceutical Management (i.e., the RPM Project). Until this time, USAID's activity in the realm of essential drugs and pharmaceutical management had been limited in scope, and implementation of its activities had been ad hoc. Indeed, USAID's general absence in the essential drugs area was conspicuous given the relative importance of drugs in the health sector. USAID's initial consultations with donors and multilateral institutions during the design of the RPM Project were met with skepticism and distrust.

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* WHO Action Programme on Essential Drugs, *WHO Essential Drugs Strategy: Objectives, Priorities for Action, Approaches.* Geneva: World Health Organization, February 1997.

The RPM initiative was designed to address the increasing difficulties developing countries faced in "funding and maintaining adequate and accessible pharmaceutical supplies," acknowledging that weak pharmaceutical sectors were undercutting the credibility of developing country health systems as a whole.* As such, the new pharmaceutical component was created to address key issues of "efficiency," "equity" and "quality" that were brought out in work conducted under the HFS Project.

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 in 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 of rational drug use.

B. PROJECT DESIGN AND EVOLUTION

1. Range of Activities

In March 1992, USAID defined the goal of the RPM Project as being "[t]o improve the health status of target populations in [least developed countries] through improvements in the allocation and use of financial, human and information resources within the health sector." USAID issued a Request for Assistance (RFA) seeking cooperating agencies' assistance in achieving these purposes.

The project was designed to use an "assessment-based" approach, under which the cooperating agencies were to work with host governments to assess and specifically tailor interventions to the needs of each individual country. This approach included collecting data in eight technical areas. Seven assessments were undertaken during the RPM Project's country-assessment phase from April 1992 to January 1994. Based on these assessments, a project plan was developed to focus on the priority technical areas described below.

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* USAID, *Health Financing and Sustainability (936-5974) Project Paper Supplement.* Washington, DC: USAID, March 1992.

2. Structure and Changes in Program Funding

In September 1992, USAID awarded five-year cooperative agreements (CAs) on a competitive basis to MSH and on a sole-source basis to USP. The CAs were originally designed to carry out core-funded, experimental programs of technical assistance in up to three developing countries. The original developing country portfolio consisted of Ecuador, Nepal, and Mozambique. However, the former Soviet Union dissolved at about the time the original CAs were awarded. To address health care concerns identified by the Newly Independent States' Task Force, an "Add-on" was awarded to the MSH CA in September 1993, and USAID's Bureau for Europe and Newly Independent States later awarded separate CAs to MSH and USP for work to be carried out in the Russian Federation. All four CAs are managed by the Global Bureau under the HFS Project.

In 1995, USAID's funding strategy changed. USAID adopted the field support funding strategy, which caused dramatic cuts in planned core funding for the two Global CAs. Contrary to the earlier direction given to MSH and USP, the project was encouraged to market itself more broadly with field missions. As a result of this process, the RPM Project has added new country programs in Peru, Zambia, and Bangladesh and has joined a regional public health logistics initiative managed by the Regional Economic Development Services Office for Eastern and Southern Africa (REDSO/ESA).

3. Funding Mechanisms Covered by the Evaluation

The RPM Project thus consists of four Cas, two awarded to MSH and to awarded to USP. As discussed above, the separate CAs for each organization distinguish between work to be carried out worldwide and work to be carried out in the Russian Federation. The separate CAs are summarized in Table 1.

TABLE 1. RPM COOPERATIVE AGREEMENTS

CA	Start/End Dates	CA Number	Total Estimated Project Cost	Estimated USAID Contribution	Obligations to March 1997
MSH Worldwide	9/25/92–9/23/97	HRN 5974-A-00-2059-00	$9,830,000	$8,900,000	$7,937,311
MSH Russia	1/6/95–12/31/97	HRN 0004-A-00-5002-00	$2,374,264	$2,374,264	$2,374,264
USP Worldwide	9/17/92–9/15/97	HRN 5974-A-00-2052-00	$2,078,156	$1,286,076	$1,285,000
USP Russia	12/22/94–12/31/97	HRN 0004-A-00-5001-00	$1,124,000	$1,124,000	$1,124,000

C. TECHNICAL ANALYSIS

1. Country-Level Activities

a. Improving Allocation, Management and Use of Resources

- Drug Selection/Formulary Development: MSH assisted country programs in drug selection and formulary development. This component of the project has been most active in Russia, and, overall, it has been extremely successful. Several successful examples of oblast and hospital formularies have been developed over a relatively short period of time. The challenge for RPM-Russia now is not to make these interventions work, but rather to disseminate more widely the lessons learned at the initial project sites to all oblasts where the project is working and to other oblasts in Russia. To meet this challenge, the project should build on one of its most notable strengths — its ability to identify and empower counterparts of unquestionable commitment and skill.

Looking to the future, support to district-level facilities in the areas of drug selection and formulary development will become increasingly important. As other countries undergo the type of decentralization that is taking place in Russia, RPM can make a significant contribution to strengthening district-level skills in drug management and formulary development.

- Drug Procurement and Supply Management: MSH has provided technical assistance in drug procurement and supply management to several countries, including Ecuador, Mozambique, Nepal, Russia, and Zambia. Although the nature of this assistance has varied by country, it can be described as providing assistance to countries for managing the purchase, storing, distribution, and control of their drug inventories.

  The project's involvement in procurement has been limited to date, but, along with drug selection and formulary development, procurement is an area where the project can assist central and district-level managers in many countries who face decentralization. Strengthening procurement mechanisms and supply management also can facilitate integration of previously vertical programs. RPM is working directly on these issues in Zambia, Ecuador, and, increasingly, Nepal. This is clearly an important thrust of the project's future work, and by coupling its work in this area with assistance on drug selection/formulary development and rational use, RPM could contribute significantly to a district drug management package, which is in growing demand as more countries take up health reform.

- Community Pharmacy Management: MSH provided assistance to individual pharmacy owners and operators with community pharmacy management in Russia. RPM's involvement has been extremely popular with the pharmacy owners and operators involved, who were instructed how to develop business plans that would allow their pharmacies to survive the enormous stresses they faced under the restructuring of the Russian economy.

  This project component, which fell under USAID/Moscow's strategic objective of strengthening democracy, has clearly empowered business owners to succeed in a free market system and improved access to needed drugs. Nonetheless, the project needs to be sensitive to the possibility that its interventions might promote the success of one private sector entity over another, equally deserving competitor.

b. Promoting the Rational Use of Drugs

RPM has worked to promote the rational use of drugs in many project countries, and its efforts have met with varying — but commendable — degrees of success. RPM has taken several approaches to promoting the rational use of drugs, including but not limited to the development of standard treatment guidelines (STGs), reform of curricula for health care providers to incorporate lessons on rational use, direct training of providers, provision of drug information to consumers through drug information centers, and introduction and implementation of hospital-based drug use review programs.

- Standard Treatment Guidelines, Curricula Reform, and Training: RPM's efforts in developing STGs, reforming curricula, and providing training in rational use have been commendable, and the components of the project should continue to be made available to developing countries as part of any USAID project support. Promotion of the rational use of drugs through these mechanisms should be expanded in order to complement improvements in drug availability achieved through strengthened capacity in drug management and logistics. Promotion of rational drug use should be part of the district drug management package and part of different health and disease management programs. As such, promotion of rational drug use can serve as an integrating force between "pharmaceutical management" and "disease management." Training in rational drug use and adoption of STGs — developed with the use of objective clinical and drug information, and with attention to pharmacoeconomic issues — have been, and will continue to be, of vital importance to global health care.

- Drug Use Review: Drug use review (DUR) is critical to improving rational drug use. To date, RPM has been most successful in imparting this notion to local stakeholders in Russia. This is an area with significant potential for the project in Russia and in other NIS countries. This component has less immediate potential at the hospital-level in countries like Zambia, Nepal, and Mozambique, which do not yet have established hospital therapeutic committees. However, for these countries, a modified DUR, an analysis of prescribing patterns, or a rapid indicator assessment on the use (and expenditure) of drugs in a hospital or primary health care setting may stimulate facilities to create such committees and to undertake more in-depth drug utilization reviews, for example, concerning the use of antibiotics.

c. Improving Level of Drug Information

RPM's efforts to improve the level of drug information have taken two basic forms: first, the development of unbiased drug information for use in developing countries, and second, assistance in disseminating this information through the development of drug information centers.

- Development of Unbiased Drug Information: USP developed monographs for 37 drugs included in the WHO Model List of Essential Drugs that had not previously been included in the USP Drug Information (USP DI). Eight additional monographs are currently under development, and nine more are planned.

  USP has also supported adaptation of the USP DI to incorporate country-specific indications, dosing schedules, and other information into existing drug monographs and to develop separate, country-specific drug monographs. Adaptation of the USP DI is underway in Russia and Nepal and is planned for Mozambique. In Russia and Mozambique, USP has worked (through side agreements not formally part of RPM) on translating the USP DI into Russian and Portuguese. In Nepal, USP's efforts have focused on adapting an English-language USP DI database into a Nepal-specific English-language database that would include, among other things, Nepal-specific brand names for drugs included in the database.

  The success of the project in this area has been mixed. The efforts in Mozambique and Russia have been very fruitful, but the work in Nepal has shown less progress. Much of the success in developing adapted, translated drug information has taken place via private sector contracts between USP and local entities. In those situations where new, adapted drug information has been produced, local counterparts in the project countries have generally greatly appreciated the information. The existence of this new, adapted material has uniformly pleased local counterparts, though they have not always shown preferences for the USP DI database format, often preferring to use hard copies of the information.

- Establishment of Drug Information Centers: One of the main areas of USP's involvement in the project has been in assisting in establishment of drug information centers (DICs). These DICs have taken two general forms: those established principally to serve target populations in facilities or regions with therapeutic information, or those established principally to "relay" drug information of a more regulatory or normative nature from a central source to regional areas. The project has been reasonably

successful with the first type, although the strengths of the various centers in disseminating information vary. The project has been significantly less involved in establishing relay centers that are part of national networks of drug information. In the team's view, the likelihood of establishing effective networks (even at the local level) appears remote, at least in the short or medium term.

The project has successfully established a significant number of DICs, and many of these are functioning and active in disseminating information. However, collectively, the evaluation team had the most concern over the ability of the DICs to effectively fulfill their potential in disseminating drug information. The team's concerns fall in four general areas. First, the ability of the DICs to effectively disseminate information varies widely in terms of staffing, goals, and location. Second, some of the centers may have been rolled out too quickly, which may prevent them from gathering momentum, which may have come if they were established at more opportune times. Third, where multiple DICs exist in a given geographical area, the delineation of responsibilities and/or goals of the different centers is not clear in some cases. Finally, under current conditions, it appears premature to expect DICs in urban centers to serve rural areas effectively due to problems with communications infrastructures and the technical capacity of rural personnel.

To improve the effectiveness of some of the less active centers, USAID would need to provide much more intensive technical assistance and financial resources than provided to date. In this regard, RPM should continue to support the dissemination efforts of the DICs that have been established, with priority given to those centers that share the project's vision for a center that actively promotes itself, disseminates information, and is well integrated into its local environment.

2. Core Activities

In addition to the country-level activities discussed above, the project has engaged in core, or central-level, activities in two areas: Studies and Operations Research, and Tools Development and Information Dissemination.

a. Studies and Operations Research

The project's principal general (as opposed to country-specific) study has involved developing an approach for estimating the drug and expendable supply costs of reproductive health programs. The study, which is not complete, seeks to develop a methodology that would assist donors and decision-makers in estimating the cost of supplying the commodities required to meet the needs of 25 reproductive health problems. The methodology is impressive in its current state, but its potential usefulness will depend on its country specificity — global cost estimates will serve only as a rough guide. It will therefore be important to clearly identify and document the potential uses of the methodology during the country-study phase (to be completed).

USAID has indicated an interest in assistance from the project in future research related to HIV/AIDS, integrated management of childhood illness (IMCI), and antimicrobial resistance. These activities are still in the early stages of development, but RPM can no doubt make a valuable contribution toward the Agency's strategic objectives in these areas. Also, given the recent USAID initiative to address emerging health issues and diseases, including antimicrobial resistance, RPM should give particular attention to research in antimicrobial resistance as related to drug management and rational use.

The project also has been engaged in several operations research projects that are part of the country programs. For example, RPM conducted important studies regarding the need and potential for restructuring supply systems in Ecuador and Zambia. The project also conducted a major feasibility study in Nepal, entitled *Nepal Drug Cost-Sharing in Pharmaceutical Distribution,* which was hailed by many people, including WHO experts in this area, as the best analysis to date in the area of drug cost-sharing schemes. Regretably, the Ministry of Health failed to act on some of the study's key recommendations. RPM also conducted major indicator-based assessments of the pharmaceutical sector in six countries (Ghana, Mozambique, Ecuador, El Salvador, the Eastern Caribbean, and Russia), which were, by and large, excellent and comprehensive.

b. Tools Development and Information Dissemination

MSH and USP have engaged in a number of activities designed to disseminate information and develop tools and documents that are general applicable. These have included presentations at various conferences and workshops and preparation of manuals, documents, and computer software.

- Manuals and Documents: The manuals produced by MSH directly under the auspices of the RPM Project include *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* and *The International Drug Price Indicator Guide.* In addition, in 1997, MSH produced the second edition of *Managing Drug Supply* (MDS 2), in collaboration with the WHO Action Programme on Essential Drugs. Although MSH produced this widely sought second edition with support from outside RPM, MSH applied the experiences of RPM to shape its content. Training materials based on MDS 2 are currently under development. The value of these publications was widely acknowledged.

- Software: In addition to the written manuals described above, MSH developed several following software products: INVEC-2 (inventory control and management software); PASS (prescription analysis software system); ESTIMED (drug needs quantification software); and ECPRO-2 (tendering and procurement software). Although the value of these programs, in the abstract, is undeniable, the use of these programs at the country level does not always reflect their value. It is important to note that the area of computer software development — and implementation at country level — is rife with donor politics. Local counterparts repeatedly cited pressure to satisfy other donors' interests by using software packages developed by these other donors.

3. Organizational Impacts

a. Linkage with USAID Strategic Objectives and Programs

RPM has contributed significantly to the achievement of the Center for Population, Health and Nutrition strategic objectives (SOs) and to the SOs of USAID missions in the countries where the project operates. At the central level, RPM has contributed most directly to 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"). To these ends, RPM has improved access to reproductive and child health services through strengthening drug management systems and has enhanced the quality of these same services through increased access to drug information and promotion of rational drug use by prescribers. RPM has also contributed to SO1 ("increased use by women and men of voluntary practices that contribute to reduced fertility") through the development of an integrated family planning and drug logistics management systems in Nepal and an integrated

assessment tool for Zambia. While RPM's contribution to SO4 ("increased use of proven interventions to reduce HIV/STD transmission") has been indirect, it is anticipated that RPM will contribute more directly to SO4 in the future as developing countries seek guidance related to the rational use of antiretrovirals and medications to treat opportunistic infections.

USAID has not yet clearly reflected the relationship of RPM — and other cross-cutting projects — to the program outcomes in the context of the strategic framework. Unless a specific indicator is identified for the relevant SOs (particularly SO2 and SO3), the specific contributions of RPM may be neither reflected through the existing framework nor tracked by monitoring plans.

b. Impact on Cooperating Agencies

The project has demonstrably strengthened the institutional capacities of both MSH and USP. MSH has accumulated significant additional expertise and staff in pharmaceutical management, particularly in direct support of country programs. USP has strengthened its institutional capacity to provide technical assistance in developing country settings, and, in areas where its prior experience was unsubstantial, USP now has an increased international presence as a drug information authority.

c. Collaboration with Other Organizations

To date, RPM has been a strong and effective collaborator. RPM's comparative advantage in technical assistance, tools development, and operations research related to drug management and rational use have informed decision-making and improved the effectiveness of child survival and reproductive health projects.

At the country level, RPM has been responsive to the needs of USAID and host countries by communicating closely with donors, nonogovernmental organizations (NGOs), and bilateral programs and by jointly financing and sponsoring a variety of activities. RPM should continue to focus on collaborating with other projects, organizations, and donors in order to coordinate activities, broaden the stakeholders in country projects, and leverage scarce resources. To these ends, RPM should disseminate information regarding technical services it has provided and the contributions of its activities to child survival and reproductive health interventions, USAID missions, NGOs, USAID global programs, and bilateral and multilateral donors.

D. ORGANIZATION AND MANAGEMENT

Overall, the expectations for the project were too ambitious, particularly regarding the drug information component, given the organizational and management constraints and the fact that funding was never provided at the levels envisaged in the original cooperative agreement program description. Short-term technical visits on the part of RPM staff have generally been effective, particularly in situations where strong host country nationals were in place and where there was strong collaboration between RPM and other local collaborating entities. However, in some settings, the mode of short-term visits has reached the limit of its effectiveness. In Nepal, Mozambique, and Zambia, the evolving situations all urge a long-term presence. The evaluation team is aware that in the past RPM has requested funding for resident advisors in selected cases, which has not been forthcoming. RPM should continue its dialogue with these missions and attempt to secure the required resources.

The expanding portfolio of RPM country programs and the leveraged resources of other donors and programs are evidence of increasing demand for RPM's services. The team expects that this demand should accelerate as missions recognize the critical role of drug management in supporting their health interventions.

1. Cooperating Agencies

a. Organizational Structure

Within MSH, the personnel dedicated to the RPM Project are located in MSH's Drug Management Program (DMP). Although MSH is based in Boston, the DMP elected to move its operations to Rosslyn, Virginia, in December 1992, in order to facilitate collaboration with USAID in implementing the RPM Project and to allow greater proximity to other clients such as the World Bank. Currently, the DMP is comprised of about 24 staff members (including 19 professionals), of which 13 full-time equivalent staff members administer the RPM Project. This current staffing level represents a significant increase over the level at the start of the project, although like USP (discussed below), the MSH staff is still stretched to capacity.

At USP, the personnel dedicated to the RPM Project currently comprise two full-time professionals, a part-time computer programmer, and additional drug and medical information specialists as needed for development of drug monographs. All are based at USP's headquarters in Rockville, Maryland. Given the scope of project activities, the USP staff remain stretched beyond its capacities. USP needs either to increase its in-house staff or to use consultants more often to fill gaps in areas such as monitoring and evaluation, field-testing, and institution-building.

b. Financial Management

Although the team did not conduct a comprehensive analysis of the project's expenditures and accounting, the team did evaluate the cooperating agencies' budgeting and strategic planning of USAID's overall allocation of resources and their ability to mobilize additional resources to achieve project objectives. These subjects are discussed below.

USAID allocated approximately (US)$11 million to the Worldwide project and approximately $3.5 million to the Russia project. For the Worldwide project, $8.9 million was allocated to MSH, and about $1.3 million was allocated to USP. For Russia, about $2.4 million was allocated to MSH, and about $1.1 million was allocated to USP. As of March 1997, both CAs had obligated nearly all of their allocated amounts. Importantly, the CAs also have been successful in mobilizing other USAID resources and leveraging funds of other donors. Generally speaking, given the ambitious work plans of the country programs, the team found that these levels of expenditure were appropriate and were matched at the country level, at least through the team's qualitative analysis. The fact that the project has expended nearly all of its funds on worthwhile activities and that it has a few months left with more to do indicate to the team that the project has been under-funded.

c. Cooperation and Collaboration

Cooperation and collaboration between and among USAID personnel and the cooperating agencies appears to have been strong, at both the central and the 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 in the cooperating agencies' collaboration.

2. USAID

Both cooperating agencies were highly complementary of USAID management, though personnel within the CAs did cite isolated instances of differences of opinion regarding administrative priorities and management processes. By all accounts, these differences were successfully managed. In light of the overall success and rapid expansion of the project, the team believes that USAID management and the cooperative agreement structure have served the project well. Indeed, it appears that the USAID Cognizant Technical Officer (CTO) has been a very effective advocate for drug management issues at the global level and has been effective in providing project support.

E. FUTURE DIRECTIONS

Selected recommendations are set forth below. Additional recommendations are included in the main body of the report.

1. Country Programs

- For the foreseeable future, the project should continue to focus on the current technical areas (i.e., improving drug management, promoting rational use, and increasing access to unbiased drug information). RPM should prioritize activities to develop strategies that bridge the gap between improved drug management systems and improved health outcomes.

- Indicator-based assessments should continue to be key in the design of country programs. RPM should complement the information gathered through these assessments with political mapping and stakeholder analysis. These additional assessment methodologies will allow RPM to more comprehensively analyze the pharmaceutical situation within the macro and micro political environment, design appropriate strategies, and identify viable counterparts. Priority areas to keep in mind in these assessments:

    - Health reform and the decentralization process: This would include integrating public health logistics, drug management, and supplies; training; and research in cost-effective purchasing, storage, delivery, and use of drugs for "vertical" disease-specific health care initiatives.

- Private sector collaboration: This would include exploring, researching, and establishing mechanisms to work with the private sector in satisfying public health goals in the procurement and distribution of drugs and in promoting the rational use of drugs. In this regard, noting the potential for insurance systems to rival the influence of government regulatory authorities regarding to drug availability, pricing, and access, RPM should explore potential opportunities to improve drug use and reduce financial waste through systems of insurance.

- RPM should identify potential country programs for drug use review and strengthen project activities in support of these activities. RPM also should undertake pilot activities in patient information. In doing so, the drug information component will be positioned to more directly contribute to improved health outcomes, particularly to improve compliance and address key issues related to antimicrobial resistance. Also, RPM should identify and/or leverage resources to assist countries in strengthening local expertise in clinical pharmacology. Experts in this area can become influential advocates for improved clinical practice and curriculum and pharmaceutical system reform.

- The organizational capacity of existing drug information centers and drug information networks should be assessed. Based on the findings of this assessment, training should be provided in organizational development including the development of DIC standard procedures, work plans, marketing plans, and financial sustainability.

- During an extension period, the project should limit its involvement in countries (and regions in countries) outside those where the project currently works. Much work remains to be done in the countries (and regions) where the project currently operates. Absent increased resources and staffing, rapid expansion could compromise the effectiveness of current interventions.

- Focused, short-term technical assistance provided by RPM is valued by USAID missions, other cooperating agencies, and host-country counterparts. This assistance should continue. However, it should be recognized that drug management involves complex and interrelated issues and a need for close collaboration at the country level. Accordingly, RPM, MSH, and the CTO should continue and intensify efforts, on a country-by-

country basis, to persuade USAID missions to fund the presence of resident advisors.

2. Core Activities

- In the short-term, RPM should continue its ongoing core activities in the areas of tools development and should finish the pending operational research regarding drug supply costs of reproductive health programs. Major new research, publications, or software development should be undertaken cautiously and only after close coordination with and endorsement by USAID.

- In the long-term, RPM should continue to engage and collaborate in operations research, focusing project resources on country-specific studies that would directly benefit country programs. RPM should also continue to develop documents and manuals, both for specific countries and for general applicability. Studies and projects to develop materials of general applicability should be chosen carefully and undertaken in close coordination with other international entities, such as WHO, that may be engaged or interested in similar studies or materials.

3. Project Management

- Assuming that RPM is extended and that increased funding is provided, both cooperating agencies should increase staffing, expand the use of existing consultants, and identify new consultants in order to provide services to existing and new programs. Additional human resources appear necessary to satisfy current demands on the project and would certainly be necessary in times of project expansion.

- The global center should develop an intermediate result (IR) for "Improved availability and rational use of necessary (STI drugs, ARI drugs, RH drugs, etc)," as well as the related performance indicator, to be incorporated into the strategic plan under relevant SOs. RPM should provide guidance to USAID missions in identifying and including performance indicator(s) in missions' strategic plans that will serve to monitor RPM contributions related to program outcomes.

- In future RPM projects, USAID should follow an approach similar to the one used to manage the current RPM project (i.e., use of cooperative agreements with a "substantial involvement" clause).

- RPM should design and carry out a study to document outcomes and, to the extent possible, the impact of program interventions. This might include outcomes such as:

  - money saved through tender procurement
  - money saved from curtailing antimicrobial resistance through the use of first line antibiotics (e.g., sulfas, tetracyclines, penicillins) versus newer, more expensive and unnecessarily broad spectrum antibiotics
  - decreased occurrence of drug stock-outs
  - improved patient care due to improved drug selection.

- USAID should allocate project resources and shape project priorities to focus on longer-term technical assistance, particularly through in-country advisers.

- RPM should continue to explore partnerships with the U.S. Food and Drug Administration (FDA) in order to strengthen host-country regulatory authorities.

I. Introduction

This report is an evaluation of the Rational Pharmaceutical Management (RPM) components of the Health Financing and Sustainability Project of the Center for Population, Health and Nutrition,of the Bureau for Global Programs, Field Support and Research, of the United States Agency for International Development (USAID).

A. Purpose and Rationale of Project Evaluation

The purpose and rationale for the project evaluation is set forth fully in Annex H, Evaluation Scope of Work. Briefly stated, the evaluation was designed to achieve two objectives, the first retrospective and the second forward-looking: first, to provide an assessment of the degree to which Management Sciences for Health (MSH) and the United States Pharmacopeial Convention, Inc. (USP)[1] were able to complete the program descriptions contained in their respective cooperating agreements, and second, to provide guidance and recommendations regarding potential modifications to the USAID cooperative agreements that would address

1 MSH is a Massachusetts-based nonprofit corporation founded in 1972. Its primary mission is to provide technical assistance to bridge the gap between what is known and what is done about improving health care for disadvantaged populations. MSH is a recognized leader in providing pharmaceutical management technical assistance.

USP, based in Rockville, Maryland, is an international leader in drug standards and the developer of the leading compendia of drug information in the United States.

USAID's need for pharmaceutical-related expertise and support the Agency's strategic objectives.

B. METHODOLOGY OF THE EVALUATION

To achieve the above objectives, USAID assembled a seven-member evaluation team:

- Ms. Susan M. Bacheller (Johns Hopkins Child Survival Fellow, seconded to USAID's Global Bureau for Population, Health and Nutrition)
- Mr. Steven W. Frank (attorney, and former consultant to USAID's Office of Health and Population, and WHO's Action Programme on Essential Drugs);
- Ms. Mary L. Harvey (Technical Advisor in AIDS and Child Survival, seconded to USAID's Africa Bureau)
- Ms. Margaretha I. Helling-Borda (public health and drug policy specialist, pharmacist, and former director of the WHO's Action Programme on Essential Drugs)
- Mr. Michael W. Noel (formulary and drug use management specialist, pharmacist, and member of the faculty of the University of Arizona)
- Ms. Ellyn W. Ogden (Technical Advisor in AIDS and Child Survival, seconded to USAID's Global Bureau for Population, Health and Nutrition)
- Ms. Wendy L. Wallace (Johns Hopkins Child Survival Fellow, seconded to USAID's Bureau for Europe and Newly Independent States).

The team convened in Washington, DC, on June 16, 1997, for a series of meetings with personnel from USAID, the cooperating agencies, and collaborating institutions. Following these meetings, the team visited four countries where RPM activities — of varying maturity and complexity — are taking place: Russia, Nepal, Zambia, and Mozambique (see Table 1.1).

TABLE 1.1. EVALUATION TEAM SITE VISITS

Country	Participating Members of the Evaluation Team	Dates of Visit
Russia	Bacheller, Frank, Noel, and Wallace	June 22–July 9
Nepal	Bacheller, Frank, Helling-Borda, and Ogden	July 13–18
Zambia	Bacheller, Frank, Harvey, and Helling-Borda	July 19–22
Mozambique	Bacheller, Frank, Harvey, and Helling-Borda	July 22–26

Members of the team (i.e., Bacheller, Frank, Helling-Borda, and Ogden) also visited Geneva to discuss technical issues and areas of potential collaboration with the World Health Organization's (WHO's) Action Programme on Essential Drugs and other WHO programs.

At the conclusion of the site visits, the team consulted again with project participants and collaborating institutions. These consultations, and the preparation of the first draft of this report, took place during August and September 1997.

On November 6 and 7, 1997, the team reconvened in Washington to give USAID and the cooperating agencies a preliminary debriefing of the team's conclusions and recommendations. This report was finalized during December 1997, following the debriefing and incorporating USAID's comments.

II. Technical Background

In most countries, pharmaceuticals account for the largest share of public health expenses other than salaries for personnel. Despite these large expenditures, the pharmaceutical sector in many countries — particularly in developing countries — is plagued by shortages of supply and, in some instances, the presence of drugs of questionable usefulness and/or quality. Also, pharmaceuticals are often prescribed and/or used ineffectively. Such "irrational use" of drugs not only wastes scarce resources, but also can compromise patients' health and present significant health concerns for the population by decreasing the overall effectiveness of drugs such as antimicrobials.

To address these problems, WHO took the seminal step in 1977 of establishing a Model List of Essential Drugs. This list includes close to 300 drugs and is a model that furnishes a basis for countries to identify their own priorities and make their own selections. The list was updated most recently in 1995 and will again be updated in December 1997. The WHO document also defines the role of drugs in health care and identifies the complementary policy, legislative, logistical, and educational actions necessary to ensure the regular supply and rational use of essential drugs. In 1981, WHO established the Action Programme on Essential Drugs:

> to contribute to reduced morbidity and mortality from common illnesses by collaborating with countries to develop and implement national drug policies

and programmes which ensure equity of access to essential drugs, rational use of drugs, and drug quality, within the context of the national health policy.[2]

This mandate remains unchanged today and has influenced RPM's mandate of efficiency, equity, and quality in drug management. The program currently provides some level of direct support to about 50 countries' national essential drugs programs and promotes rational drug use, sponsors training and development work, and engages in operational research.[3]

Other multilateral institutions, such as the World Bank and United Nations Children's Fund (UNICEF), have actively supported essential drugs programs and reform of pharmaceutical sectors in developing countries. Bilateral donors, including Denmark, France, Japan, Netherlands, Sweden, and the United Kingdom, also have supported essential drugs initiatives — both through targeted support to multilateral institutions and through direct support to country programs. It is important to note, however, that much of this donor support has consisted of actual provision of pharmaceutical supplies rather than technical assistance.

Until 1992, USAID's activity in the realm of essential drugs and pharmaceutical management had been limited in scope, and implementation of its activities had been ad hoc. Indeed, USAID's general absence in the essential drugs area was conspicuous given the relative importance of drugs in the health sector and had generated substantial distrust among some donors and multilateral institutions. Against this backdrop, in 1992, USAID supplemented the funding for its Health Financing and Sustainability (HFS) Project to include a component on Rational Pharmaceutical Management (i.e., the RPM Project).

The RPM initiative was designed to address the increasing difficulties developing countries faced in "funding and maintaining adequate and accessible pharmaceutical supplies," acknowledging that weak pharmaceutical sectors were undercutting the credibility of developing country health systems as a whole.[4] As

2 WHO Action Programme on Essential Drugs, *WHO Essential Drugs Strategy: Objectives, Priorities for Action, Approaches.* Geneva: WHO, February 1997.

3 WHO Action Programme on Essential Drugs, *Progress Report 1996: Interim Report of the Biennium (1996–1997).* Geneva: WHO, February 1997.

4 USAID, *Health Financing and Sustainability (936-5974) Project Paper Supplement,* Washington, DC: USAID, March 1992.

such, the new pharmaceutical component was created to address key issues of "efficiency," "equity" and "quality" that were brought out in work conducted under the HFS Project.

III. Project Design and Evolution

As described in USAID's March 1992 Project Paper Supplement to the HFS Project, the RPM Project's goal was "[t]o improve the health status of target populations in LDC's through improvements in the allocation, and use of financial, human and information resources within the health sector." To this end, the project intended:

> 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, and (2) improving the allocation, use and management of health sector resources, both public and private, and (3) enhancing access to, and dissemination and utilization of accurate, unbiased drug information.

USAID issued a Request for Assistance (RFA) seeking cooperating agencies' assistance in achieving these purposes. Cooperative agreements (CAs) were chosen as the appropriate funding mechanism because USAID recognized that flexibility and innovation were required to develop suitable approaches to pharmaceutical management issues and that the adaptability inherent in a CA made it the most appropriate mechanism for improving country situations.

A. Range of Activities

The RFA highlighted three technical areas as illustrative examples of the types of activities to be undertaken:

- Establishment and automation of drug registration systems
- Strengthening and rationalization of public sector pharmaceutical procurement and supply management
- Expansion of drug information resources and promotion of rational use.

Within these technical areas, RPM was to provide such services as long-term assistance at the country level and information dissemination. Examples of specific modes of operation to carry out included diagnostic assessments of pharmaceutical sectors, policy analysis and dialogue, training, studies and operations research, communications strategies and social marketing, and collaboration with other donors.

B. PURSUIT OF AN ASSESSMENT-BASED APPROACH

Consistent with USAID's desire to have a cooperating agency — not a contractor — assist the Agency with this project, the project was designed to use an assessment-based approach. Through this approach, the cooperating agencies were to work with host governments to assess the needs of each individual country and specifically tailor interventions to meet those needs.

As discussed more fully below, the development of an indicator-based approach in assessing pharmaceutical sector operations has been integral to the project design and operation. This approach included collecting data in the following eight areas:

- Policy, Legislation and Regulation
- Formulary/Essential Drug Lists and Drug Information
- Ministry of Health Pharmaceutical Budget and Finance
- Ministry of Health Pharmaceutical Procurement
- Ministry of Health Pharmaceutical Logistics

- Patient Access and Drug Utilization
- Product Quality Assurance
- Private Sector Pharmaceutical Activity.

During the RPM project country-assessment phase (April 1992 to January 1994), seven assessments were undertaken in:

- the Eastern Caribbean
- Ecuador
- El Salvador
- Ghana
- Mozambique
- Nepal
- Ukraine.

This process made it clear that the establishment and automation of drug registration systems was generally not feasible within the confines of the project or was not then a priority of host governments. Thus, RPM's activities were focused on three technical areas (described below):

- Improving Allocation, Management and Use of Resources
- Promoting the Rational Use of Drugs
- Improving Level of Drug Information.

For the purpose of discussing country program outcomes and impacts (see section IV.A. below), this report uses this classification of activities.

C. STRUCTURE AND CHANGES IN PROGRAM FUNDING

In September 1992, USAID awarded five-year cooperative agreements (CAs) on a competitive basis to MSH and on a sole-source basis to USP. The CAs were originally designed to carry out core-funded, experimental programs of technical assistance in up to three developing countries. The original developing country portfolio consisted of Ecuador, Nepal, and Mozambique. However, the former Soviet Union dissolved at about the time the original CAs were awarded. To address health care concerns identified by the Newly Independent States' Task Force, an "Add-on" was awarded to the MSH CA in September 1993, and USAID's Bureau for Europe and Newly Independent States later awarded separate CAs to MSH and USP for work to be carried out in the Russian Federation. All four CAs are managed by the Global Bureau under the HFS Project.

In 1995, USAID's funding strategy changed. USAID adopted the field support funding strategy, which caused dramatic cuts in planned core funding for the two Global CAs. Contrary to the earlier direction given to MSH and USP, the project was encouraged to market itself more broadly with field missions. As a result of this process, the RPM Project has added new country programs in Peru, Zambia, and Bangladesh and has joined a regional public health logistics initiative managed by the Regional Economic Development Services Office for Eastern and Southern Africa (REDSO/ESA).

D. FUNDING MECHANISMS COVERED BY THE EVALUATION

The RPM Project thus consists of four CAs. These include two CAs awarded to MSH and two to USP. As discussed above, the separate CAs for each organization distinguish between work to be carried out worldwide and work to be carried out in the Russian Federation. The CAs are summarized in Table 3.1.

TABLE 3.1. RPM COOPERATIVE AGREEMENTS

CA	Start/End Dates	CA Number	Total Estimated Project Cost	Estimated USAID Contribution	Obligations to March 1997
MSH Worldwide	9/25/92–9/23/97	HRN 5974-A-00-2059-00	$9,830,000	$8,900,000	$7,937,311
MSH Russia	1/6/95–12/31/97	HRN 0004-A-00-5002-00	$2,374,264	$2,374,264	$2,374,264
USP Worldwide	9/17/92–9/15/97	HRN 5974-A-00-2052-00	$2,078,156	$1,286,076	$1,285,000
USP Russia	12/22/94–12/31/97	HRN 0004-A-00-5001-00	$1,124,000	$1,124,000	$1,124,000

IV. Technical Analysis

The project's activities can be broken down into two general categories: those designed specifically for country programs and those of more generalized application. These two categories are described below as "Country-Level" and "Core" activities.

A. Country-Level Activities

The project defined certain principal goals for its country-level activities, including:

- Improving Allocation, Management, and Use of Resources
- Promoting the Rational Use of Drugs
- Improving Level of Drug Information.

This section of the report addresses these three principal goals, setting forth for each goal the key approaches and activities undertaken by MSH and USP and the conclusions and recommendations reached by the evaluation team.

1. Improving Allocation, Management, and Use of Resources

a. Key Approaches and Activities

MSH and USP addressed the project goal of improving allocation, management, and use of resources through activities in three key technical areas: Drug Selection/Formulary Development, Drug Procurement and Supply Management, and Community Pharmacy Management.

(1) Drug Selection/Formulary Development

MSH assisted country programs in the areas of drug selection and formulary development. Depending on the interest and need of the host country, efforts in this technical area were directed at the federal, regional, or facility level.

This component of the project has been most active in Russia.[5] Overall, it has been extremely successful, and, in fact, many Russians point to the progress in formulary development as the project's greatest success in Russia. Professors of clinical pharmacology at the St. Petersburg Institute of Medicine commented, "Five years ago, nobody in Russia knew what a formulary was, now, thanks to RPM, everyone does." Hyperbole aside, the evaluation team agrees that this aspect of the project deserves these accolades.

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5 Formulary development has not been a primary focus of technical assistance in most other long-term RPM countries except for Ecuador, although formulary status and contents were considered in the assessments in Ghana, Nepal, Ecuador, Mozambique, and the Eastern Caribbean. In Ecuador, the Manual for the Development and Maintenance of Hospital Drug Formularies was translated into Spanish and applied in the Hospital Eugenio Espejo. In Nepal, RPM is currently considering providing financial support (along with WHO) to the Department of Drug Administration for the publication of the country's essential drug list and a "draft" formulary. This would be important because, despite the strong leadership of Professors Kafle and Joshi (among others) at Tribhuvan University, few hospitals have formularies in Nepal (the notable exception is Patan Hospital, run by the United Mission of Nepal). Anecdotal evidence indicates that the reason for this has been resistance to change on the part of physicians who have good relations with drug company representatives who also resist such change. Another reason for the lack of formulary development in Nepal may be the fact that 80 percent of the drugs in the public sector in Nepal are donated. The lack of fiscal accountability over this large share of drugs may have eliminated the financial pressures on hospitals and regional governments (in contrast to the situation seen in Russia) that promote adoption of essential drug lists and formularies.

- Russia: In Russia, the project has pursued development of formularies as a matter of policy at the oblast level[6] (e.g., in the Novgorod and Pskov oblasts) and at individual health care facilities (e.g., in the Ryazan oblast).

  - Oblast-wide interventions in Novgorod and Pskov: Novgorod and Pskov have shown strong success in the development of "all-oblast" formularies, building on the work of formulary committees assembled at key hospitals within the oblasts. Novgorod has also taken the remarkable step of enacting resolutions embodying the principles embraced by RPM, including a mandate requiring development and maintenance of an oblast-wide drug formulary.

    The achievements of Novgorod and Pskov at the oblast level are impressive, although it is also impossible to ignore the fact that the majority of hospitals in these oblasts have until now continued to operate without their own formularies and that no published formularies have yet been produced (in contrast to Ryazan, which is discussed below). Consistent with RPM's plan, certain hospitals in the oblasts have adopted formularies, following the achievements in "seed" hospitals, without any direct technical assistance from MSH or USP (e.g., City Hospital #1 in Pskov). It should be noted that RPM provided intensive, hands-on technical assistance to only one of the 59 hospitals that eventually adopted formularies (Ryazan Oblast Clinical Hospital). All other hospitals implemented formularies after attending RPM workshops and utilizing the RPM manual on formulary development.

    The evaluation team also noted a close correlation between successful interventions at the oblast-level and the presence of strong, committed politicians within the oblast government. Similarly, politics and changing political structures pose a significant challenge to enacting and sustaining policy successes at the oblast level.

  - Hospital-level interventions in Ryazan: RPM intentionally began its technical work in Ryazan Oblast at the hospital level because, at the time, very few health professionals in Russia had even a basic

6 Oblasts are the equivalent of regions or states.

understanding of formulary concepts. Focusing on the hospital level allowed RPM to reach large numbers of people through its training activities and create a "critical mass" of formulary supporters. The oblast administration, with whom RPM has always worked very closely, endorsed this approach at the November 1994 Policy Options Workshop.

In many respects the Central Hospital in the City of Ryazan remains a model of the project's success, despite its financial struggles. With RPM's assistance, the hospital was able to reduce the number of drugs it used from approximately 1,500 to 424 by eliminating unsafe, ineffective, and duplicate drugs. The hospital also published a formulary for use by prescribers which includes information on each drug in the formulary.

Following the experience of Ryazan's Central Hospital, seven other hospitals in Ryazan, including the Oblast Children's Hospital, have implemented formularies. In Ryazan (and the other oblasts mentioned above), the project has significantly exceeded the ambitious targets set by the USAID mission for the number of hospitals to adopt formularies. Yet most hospitals in Ryazan have not developed formularies, and building on the success of the Central Hospital will not be easy. Progress has been slow due to the very difficult economic situation in the oblast and recent leadership changes in the Oblast Health Administration. In addition, significant cultural and/or educational challenges exist — Ryazan is a large rural area, about one-third the size of France. Nonetheless, there is substantial interest at the hospital level in Ryazan, and the widespread Russian interest in formularies is almost entirely due to RPM's work which began in Ryazan.

The health impact of the project have not been well quantified, but hospital personnel attribute to the project shorter hospital stays, better quality of care, and fewer drug complications in patients. Hospitals used safety and efficacy criteria in drafting formulary lists, and many drugs were eliminated from use on this basis. Drug use reviews (discussed below) are being developed at many sites and these should help to quantify the possible health impacts from formulary development.

(2) Drug Procurement and Supply Management

MSH has provided technical assistance in the area of drug procurement and supply management to several countries, including Ecuador, Mozambique, Nepal, Russia, and Zambia. Although the nature of this assistance has varied by country, it can be described as providing assistance to countries for managing the purchase, storing, distribution, and control of their drug inventories.

The project's involvement in procurement has been limited to date, but, along with drug selection and formulary development, procurement is an area where the project can assist central and district-level managers in many countries who face decentralization. Strengthening procurement mechanisms and supply management also can facilitate integration of previously vertical programs. Comments on specific country interventions follow.

- Ecuador: RPM's work in developing and implementing the decentralized drug management model in Ecuador is an important innovation. The model is a departure from the planned procurement reform, and it shows RPM's flexibility and responsiveness to the opportunities in each country and over time.

- Mozambique: The government and donors currently are concerned about leakage of drug donations (e.g., by Netherlands, Norway, and Switzerland) to the private sector and to other countries. Some donors have estimated that the leakage may be as high as 50 percent of public drug donations, which would translate into US$10–15 million worth of drugs in the past year. DGIS (the Dutch aid agency) is funding a study by STS and Coopers and Lybrand to to quantify the volume of drugs lost and determine the reasons by reviewing inventory control records. Although the results of the study are not expected for months, there is little doubt that the study will highlight the need for better inventory controls at the central and regional levels. Some donors and providers have identified RPM as a potential provider of technical assistance to create better inventory control because of RPM's positive experience with logistics training for provincial, district, and health facility level staff, plus its capacity to install the INVEC-2 software for inventory management. The evaluation team concurs with those who believe that RPM's experience in this area could be extremely valuable.

- Nepal: One key project activity in Nepal has been the project's work to improve logistics management, undertaken in close cooperation with the logistics management project administered by John Snow, Inc. The effort, which has been very well received by country officials, has included "dejunking" of central and regional warehouses, organizing inventories, and removing expired and contaminated medicines, among other things.

  The results of the project's procurement work in Nepal have been mixed. Both USAID and RPM regarded the absence of a counterpart for RPM's procurement advisor to be a serious problem that has minimized the chances of successfully transferring technology. They also felt that the Logistics Management Division (LMD) of the Nepal Ministry of Health (MOH) had kept RPM at arm's length when procurements were actually being carried out. For example, LMD declined to use a supplier database and procedures designed by RPM for evaluating bids despite opportunities to do so. On the other hand, the head of LMD expressed appreciation for RPM's work. In particular, he explained that RPM had assisted with the preparation of a supplier pre-qualification manual, which apparently is being disseminated and was used for at least one tendering cycle. This suggests that RPM did have some influence on MOH procurement practices, although not nearly to the degree the staff had hoped.

  Because the government has begun to allow the regions to allocate their own drug budgets (instead of receiving from the government a "set package" of drugs), needs for procurement and supply management assistance appear very high. However, given the ambiguities in the government's commitment to reform in this area, it is difficult to predict how successful such support could be. In any case, RPM's collaboration with GTZ (the German aid agency) to develop a comprehensive drug management system for two districts in Nepal is an important development that is worthy of support and which could be a prototype for others (this is discussed more fully in Annex B, Country Report — Nepal).

- Russia: As in the formulary area, Western procurement concepts were poorly understood in Russia prior to RPM. A significant amount of time was spent early in the project convincing oblast officials that the introduction of competitive procurement techniques could lower drug costs. In Novgorod, Pskov, and Ryazan, the project assisted local governments to conduct tenders of limited numbers of drugs, which were reasonably successful. In particular, Ryazan conducted a "mini-tender" for

human insulin that resulted in a cost savings of approximately $500,000, and Novgorod and Pskov have cited savings of between 20 and 40 percent from mini-tenders of drugs in specific therapeutic classes. However, somewhat surprisingly, local officials have expressed a need for close supervision and training for future tenders — a lack of confidence that is probably the result of continued uncertainty about operating under a free market. The evaluation team expects that this lack of confidence will easily be overcome and that project interventions in this area will be extremely productive.

- Zambia: Assistance in supply management is one of the most promising areas for project support in Zambia because the government is currently engaged in an ambitious plan of decentralizing decision-making about the allocation of drug budgets and reorganizing the role of the central medical stores. RPM has begun to assist the government in inventory control, and this work has been very well received by local officials. The future seems very strong for this area, and the government already has made specific requests for additional technical assistance to help the regions quantify drug needs, order the necessary drugs, and manage their supplies. Similarly, the central medical stores have received some assistance in responding to regional orders and controlling their drug inventories, and they are seeking additional help. RPM's technical assistance in the application of INVEC-2 in August 1996 helped the Zambians prepare the documentation necessary to qualify for a World Bank loan and thereby to avert a serious crisis in drug availability.

  The development, testing, and application of DILSAT (the District Integrated Logistics Self Assessment Tool) started in two districts in 1997, and a nationwide application is planned for 1998. This has the strong backing of the government. DILSAT promises to be an important supervisory and monitoring tool for district health managers and facilities under the integrated drug and supply management system that is part of Zambia's decentralized health system. DILSAT generated a lot of interest in REDSO at a meeting held in Kenya during the spring of 1997.

(3) Community Pharmacy Management

MSH provided assistance to individual pharmacy owners and operators in Russia in the area of community pharmacy management.

- Russia: The project's involvement in this area has been widely popular with the pharmacy owners and operators involved, RPM's involvement has been extremely popular with the pharmacy owners and operators involved, who were instructed how to develop business plans that would allow their pharmacies to survive the enormous stresses they faced under the restructuring of the Russian economy. Some of the pharmacies visited by the team had faced bankruptcy before the project's assistance, but now had well organized inventories and appeared to have rebounded financially.

This project component, which fell under USAID/Moscow's strategic objective of strengthening democracy, has clearly empowered business owners to succeed in a free market system and improved access to needed drugs. By helping these pharmacies to survive threatened bankruptcy, access to needed drugs is improved. Indeed, families sometimes must purchase drugs even for hospitalized family members since the necessary drugs are not always available in the hospitals.

Nonetheless, in those countries where strengthening the private sector's ability to deliver health products and services is a priority, the project needs to be sensitive to the possibility that its interventions might promote the success of one private sector entity over another, equally deserving, competitor. In such situations, the private sector's ability, as a whole, to deliver health care services would not be benefited by the project. (It should be noted that selection of the pharmacies for participation in this activity was done by the oblast public health authorities, not RPM.) The evaluation team was unable to determine whether the project's interventions in support of certain pharmacies had an adverse effect on other pharmacies and the degree to which this component of the project had a positive effect on the delivery of health products to the local communities.

b. Conclusions and Recommendations

(1) Drug Selection/Formulary Development

In Russia, several successful examples of oblast- and hospital- formularies have been developed over a reasonably short period of time. The challenge for RPM-Russia now is not to see whether these interventions can work (they clearly can),

but to spread the lessons learned at the initial project sites throughout the oblasts where the project works and in other oblasts in Russia. To meet this challenge, the project should build on one of its most notable strengths — namely, its ability to identify and empower people of unquestionable commitment and skill. The leadership and professionalism of Russian personnel has been impeccable, highlighting the excellent work done in initial selection of pilot oblasts and in the assessment studies. The value of these personnel in educating others in Russia (and other NIS countries) should not be underestimated.

Looking beyond Russia, in this era of decentralization, support to district-level managers for drug selection and formulary development for districts and hospitals will become increasingly important. Countries such as Zambia, Mozambique, and Nepal may need long-term support in this area. For example, in Zambia, this area is already starting to get support from the Swedish International Development Agency (SIDA). RPM's experience in Russia and the materials the project developed there are worth sharing and discussing with other countries such as Zambia.

Recommendations

- The project should help ensure sustained success in the areas of drug selection and formulary development where the project currently works. If the project expands its work in this technical area to other regions or countries, it should seek to ensure that, whenever possible, local counterparts who have played key roles in drug selection and formulary development are the ones to "spread the message" (particularly in Russia). This can elevate these stakeholders' professional status and give them added incentives for participating in the project, at the same time freeing RPM's project staff for other tasks.

- The project should expect to become more heavily involved in drug selection and formulary development at district levels in those developing countries that are undergoing decentralization. Many of these countries may not adhere to their national essential drug lists or have effective national drug policies and will need significant amounts of long-term technical assistance. For this effort, it may be possible to use technology provided through the drug information component of RPM to create formulary manuals modeled after those developed for Russia.

(2) Drug Procurement and Supply Management

There is great potential impact for this element of the project to grow in Mozambique, Nepal, Russia, and Zambia. Although the evaluation team did not visit Ecuador, Peru, Bangladesh, or REDSO/ESA, it appears that these programs also have significant potential in procurement and supply management. Along with drug selection and formulary development, procurement is an area where the project can assist central and district-level managers in many countries who face decentralization. Strengthening procurement mechanisms and supply management also can facilitate integration of previously vertical programs. RPM is working directly on these issues in Zambia, Ecuador, and, increasingly, Nepal. This is clearly an important thrust of the project's future work, and by coupling its work in this area with assistance on drug selection/formulary development and rational use, RPM could contribute significantly to a district drug management package, which is in growing demand as more countries take up health reform.

Recommendation

- The project should continue to maintain its strong capacity to assist countries in the area of drug procurement and supply management. If and when greater assistance in this area is requested from RPM, the project should prioritize its assistance to those countries where it currently works, where there is a positive political environment to effect change, and where long-term assistance from project or collaborating personnel is available.

(3) Community Pharmacy Management

From a health perspective, this area of the project should not be a high priority. The principal value of this area of the project is in those countries where it meets a specific strategic objective, such as strengthening private sector mechanisms for delivering health products or services. This is, of course, the case for Russia. However, for other countries, where the strategic objectives are more health-impact based, this component of the project appears to be of less direct benefit.

Recommendation

- The project should consider involvement in this area, as it has currently been defined, only where there is a clear program mandate from the USAID mission to implement measures to strengthen the private sector's

ability to deliver health care products and services. In such countries, the project should attempt to make training and other assistance available to all interested local private sector entities, as funding allows and with the concurrence of USAID and local authorities.

2. Promoting the Rational Use of Drugs

a. Key Approaches and Activities

RPM has worked to promote the rational use of drugs in many project countries, including all the countries visited by the evaluation team. The project's efforts have met with varying — but commendable — degrees of success. The project has built up a very good network, both within individual countries and internationally (not least because of MSH's role in coordinating the International Network for Rational Drug Use, or INRUD). This mean the project can share its expertise and draw on others' in this difficult area. One opportunity to do this was provided by the Chang Mai conference held in April 1997, a joint undertaking by INRUD, WHO, USP, and USAID's Applied Research on Child Health (ARCH) Project. The conference analyzed different approaches to effective promotion of rational use of drugs and outlined needed interventions and research that should guide the project in the future.

The RPM Project has taken several approaches to promote the rational use of drugs, including, but not limited to, developing standard treatment guidelines (STGs), reforming curricula for health care providers to incorporate lessons on rational use, directly training providers and consumers, and introducing and implementing hospital-based drug use review programs.[7]

(1) Standard Treatment Guidelines, Curricula Reform, and Training

RPM has worked to develop and introduce standard treatment guidelines and/or conduct training for public sector health workers in Mozambique, Nepal, Russia, and Zambia. This work has been conducted as part of the project's support to

7 Of course, the development and dissemination of unbiased drug information to providers and consumers is critical to the promotion of rational use. This area is discussed at length in section IV.A.3 of this report.

district level managers. When combined with both supervision and monitoring of drug use (i.e., drug use review, discussed below) and a constant supply of agreed-upon priority drugs, the approach taken by the project in these countries has proven to have a significant, cost-effective health impact. However, when these two factors are not in place, STGs and training will not achieve the elusive goal of rationalizing drug use. Thus, while the project components related to rational use have been appropriate and much needed, they — and their potential impact — must be seen in the larger context of adequate supplies and follow-up reviews.

Russia provides examples of many of the types of activities the project has supported in the area of training. RPM's training assistance has comprised development and distribution of written reference materials, presentations at meetings, hands-on assistance by RPM staff and consultants, study tours, workshops, and courses. The reference materials developed include Russian translations of the *WHO Guide to Good Prescribing, Managing Drug Supply* (which was adapted in collaboration with WHO), and *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach,* as well as how-to manuals on formulary development, drug use review, and inventory management.

Descriptions of the project and its accomplishments have been presented at the past three "Man and Drugs Congresses," annual meetings attended by thousands of physicians from throughout Russia. The majority of such presentations were made by Russian officials and specialists from the three RPM oblasts. Presentations also have been made at the American International Health Alliance (AIHA) Annual Conference, held in the United States; a conference sponsored by Abt Associates; a pharmacology conference at St. Petersburg State Medical University; and at many other U.S. and international meetings.

MSH staff, noted Russian physicians, and American experts conducted a number of visits and consultations to assist the Russian counterparts in understanding and moving ahead with formulary development, drug use review, and tendering. Workshops were held on several subjects including indicator-based assessments, formulary development, drug use review, community pharmacy management, and rational drug use. A three-week course on clinical pharmacology was conducted in collaboration with the Moscow Medical Academy for 140 physicians from Novgorod and Pskov.

RPM also has been very active in curricula reform in the Ryazan oblast, where the project has introduced the concept of rational drug use in medical and pharmacy school curricula. The project's support to the Medical University in Ryazan is

exemplary, though much work remains to be done in the other oblasts and, of course, throughout Russia as a whole. Measuring the meaningful impact of curricula reform requires a long-term approach, as for measuring the impact from standard treatment guidelines. In Ryazan, it is too early to measure the health impact from changes in curricula, although the project deserves praise for successfully introducing these reforms.

In contrast to the rapid progress in Russia, Nepal has still not been able to introduce the concept of rational drug use or the *WHO Guide to Good Prescribing* as a permanent feature of its medical education, despite the advocacy of INRUD members in Nepal and WHO assistance dating back to 1986.

(2) Drug Use Review

As mentioned, drug use review (DUR) is critical to improving rational drug use. The RPM Project has been most successful in imparting this notion to local stakeholders in Russia, where it is now well understood, at least in the oblasts where RPM has worked.

In Russia, limited DUR activities have been undertaken in the three blasts under the auspices of the local formulary committee. MSH-provided manuals and training have been used in developing criteria for the institutions conducting DUR. In some instances, there was knowledge of the process but a hesitancy to commence activities, which local counterparts attribute to a lack of personnel and/or computers to carry out a seemingly daunting task. This indicates that some local counterparts misinterpreted how to conduct and report findings of DUR — for example, nothing in the MSH materials implies the need for a computer, and this is certainly not the case.

It appears that drug use review is perceived by the Russians as an activity that takes place only after the formulary is developed. Having a formulary is not a requirement, although it may assist in the development and acceptance by the medical staff of the criteria and process and may improve the long-term acceptance and effectiveness of DUR activities, even if it slows the process. Given the fact that the RPM Project has been implemented for just over two years and for only one year in many of the areas visited, the extent of locals' understanding of the DUR concept and the fact that some reviews have been completed is promising.

The team believes that some of the Russians' apprehension about conducting DUR activities in certain settings reflects a lack of confidence (and a need to be

"jump started") as well as a natural tendency to avoid conducting or outwardly discussing studies to identify deficiencies in physicians' prescribing practices. It is understandable that finding fault in one's own processes is seen to be an imposing task that is postponed. In addition, there is no tradition of a "clinical pharmacist" in Russian hospitals, nor is there the type of collaborative working relationship between pharmacists and physicians, as in the United States. Thus, the project may need to redouble its efforts to educate the facilities' staffs about how to conduct DURs and the potential economic and health care benefits of improving prescribing. These efforts will be enhanced once the process is completed and positive results are shown in Russian facilities and shared with others.

b. Conclusions and Recommendations

(1) Standard Treatment Guidelines, Curricula Reform, and Training

The project's efforts to develop standard treatment guidelines, reform curricula, and conduct training in rational use have been commendable, and the components of the project should continue to be made available to developing countries as part of any USAID project support. Promotion of rational use of drugs through these mechanisms should be made part of the whole district drug management and logistics support package and would serve to integrate different health programs. Training in rational drug use and adoption of standard treatment guidelines — developed with the use of objective clinical and drug information, and with attention to pharmacoeconomic issues — are of vital importance to global health care.

Recommendation

- The project should continue to make technical assistance available to developing countries in the areas of standard treatment guidelines, curricula reform, and training. Adapting U.S. and international treatment guidelines to local environments will be an excellent use of resources. Further, integrating the principles of rational drug use into the core curriculum of medical and pharmacy students and practitioners will foster sustainability of the project.

(2) Drug Use Review

This is an area with significant potential for the project in Russia and other NIS countries. This component of the project, however, has less immediate potential at the hospital-level in countries such as Mozambique, Nepal, and Zambia, which do not yet have established hospital therapeutic committees. However, for these countries, a modified DUR, an analysis of prescribing patterns, or a rapid indicator assessment on the use (and expenditure) of drugs in a hospital or primary health care setting may stimulate facilties to create such committees and undertake more in-depth DURs, for example, related to the use of antibiotics.

Recommendations

- The project should identify opportunities to study prescribing patterns as a modified approach to DUR in settings that do not have therapeutics committees. The findings of such studies will serve to guide the design of follow-up training activities.

- Efforts should be made to demonstrate the impact of the DUR process. This process is labor-intensive and requires a significant commitment of resources, and without being informed about the benefits of an organized DUR program, local counterparts will find it difficult to justify commiting resources to a function that does not appear to be directly related to patient care.

- Assistance should be provided to local counterparts in Russia and other countries for interpreting the results of DURs and for providing the necessary training to modify prescribing behavior. This may be most effectively done — at least initially — by using outside consultants in order to minimize the difficulty of pointing out the deficiencies of one's own processes or behaviors.

- Assistance also should be provided for implementing a reassessment of post-training prescribing in order to determine whether DUR, along with follow-up training, improves prescribing practices. Positive results should be shared at appropriate conferences such as Russia's annual congresses on "Man and Drugs."

3. Improving Level of Drug Information

a. Key Approaches and Activities

The project's efforts to improve the level of drug information have taken two basic forms: development of unbiased drug information for use in developing countries, and assistance in disseminating this information through the development of drug information centers.

(1) Development of Unbiased Drug Information

USP developed monographs for 37 drugs included in the WHO Model List of Essential Drugs that had not previously been included in the USP Drug Information (USP DI). Eight additional monographs are currently under development, and nine more are planned.

USP has also supported adaptation of the USP DI to incorporate country-specific indications, dosing schedules, and other information into existing drug monographs and to develop separate, country-specific drug monographs. Adaptation of the USP DI is underway in Russia and Nepal and is planned for Mozambique. In Russia and Mozambique, USP has worked (through side agreements not formally part of the RPM Project) to translate the USP DI into Russian and Portuguese. In Nepal, USP's efforts have focused on adapting an English-language USP DI database into a Nepal-specific English-language database that would include, among other things, Nepal-specific brand names for drugs in the database. Each of these country programs are discussed below.

- Mozambique: The delivery of USP drug information materials in Portuguese to the Library and Documentation Center of the National Institutes of Health of the MOH has been extremely well received by local counterparts. Indeed, the delivery of this information in Portuguese appears to have been critical to the interest of local counterparts in the drug information component of the project. Prior to RPM's assistance, the MOH's library of drug information was reasonably well developed, but major drug reference texts were available only in languages other than Portuguese. Local counterparts expressed strong appreciation for this information and showed great command in accessing the information electronically, something not seen at all project sites (discussed further below). A counterpart has been identified to adapt the USP DI to include

annotations and monographs for Mozambique-specific drugs. In this regard, a physician at the MOH's department of Maternal and Child Health conveyed to the team that there is a need for unbiased drug information on contraceptive products in Portuguese and that RPM could assist in developing this information.

- Nepal: The project provided the USP DI in both book and database form and provided additional drug reference books. Prior to the project, many sites had drug reference information that was incomplete and often out-of-date. Several people at various drug information centers (including those in charge of the centers at the Department of Drug Administration and the Institute of Medicine) expressed their great appreciation for the written materials and commented that they preferred to use written materials rather than the USP DI database.

  The project's effort in Nepal has focused on adapting the USP DI database to include Nepal-specific information. Although the need — and value — of this effort is widely acknowledged by health officials and physicians, progress in completing the adaptation has been limited. The Department of Drug Administration has been (by design) the only entity to return Nepal-specific data to USP, and the DDA has completed and submitted to USP annotations for 25 drug monographs. Given the limited progress to date, the evaluation team recognized that this work will take longer than originally planned.

- Russia: The project has a strong collaboration with Pharmedinfo, alongside USP's independent agreement with Pharmedinfo to translate the USP DI into Russian. To date, two volumes of drug monographs have been produced — dealing with cardiovascular and psychotropic medicines. Translation of the entire USP DI is not yet finished but is apparently 90 percent complete. USP has also entered into a contract with Geotar Medical Publishing to translate USP patient information leaflets.

  The incomplete translation and adaptation of the USP DI, although not a part of the RPM, has limited the capability of the oblast drug information centers to support activities in formulary development and drug use review and has constrained drug information dissemination. The two volumes of monographs that have been completed, though a notable achievement, have not fully met the needs of Russians for a comprehensive source of unbiased drug information. Also, concern over intellectual property piracy

have limited the distribution of USP materials in electronic formats and thereby hindered development of the drug information centers (see below).

(2) Establishment of Drug Information Centers

One of USP's main areas of involvement in the RPM Project has been assisting with the establishment of drug information centers (DICs). These have taken two general forms: those established principally to serve target populations in facilities or regions with therapeutic information and those established principally to "relay" drug information of a more regulatory or normative nature from a central source to regional areas. The project has been reasonably successful with the first type, although the strengths of the various centers in disseminating information vary. The project has been significantly less involved in establishing relay centers that are part of national networks of drug information. In the team's view, the likelihood of establishing effective networks (even at the local level) appears remote, at least in the short or medium term.

The project has successfully established a significant number of DICs, and many of these are functioning and active in disseminating information. However, collectively, the evaluation team had the most concern over the ability of the DICs to effectively fulfill their potential in disseminating drug information. The team's concerns fall in four general areas:

- The ability of the DICs to effectively disseminate information: The quality of the DICs — in terms of staffing, goals and location — and their ability to effectively disseminate information is varies widely widely-variable.

- Premature roll-out: Materials in the briefing binders indicate there was significant pressure on USAID and the cooperating agencies to establish the centers. Though many of the centers are new and not yet mature, it appears that some of them may have been rolled out too quickly. Premature roll-out may result in disuse of the centers and may keep some of them from gathering momentum that could have been gained from being established at more opportune times.

- Duplication of effort: Where multiple drug information centers exist in a given geographical area, the delineation of responsibilities and/or goals of the different centers is occasionally unclear. Establishment of duplicative centers can send inappropriate signals to country personnel who are understandably attracted to the prospect of establishing such centers. The

project needs to be extra sensitive to the problem of intra- and intergovernmental competition regarding who has the biggest and best drug information center, which, in turn, increases the likelihood of duplicative centers.

- Ability to serve rural areas: Under current conditions, it appears premature to expect drug information centers in urban centers to serve rural areas. The information flow to rural areas is very weak: phone service is not reliable, and computers are often nonexistent, and the technical capacity of rural personnel is often not up to the level of those in major urban centers.

Additional thoughts regarding the relative strengths and merits of the country initiatives are set forth below.

- Mozambique: The drug information center in Maputo opened in May 1997. It is equipped with a computer and printer, the USP DI database has been installed, and the staff are competent in their use. The first drug information workshop, scheduled for September 1997, was designed to draw attention to the issues related to drug information and rational use, and likely will contribute to increased use of the USP DI and other resource materials. The decision to locate the center in the Library and Documentation Center of the National Institute of Health appears to have been an appropriate choice due to the fact that practitioners are accustomed to using the center and the fact that staff are available and trained to assist users. A study tour to South Africa in September 1997 will motivate the already-enthusiastic staff. Adaptation of the USP DI must be a high priority in order to ensure that early interest resulting from the workshop does not wane in subsequent months.

- Nepal: The establishment of drug information centers in Kathmandu in such a short period of time is a significant accomplishment. The centers were well conceived and cover all target groups for drug information. Nonetheless, the quality of the centers, collectively referred to as DINoN, is mixed. For example, the center at RECPHEC is staffed by enthusiastic professionals and shows great potential. Also, the DIC in the Institute of Medicine seems to be well established, well used, and sustainable. In contrast, the DIC at the Nepal Chemists and Druggists Association has lagged behind due, in part, to staffing changes and to technical difficulties in installing computer software. The DIC at the Department of Drug Administration has well organized, dedicated space, although the DDA has not committed sufficient permanent staff for the center, and its use is

low (only about ten inquiries a month are received, including those not recorded). At the DDA, staff could not articulate a standard process for responding to inquiries, an area that could use improvement.

Coordination among the different DINoN members is currently weak, as exemplified by the fact that only one meeting of the DINoN steering committee had been held. Personality differences among the different members accounts for part of this weakness, and leadership from the DDA (the acknowledged "focal point" of the network) has not always been effective or accepted by others. Given the difficulties in coordinating and managing the current network of DICs, expansion of the network to the two identified sites in the regions seems imprudent.

- Russia: Drug information centers have been established with the support of USP at both the central and oblast levels. At the time of the evaluation team's site visits, most of the centers were a few months old (at the most), and many had just received key books and computer equipment in the weeks preceding the team's visit. Thus, it was too early to tell whether, or to what extent, these drug information centers will be successful in improving the level of drug information available to providers and patients. Nonetheless, hints of concern in the above-mentioned areas were evident.

  For example, regarding their relative abilities to disseminate information effectively, the capacities of the centers were mixed. The drug information centers at Ryazan's Central Hospital and in Ryazan's Medical University exuded vitality. There, the centers were well integrated into hospital operations, formulary development and DUR, and the university curricula. Indeed, the hospital center in Ryazan had already received many calls on its hotline from patients seeking drug information. At the other end of the spectrum, the staff at the center at the Moscow Medical Academy appeared to lack a clear vision about how the DIC could support curriculum development, and the current location of the center (among lab benches in a laboratory) was ineffectual.

  The team also was concerned that roll out of many of the centers may have been premature. The basis for the team's concern is that key information still exists only in English, availability of USP DI database has been limited, and staffing has not yet been found for some of the centers. Also, the team observed some confusion regarding the roles of the different centers in Novgorod. This confusion may have its genesis in the local

government's request for three centers (two have been established) with apparently little technical justification for the third. The team recognizes that USP was under pressure to equip the DICs quickly to demonstrate commitment to the project and because the Russian counterpart institutions were not likely to hire the needed personnel to staff the DICs until they were established.

Finally, despite the success of the centers in Ryazan and the excellent integration of hospital and university DICs into the local communities, the inability of these centers to effectively service rural areas was widely acknowledged. Communication infrastructure in Russia is still weak: rural hospitals lack computers, and phone lines are unreliable. Where computers are present, local counterparts are extremely capable and comfortable with their use.

b. Conclusions and Recommendations

(1) Development of Unbiased Drug Information

The success of the project in this area has been mixed. The outcomes from the project in Mozambique and Russia have been very fruitful, but there has been less progress in Nepal. Much of the success in developing adapted, translated drug information has taken place via "private sector contracts" between USP and local entities. In those situations where adapted, translated drug information has been produced, local counterparts in project countries have generally been greatly appreciative of the information. Local counterparts have not always shown preferences for the USP DI database format, often preferring to use hard copies of the information.

Recommendations

- The project should work with local counterparts to translate USP drug monographs (or other sources of unbiased drug information) for a limited number of essential drugs into national languages where that information does not already exist. The creation of state-of-the-art, country-specific drug information databases is potentially valuable, but experience to date suggests that this is work that requires not only intensified support from RPM but also qualified, trained, and motivated counterparts in order to achieve acceptable degrees of progress. Before proceeding further with these activities, the project should take stock of what has been

accomplished and what constraints exist and make a candid assessment of the changes that will be required to achieve expected results.

- RPM should reassess the merits of the sole partnership with the DDA for the adaptation of the Drug Information Database for Nepal. The technical nature of this task may lend itself more to the leadership of a scientific and/or academic institution than an administrative/regulatory body.

(2) Establishment of Drug Information Centers

The project has successfully established a significant number of drug information centers, many of which are functioning and active in dissemination of information. However, some of the centers do not currently have the capacity to disseminate information actively and effectively. For these centers to become more active in this area will require much more intensive technical assistance than provided to date. This, in turn, may require a significant amount of additional project funding in order to support in-country advisers for this element of the project.

Recommendations

- The project should approach the idea of creating new drug information centers very cautiously. Although RPM's efforts in rural areas could build important linkages to urban health systems, plans to create drug information networks that would extend out from country capitals need to be implemented slowly, if at all, given current levels of project resources and the limited communication infrastructure.

- The project should provide long-term in-country support to these centers in order to help them with challenges concerning technical issues (particularly in DICs outside major urban centers) and the need to spur demand among providers and users of appropriate drug information.

- The project should continue to support the dissemination efforts of the centers that have been established. Priority should be given to those centers that share the project's vision for a center that actively promotes itself, disseminates information, and is well integrated into its local environment. Significant project resources should be channeled only to those centers that have made demonstrable commitments in these areas.

Such resources should be directed toward strengthening the organizational and management capacity of existing DICs and, to the extent possible, the drug information networks in Russian and Nepal. By strengthening the capacity of the networks to plan and manage their own activities and resources, the networks could develop their own strategic plans that would include possible expansion and criteria for establishment of new DICs.

- The drug information networks are still in the early stages of development. While they show some promise, they will require significant resources and technical assistance to become fully functional. This should be a secondary priority to strengthening individual DICs, and the project therefore should assess the organizational and management capacity and the commitment of the existing drug information networks for selected technical assistance and institutional strengthening.

B. CORE ACTIVITIES

In addition to the country-level activities undertaken by the RPM Project (discussed above), the project has engaged in "core," or "central-level," activities which are designed to be of general applicability to country programs. These core activities fall into two areas: Studies and Operations Research, and Tools Development and Information Dissemination.

1. Studies and Operations Research

a. Key Activities

The RPM Project has engaged in studies and operations research other than those studies conducted in the context of the country-level programs. All activities in this area have been conducted by MSH.

(1) Studies with General Applicability

The principal study with general applicability is the development of an approach for estimating the drug and expendable supply costs of reproductive health programs. This study along with some possible future studies are discussed below.

- Drug supply costs of reproductive health Programs: The overall goal of this study is to develop a methodology to assist donors and decision-makers in estimating the cost of supplying the commodities required to meet the needs for 25 reproductive health problems. The study is of great interest to project managers, MOH planners, and policymakers.

  Two out of four development stages of this activity have been completed:

  - estimating the cost of one treatment episode of a defined set of reproductive health (RH) problems, based on a set of RH services (also of drugs for sexually transmitted diseases)

  - using published data to model a cost estimate for pharmaceuticals, medical supplies, and equipment.

  The two remaining stages are:

  - conducting country studies and using country-specific data to estimate costs of commodities based on local epidemiological data, standard treatment guidelines, and supply costs

  - refining the cost estimates by accounting for country-specific use rate of local RH services, availability of RH commodities, and inefficiencies of supply systems.

  The team was impressed by the current state of development when the methodology was demonstrated in Washington. However, in view of the variety of drug use and supply systems that exist, it is important that clear criteria for country selection are discussed and spelled out before country testing begins. The study's potential usefulness will be in its country specificity, with global cost estimates just serving as a rough guide. As part of the country studies, it will be important to clearly identify and document who will use the new methodology,[8] when it will be used, and how it will be used. In this regard, the team expects the study to be quite useful to country officials involved in the areas of estimating reproductive health costs and selecting drugs and expects that the study will help in efforts to integrate vertical programs. Furthermore, the methodology can

8 In an operational context, targeting the study to "donors and decision makers" is not sufficiently specific.

easily be adapted to programs for integrated management of childhood illnesses (IMCI) and AIDS/HIV.

- Possible future activities: USAID has indicated interest in the project's assistance in the future regarding research related to HIV/AIDS, IMCI, and antimicrobial resistance. To date, these activities have not been defined with precision and have not yet commenced.

  RPM can no doubt make a valuable contribution towards the Agency's strategic objectives in these areas. RPM and MSH have long operational experience in many countries. The technical and managerial expertise of the project in drug selection, needs estimation, cost-effectiveness, logistics system development, and integrated drug and supplies management at the central and district levels are certainly relevant for these and other areas identified by the Agency. Finally, given the recent USAID initiative to address emerging diseases, including antimicrobial resistance, RPM should give particular attention to research in antimicrobial resistance as related to drug management and rational use.

(2) Country-Specific Studies

The project has engaged in several operations research projects in the context of country programs. Major studies have been conducted in the following subject areas:

- Reforming supply systems: The project has conducted important studies regarding the need and potential for restructuring country supply systems. These have included:

  - *Pharmaceutical Supply System in Ecuador: Evaluation and Proposal for Reform:* an evaluation for financial and operational restructuring of the parastatal drug procurement and distribution agency in Ecuador. The study was conducted in Ecuador in 1994–95, was well received, and would probably have been followed by significant reform on policies concerning procurement integrity, fiscal management, and relations with the private sector. However, when it was to be acted upon, there was a change of government, and the recommendations were not implemented.

- *Establishment of the Essential Drugs and Medical Supplies Store, Zambia:* a joint study supported by the Swedish International Development Agency, the Dutch aid agency, the World Bank, and USAID (through RPM) on restructuring the Zambia Medical Stores Limited and decentralizing drug management operations.

  Many countries now face the consequence of failed and bankrupt central medical stores in the public sector. Studies and proposals for solutions for restructuring are therefore in high demand. RPM studies in these areas have been important because there is limited expertise in the world on how to restructure in a manner that satisfies both commercial and public health goals and services.

  Fortunately, this study, issued in late 1996, found a more conducive political climate than the Ecuador study (above) and is now in the process of being implemented. RPM's participation in this study and mission was instrumental for setting the project up to assume a leadership role in developing an integrated approach to public health logistics (drugs, contraceptives, lab supplies, and immunization supplies) in support of decision-making to the district level in Zambia.

- Cost-sharing schemes: RPM conducted a major feasibility study in Nepal, entitled *Nepal Drug Cost-Sharing in Pharmaceutical Distribution.* This study evaluated existing drug cost-recovery activities in response to a request from UNICEF concerning the design and implementation of the troubled Community Drug Program sponsored by the Ministry of Health. The study was hailed by many people, including experts in this area at WHO, as the best analysis to date in the area of drug cost-sharing schemes. Regretably, the findings of this very important study may not have been discussed widely enough at the policy level. Also, the MOH failed to act on the study's key recommendation that nongovernmental organizations should assume responsibility of establishing community drug cost-sharing schemes, perhaps because it was not politically acceptable nor feasible at the time. Nonetheless, even with hindsight, it is not clear how much RPM could have pursued the studies' (or other) recommendations in such a politically charged environment.

- Indicator-based assessments: RPM conducted major indicator-based assessments of pharmaceutical sector operations in six countries (i.e., Ghana, Mozambique, Ecuador, El Salvador, the Eastern Caribbean, and

Russia). These assessments have, by and large, been excellent and comprehensive. For example, the Mozambique Pharmaceutical Sector Assessment, which was undertaken in October 1993, served to identify RPM support to that country. This and other overall country assessments (or specific technical areas within them) merit wide dissemination, discussion, and follow-up in the countries where RPM works. Importantly, these initial assessments have also served to create stakeholders and to get nationals interested and involved with improving the pharmaceutical sector.

RPM has also undertaken more focused assessments, using a subset of the overall list of indicators for rapid assessment. Demand for these useful specialized assessments is growing. The self-assessment tool, which focuses on drug management at the district level, is one example. Assessments that support implementation of a specific program such as IMCI is another.

b. Conclusions and Recommendations

The studies and operations research carried out by RPM — alone or jointly with other entities, and at the central or the country level — have been essential to identifying problems and finding solutions in the pharmaceutical sector. Working closely with national counterparts has helped to create an interest for future studies and reform.

Recommendations

- Country-specific research should be the priority of the project's operations research portfolio. Research of general applicability should be also pursued when it is in areas that may serve to promote integration of and collaboration among health programs.

- The rapid assessment technology is particularly promising for follow-up interventions, and RPM should continue to focus on this technique where quick response is necessary and/or when there have been recent assessments conducted by other parties.

- There is a great potential for use of the study regarding estimating the cost of supplying reproductive health and STD services. RPM should complete

this study as soon as possible, disseminate the findings and methodology, and begin to identify possible applications in other program areas.

2. Tools Development and Information Dissemination

a. Key Activities

Under the RPM Project, MSH and USP have engaged in a number of activities designed to disseminate information and develop tools and documents of general applicability. These have included various presentations at conferences and workshops. They have also included preparation of manuals, documents, and computer software, which are discussed below.

(1) Manuals and Documents

The manuals produced by MSH directly under the auspices of the RPM Project have included the following:

- *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*[9]
- *The International Drug Price Indicator Guide.*

In addition, in 1997, in collaboration with the WHO Action Programme on Essential Drugs, MSH produced the second edition of *Managing Drug Supply* (MDS 2). Although MSH produced this widely sought second edition with support from outside RPM, MSH applied the experiences of RPM to shape its content.[10] Training materials based on MDS 2 are currently under development.

The value of these publications was widely acknowledged. Officials at the World Health Organization and the U.S. Food and Drug Administration — where

9 MSH translated this manual into Spanish and held a workshop in 1995 for participants from nine countries and for PAHO staff in Santa Cruz, Bolivia.

10 Specifically, RPM training activities have been incorporated into MDS 2, and MSH has proposed the development of a "new generation" of training materials based on MDS 2.

Managing Drug Supply and the *International Drug Price Indicator Guide* are extensively used — were particularly vocal in expressing their appreciation for and belief in the technical value of these publications. Personnel at WHO, in particular, expressed significant gratitude for the copies of the latter provided by RPM.[11] The effort in reaching consensus over *Managing Drug Supply* and the extensive involvement of many officials from many organizations was widely noted and appreciated.

(2) Software

In addition to the written manuals discussed above, MSH has developed the following software products:

- INVEC-2: inventory control and management software
- PASS: prescription analysis software system
- ESTIMED: drug needs quantification software
- ECPRO-2: tendering and procurement software.

Software has proven valuable in supporting drug management at the country level. The use of INVEC-2 was instrumental in assisting the pharmaceutical department of Zambia's MOH in evaluating bids for a World Bank–financed drug procurement. In collaboration with The Central Asia Infectious Disease Project, RPM utilized PASS to analyze survey data on prescribing practices and to demonstrate the cost implications of irrational prescribing practices on drug expenditures. The IMCI Drug Management Tool also will utilize PASS for some of the data analysis necessary in application of the tool.

Though the value of these programs, in the abstract, is undeniable, the level of use of these programs at the country level does not always reflect their value. In some situations, local counterparts were extremely fond of and adept in use of the software. In other situations where MSH and/or USP had attempted to train local counterparts in the use of these programs, the counterparts had failed to

11 These people offered minor technical comments for improvement of these materials (which have been passed on to the RPM Project CTO), but these comments were so minor as not to warrant further discussion in this report.

implement the software fully, preferring less artful, but more established, systems. Although the team did not personally see INVEC-2 in wide use in the countries visited, this tool is installed and in regular use in Zimbabwe, Mexico, Ecuador, Yemen, five countries in the Caribbean, and Cambodia. It is possible that the program soon will be installed in Zambia and Mozambique as the main inventory management tool, and it is expected that the program will be more widely used in RPM programs as well as in non-RPM countries in the future. It is likely that if a Windows™-based software suite of RPM tools is developed, demand will be extremely high.

The area of software development — and implementation at country-level — is rife with donor politics. Local counterparts repeatedly expressed the pressure to satisfy other donors' interests by using software packages developed by these other donors. These counterparts requested that donors coordinate their activities better in this area in order to remove the explicit or implicit pressures to use different software packages.[12] The use of different packages within a given country program, of course, leads to unnecessary complications.

b. Conclusions and Recommendations

The project's contributions in development of tools have been extremely well received by collaborators in other U.S. government programs and in other international organizations. The value of the manuals and documents produced has been recognized widely. The products appear to be the result of well structured plans and close collaboration between RPM and its collaborators. This approach should continue.

Recommendations

- The project should continue to engage in tools development activities, particularly in areas where the tools have direct relevance for shaping country interventions. In development of materials of general applicability, the project should continue to coordinate closely with other entities with a global mandate to ensure that the materials satisfy clearly defined needs and that there is no duplication of effort.

12 For instance, Zambian officials have specifically requested implementation of INVEC-2 on a national level, to the exclusion of software packages being developed and promoted by other donors.

- The project should approach investment in additional software or packages (i.e., "suites") of software very cautiously. Any future investment in this area should be made after coordination and consensus-building among the various donors involved in this area.

- The evaluation team is aware that the USAID Office of Procurement expressed concern that the *International Drug Price Indicator Guide* indirectly encouraged procurement of non–U.S. pharmaceuticals and, in consequence, the Global Bureau directed RPM to cease supporting the production and dissemination of this document. In view, however, of the high degree of appreciation that other donors and country counterparts have shown for this publication, the evaluation team urges that all concerned parties explore ways for RPM to support this activity.

C. ORGANIZATIONAL IMPACTS

1. Linkage with USAID Strategic Objectives and Programs

a. Key Issues

(1) SOs of the Global Center for Population, Health and Nutrition

RPM supports the Global Center for Population, Health and Nutrition Strategic Plan, as well as the strategic plans of individual USAID missions. At the global level, RPM most directly supports Strategic Objective #2 (SO2) "Increased use of safe pregnancy, women's nutrition, family planning and other key reproductive health interventions," and Strategic Objective #3 (SO3) "Increased use of key child health and nutrition interventions." To a limited extent, RPM also supports Strategic Objective #1 (SO1), "Increased use by women and men of voluntary practices that contribute to reduced fertility." Finally, RPM expects to contribute to Strategic Objective #4 (SO4), "Increased use of proven interventions to reduce HIV/STD transmission," as activities related to HIV/STDs are in the early development stage.

The RPM Project's package of interventions as described in section III of this report contribute to the achievement of the following SO2 and SO3 intermediate results (IRs) at the global level:

- SO2, IR 2.1, "Approaches and technologies to enhance key reproductive health interventions identified, developed, evaluated and disseminated." In collaboration with Mothercare, RPM has begun developing a tool for costing RH commodities used to address key reproductive health episodes. The model will be field-tested in Kenya in September. The adaptation of the USP DI database for use in Russia, Nepal, and Mozambique provides practitioners with up-to-date information on drugs used in RH problems including STDs, reproductive tract infections, eclampsia, and pre-eclampsia, as well as on contraceptive products and devices.

- SO2, IR2.2, "Improved policies and increased public and private sector resources and capacity to deliver key reproductive services." Access to unbiased drug information is necessary for providers to correctly select and prescribe drugs. Drug information centers in Mozambique, Nepal, and Russia provide access to unbiased information previously not available in these countries. The Drug Information Network of Nepal (DINoN) consists of five DICs, each providing information for a particular audience (i.e., physicians, pharmacists, students, primary health care workers, patients, consumers, and MOH personnel). In Russia, the oblast DICs (Ryazan, Novgorod, and Pskov) disseminate drug information and actively support formulary development and drug utilization review in oblast health facilities. The recently established All Russia Drug Information Network (ARDIN) consists of regional DICs that will actively promote formulary development as a means to provide high-quality medical care and improved management of financial resources and will serve as focal points for information dissemination. The DIC in Mozambique was equipped with a computer and the USP DI database in May 1997, and will officially kick off activities in September during the first drug information workshop ever held in Maputo. Initial activities will focus on information dissemination for physicians, pharmacists, and students; completion of the USP DI database adaptation; and translation into Portuguese of information on contraceptive products.

- SO3, IR 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 58 hospitals in three target oblasts. DUR programs underway in oblast hospitals help to ensure that physicians comply with the established formulary and assist hospital therapeutics committees to assess prescribing and use patterns and to identify opportunities for improvement. DUR manuals and training materials developed by RPM have been widely distributed and are in use throughout Russia and the NIS.

- SO3, IR 3.2, "Improved policies and increased global, national, and local resources for appropriate child survival interventions." In Ecuador, RPM is collaborating with the MOH, FASBASE, and CEPAR (a local NGO) to design and implement a decentralized pharmaceutical management plan, including guidelines for drug selection, quantification, procurement, inventory control, and cost-recovery at the district level. RPM, MOH, and host-country counterparts developed and revised the *Decentralized Drug Management System for Health Areas* (Spanish-language version) to support sustainability of these activities. In Russia, health officials in two oblasts have passed laws to mandate the development of hospital formularies, which offer potential for financial savings through the elimination of ineffective and costly drugs. RPM technical assistance has improved the skills of Russian and Nepalese counterparts in managing competitive procurements. In Zambia, RPM collaborated in the development of DILSAT (an integrated drug, family planning, and lab management and assessment tool), expected to contribute to improved drug management at the district level. In Mozambique, RPM has capacitated a core group of local trainers, who in turn are training provincial, district, and facility-level staff in logistics management and promotion of rational drug use.

- SO3, IR 3.3, "Enhance knowledge of key child health and nutrition behaviors/practices in selected countries." Russian medical universities have introduced formulary development, DUR, and rational drug use into medical and pharmaceutical training programs, and Russian officials and specialists actively teach and promote these practices. The studies undertaken by RPM under the Central Asia Infectious Disease Program provided valuable baseline information to assist the design of diarrhea and acute respiratory infection (ARI) case management training. RPM has developed and facilitated training on rational drug use in Russia, Nepal, and Mozambique.

- SO3, IR 3.4, "Improved quality and availability of key child health/nutrition services." In Nepal, RPM provided technical assistance in the development of improved standard treatment guidelines and collaborated in the design and implementation of the logistics system management plan. RPM technical assistance and application of INVEC-2 supported the Zambian MOH's loan application to the World Bank, which resulted in funding to purchase essential drugs. National, regional, and provincial-level training in Mozambique improved the skills of MOH personnel in drug and logistics system management and rational use. RPM participation in the LAC Regional IMCI Initiative has resulted in the development of an IMCI Drug Management Assessment Module (soon to be field-tested), to be followed by training on how to use the assessment tool. The module will assist program managers (at the country level) to determine gaps in existing drug and vaccine delivery services that must be addressed for successful implementation of IMCI.

As mentioned above, RPM has also contributed to SO1 and SO4. With respect to SO1, RPM has collaborated with FPLM (a USAID-funded project) in the development of an integrated family planning system in Nepal and Zambia and in the context of the REDSO/ ESA Regional Logistics Initiative. RPM's contribution to SO4 has been indirect — in countries where RPM country programs exist, improved drug management and rational use contribute to increased availability and quality of services to treat STDs.

(2) SOs of USAID Missions

RPM also contributes to the achievement of strategic objectives defined by USAID missions in countries where RPM is implementing country programs. A brief description of RPM support to USAID missions' strategic objectives follows for those countries in which the project is most active.

- Ecuador: RPM contributes to the achievement of the mission's SO 2, "Increased use of sustainable family planning/maternal child health services." Under SO2, RPM contributes to the following intermediate results (IRs): improved quality and access of MCH services and increased sustainability of health NGOs.

- Mozambique: RPM supports the mission's SO 3, "Increased use of maternal child health services in focus areas." Within this strategic objective, RPM contributes to the achievement of three specific IRs:

increased supply of quality maternal and child health/family planning services, more health facilities equipped to provide essential health services, and more health facilities with trained staff.

- Nepal: RPM supports the mission's SO 2, "Reduction of fertility and improvement in maternal and child health. Under SO 2, RPM contributes to the following IRs: increased use of family planning services, increased quality of family planning services, and increased use of selected maternal and child health services.

- Russia: RPM-Russia contributes to the achievement of the mission's Strategic Goal 3, "Respond to humanitarian crises and strengthen the capacity to manage the human dimension of the transition to democracy. Specifically, RPM supports SO 3.2, "Improved effectiveness of selected social benefits and services." Under SO 3.2, RPM contributes to the achievement of intermediate results 3.2.1 and 3.3.2; policies, laws, and regulations that improve effectiveness have been approved, and new approaches to service delivery have been adopted.

- Zambia: RPM interventions support the mission's SO 3, "Increased use of integrated child and reproductive health and HIV/AIDS interventions." RPM's contributions to date have supported IR 5, "improved capacity for policy analysis, planning, and support for the delivery of PHN interventions."

Improved drug management, availability, and rational use are vital to the delivery of quality reproductive and child health services. The successful treatment of conditions such as post-partum infections, ARI, diarrheal diseases, and STDs depend on access to and correct use of appropriate drugs. Improved management skills contribute to better allocation of financial resources for essential drugs, and, in combination with strengthened logistics systems, the availability of necessary drugs in health facilities is improved. Finally, increased availability of essential drugs stimulates demand for health services, as patients highly value drugs and are more likely to seek care when necessary drugs are available.

RPM has contributed significantly to the achievement of the Center for Population, Health and Nutrition Strategic Objectives, and to the Strategic objectives of USAID missions in the countries where the project operates. At the central level, RPM has contributed most directly to SO2 and SO3, and, to these

ends, has improved access to reproductive and child health services through strengthening drug management systems, and improved the quality of these same services through increased access to drug information and promotion of rational drug use by prescribers and clients. RPM has also contributed to SO1 through the development of an integrated family planning and drug logistics management systems in Nepal and an integrated assessment tool for Zambia. While RPM's contribution to SO4 has been indirect, it is anticipated that RPM will more directly contribute to SO4 in the future as developing countries seek guidance related to rational use of antiretrovirals and medications to treat opportunistic infections.

Progress in rational drug use requires integration of activities that address rational drug selection, prescribing behavior, drug availability, and patient compliance. To date, RPM interventions in the area of rational use have focused almost exclusively on the provider side through formulary development and drug use review, development of standard treatment guidelines, training in rational prescribing practices, and dissemination of unbiased drug information. Constraints in funding and staffing and the slow development of drug information activities/database adaptation and translation have prevented the initiation of activities in the area of consumer and patient information that were originally planned. In order to more fully address rational drug use, activities that target patient behavior and consumer knowledge should be initiated. Furthermore, such activities will serve to more closely link the USP/drug information component of RPM to improved health outcomes.

USAID has not yet clearly reflected the relationship of RPM, and other cross-cutting projects, to the program outcomes, in the context of the strategic framework. Under SO2 for instance, IR 2.1 ("approaches and technologies to enhance key reproductive health interventions identified, developed, evaluated and disseminated"), and the related performance indicator for IR 2.1 ("approaches evaluated and available i.e., costs of provision of essential obstetric care) relate directly to the development of the Reproductive Health Costing Model undertaken by RPM and Mothercare. However under SO3, the SO under which RPM is most active, delineation of RPM contributions is less clear. A SO3 RPM-related IR is 3.4 ("improved quality and availability of key child health/nutrition services") broadly encompasses many interventions. The related performance indicator for IR 3.4 ("percent of facilities capable of (a) providing standard case management for ARI, and (b) capable of providing case management for diarrhea") relies on technical support provided by RPM, such as improved drug management and rational use, as well as other factors including availability of human resources, training of health facility personnel, etc. Thus, even in country programs where

RPM has provided the appropriate and necessary technical assistance in drug management, for instance, other factors influence the achievement of the related performance indicator, and thus the ability to track RPM contributions is difficult.

The strategic framework's imperfect articulation of program outcomes that relate to drug management and rational use, as well as lack of relevant indicators, have implications for RPM. Unless a specific indicator is identified for the relevant SOs (particularly SO2 and SO3), the specific contributions of RPM may not be reflected through the existing framework or tracked by monitoring plans. Furthermore, the lack of an indicator related to drug issues that can serve as a marker contributes to the inadequate attention given to these issues on the part of program managers and mission PHN officers.

At the mission level, the evaluation team found USAID personnel in the countries visited to be very knowledgeable regarding the components of the project and the relationship between the project and missions' SOs. However, several PHN officers, global center personnel, and collaborating institutions communicated their concerns that:

- drug issues are not being adequately addressed in terms of their relationship to desired program outcomes
- there is a general lack of understanding of the fundamental issues of drug management and supply and rational use
- unless USAID global or mission personnel have had direct contact with RPM, they are not familiar with the project's components or potential benefits. Numerous parties interviewed encouraged RPM to widely disseminate information about the project components, available tools, and success stories.

Recommendations

Based on these findings and conclusions, the evaluation team proposes the following:

- RPM should continue the present intervention strategies and activities. Current interventions are contributing to the achievement of Global Center Strategic Objectives, as well as those of country missions.

- The Global Center should develop a IR for "Improved availability and rational use of necessary (STI drugs, ARI drugs, RH drugs, etc)," as well as the related performance indicator, to be incorporated into the strategic plan under relevant SOs. RPM should provide guidance to USAID missions in identifying and including performance indicator(s) in missions' strategic plans that will serve to monitor RPM contributions related to program outcomes.

- RPM should continue to undertake operations research as related to drug issues in terms of child survival, reproductive health, AIDS/STDs, antimicrobial resistance, etc. In doing so, RPM will be able to identify interventions and implementation strategies that contribute the most to improvements in resource management, the quality of health services, and access to health care. Research findings should be widely disseminated.

- RPM should undertake pilot activities in patient and/or consumer information (Russia and/or Nepal seem to be the most appropriate). By initiating patient information development, the drug information component will be positioned to more directly contribute to improved health outcomes (which is already being supported on the provider side through formulary development, DUR, drug management, and rational prescribing).

- RPM should develop an informative guide that will assist mission PHN officers and program managers to better understand the cause and effect relationships that exist within essential drug programs, drug management, logistics, and rational use. An alternative approach would be the presentation of training workshops on RPM and related issues for PHN officers.

- In light of the present initiative to develop a USAID Strategic Objective that addresses infectious diseases, RPM should provide technical leadership in the implementation of the "infectious diseases strategic objective," particularly as related to measures to address antimicrobial resistance. RPM should undertake immediate action to document interventions to date that have demonstrated the most promise in improving rational antimicrobial use and should disseminate these findings. RPM should provide recommendations to Global PHN regarding

the implementation of interventions to address rational use of antimicrobials.

2. Impact on Cooperating Agencies

A key element of the scope of work for the evaluation was to "assess the impact of USAID's funding via CA's on MSH and USP." In particular, the team was asked to evaluate "MSH's capability to develop state of the art approaches to improve pharmaceutical management" and "USP's involvement in the international arena as a provider of accurate, up-to-date drug information for enhanced health outcomes" (See the Scope of Work, Annex H).

a. MSH

Long before the start of the RPM Project, MSH was active in the area of assisting developing countries improve their systems of pharmaceutical management and use. Indeed, MSH's existing institutional capacity was key in the award of the Cooperative Agreement to MSH. The RPM Project has offered MSH an opportunity to continue this work, learn more about operationalizing pharmaceutical management activities, and conduct or develop cutting-edge research tools. Due in part to the RPM Project, MSH has increased its staff and undertaken many country-level activities and core activities.

b. USP

USP has been, and undoubtedly will continue to be, a key player in the international arena as a provider of accurate, up-to-date drug information. Prior to joining the RPM Project, USP had limited experience in developing country settings. Although USP has not, through the RPM Project, developed a vast amount of new drug information, the RPM Project has provided opportunities for USP to improve its capacity to work with developing countries in the use of drug information. USP has initiated activities to provide direct country assistance in the development of adapted country-specific drug information, installation of automated drug information systems, and implementation of strategies to disseminate drug information. USP is gaining experience in assessing the skills of its developing country counterparts and the level of technical assistance needed from Washington.

c. Conclusions and Recommendations

The project has demonstrably strengthened the institutional capacities of both MSH and USP. MSH has accumulated significant additional expertise and staff in the area of pharmaceutical management, particularly in direct support of country programs. Much of this experience has been reflected in MSH documents and publications, although most experience remains in the individual capacities of MSH staff members. Similarly, USP has strengthened its institutional capacity to provide technical assistance in developing country settings, where its prior experience was limited.

Recommendations

- The MSH component of RPM was a competitive procurement. MSH has been a good choice to implement USAID's project. They have applied their considerable expertise and improved their capacity as in other successful USAID projects. When considering "past performance" on future competitive procurements, MSH should receive high marks.

- The cooperative agreement with USP resulted from a sole source procurement with USP because no other entity existed with equivalent expertise to implement the drug information components of the project. USP remains uniquely qualified in developing unbiased drug information, and it is clear that the RPM Project has strengthened USP's capacity to work with developing countries. When considering the form and recipient of future procurements, the qualifications of USP should be duly noted, along with USP's acknowledged needs and desires for additional experience in working with developing countries.

3. Collaboration with Other Organizations

a. Key Issues

Collaboration with other organizations and donors has been a necessary and effective implementation strategy for RPM. There are several reasons behind the need for collaboration. First, with the exception of Russia, RPM did not have a broad mandate or adequate funding to undertake comprehensive activities at the country level, creating a need for RPM to leverage resources with other projects and organizations. Second, USAID missions' strategic plans to improve maternal health and child survival are typically implemented either through bilateral

contracts or through field support from global projects such as Basic Support for Institutionalizing Child Survival (BASICS) and Mothercare. As such, activities to improve drug management and rational use fall under the rubric of these bilateral contracts or global projects, creating a need for RPM to collaborate within this framework. Finally, projects in the area of drug management encompass complex issues such as policy, regulation, procurement, and logistics, among others and require the technical expertise and cooperation of a variety of partners. Collaboration has allowed RPM to leverage the resources and technical skills of key players in the essential drug world.

The principal actors involved in developing country drug programs are bilateral and multilateral donors that finance essential drug procurement, organizations that provide technical assistance and global leadership, and the clients, i.e., developing countries. The organizations most commonly engaged in drug procurement are the World Bank, UNICEF, and the numerous bilateral aid agencies. Some of these bilateral agencies provide direct technical assistance to countries and/or provide funding to support training and technical assistance carried out by other programs such as RPM.

The World Health Organization's Action Programme on Essential Drugs (DAP or WHO/DAP) is widely recognized as the global leader in developing national drug policies. Since the inception of DAP in 1981 and following the First Model List of Essential Drugs published in 1977, DAP has acquired vast experience and developed a comparative advantage supporting national authorities in the establishment of national drug policies. DAP also serves as a technical leader in the development of guidelines and methodologies and in support of their use by both donors and developing countries (see Annex E). While DAP carries out programs in a limited number of target countries and will continue to do so, the WHO/ DAP revised strategic plan of April 1997 calls for DAP to increasingly focus on technical and leadership activities at the central level.

Until the initiation of the RPM Project in 1992, USAID's activity in the realm of essential drugs had been limited in scope, and implementation of these activities had been ad hoc. Drawing on over 20 years of MSH's experience in drug management and on USP's historical leadership in the development and dissemination of unbiased drug information, RPM has been able to quickly demonstrate a comparative advantage in on-the-ground technical assistance in drug management and procurement, development and dissemination of drug information, and promotion of rational drug use. The presence of USAID missions in numerous countries and of related projects in child survival that

depend on essential drug availability and proper use has provided points of entry and a natural clientele for RPM's services.

Finally, host country counterparts play an important role in the implementation of drug management and rational use activities. Key actors vary between countries but typically include one or more departments of the MOH, drug wholesalers, private pharmacies, pharmaceutical manufacturers, teaching institutions, NGOs, and providers (physicians, pharmacists, and other health workers). As such, these actors can be technical resources to support implementation or key stakeholders without whose support progress in drug management and related activities would be impossible.

RPM has engaged in collaboration at the central, regional, and country levels. Central-level collaboration has largely consisted of several global and regional activities in the area of tools development and operations research.

- RPM collaboration with the MSH Drug Management Program (and a multitude of other parties) has resulted in the development of *Rapid Pharmaceutical Assessment: An Indicator-Based Approach.* RPM experiences and methodologies have made considerable contribution to the second edition of *Managing Drug Supply*, published by MSH DMP in collaboration with WHO/DAP.

- RPM adapted and translated into Russian the *WHO Guide to Good Prescribing* in cooperation with WHO and cosponsored a NIS–wide workshop based on the guide. RPM is presently collaborating with WHO/DAP in harmonizing RPM and DAP indicator-based assessments.

- INVEC-2 was developed with technical input from the Zimbabwe Essential Drugs Programme, funded by DANIDA, the Danish aid agency.

- The MSH-DMP role as network coordinator for the International Network for Rational Use of Drugs (INRUD) has been principally supported by DANIDA, but this activity does qualify as a cost-sharing activity under RPM, and RPM has provided some degree of technical input into a number of INRUD activities. INRUD is active in information dissemination and supports operations research designed to promote rational drug use.

- MotherCare and RPM have developed the tool, *Estimating the Cost of Supplying Reproductive Health Commodities*, presently being field-tested in Kenya.

- In collaboration with BASICS, RPM is developing a specialized IMCI assessment tool.

- RPM collaborated with BASICS and the U.S. Centers for Disease Control and Prevention in the analysis of drug availability and prescribing behavior for diarrheal disease and ARI in health clinics and hospitals in the Central Asian Republics.

- REDSO Eastern and Southern Africa Logistics Initiative (REDSO/ESA) has engaged RPM to contribute to a planned assessment of logistics consequences of health reform in six countries to be conducted in the fall of 1997.

Collaboration at the country level has contributed significantly to the implementation of RPM interventions. Specific collaboration will be discussed in the country profiles, however several examples are illustrative of RPM's strength in this area:

- In Ecuador, RPM has collaborated with the World Bank's FASBASE project in the design of a Decentralized Drug Management Model. Active coordination with other donors including WHO/PAHO, Belgium Foreign Aid, and UNICEF contributed to consensus on the model design and adoption by other projects.

- In Mozambique, RPM is collaborating with the USAID–funded URC project, UNICEF, and the MOH's Pharmaceutical Department to provide training in drug management and rational use and with the National Institute of Health in the establishment of a drug information center.

- In Nepal, RPM and FPLM collaborated with the Logistics Management Department in the MOH to develop an integrated logistics management system. RPM collaborated with UNICEF in the *Nepal Cost-Sharing in Pharmaceutical Distribution* study, and has negotiated an agreement with the German aid agency (GTZ) to collaborate in the design and implementation of a district-level improved drug management strategy.

- In Russia, RPM has disseminated materials and has gained general acceptance of RPM approaches through collaboration with Russian counterparts, WHO, and other USAID–funded projects such as Abt Associates' Zdrav Reform Project and the AIHA Hospital Partnership Project. Effective collaboration has resulted in development of a network of Russian stakeholders who have engaged in the rapid implementation of hospital formulary development, initiation of drug utilization review, establishment of the drug information centers, and dissemination of RPM materials beyond the target oblasts in Russia and throughout the NIS.

- In Zambia, RPM collaborated with FPLM, Irish Aid, and the MOH to develop DILSAT (the district-level self-assessment tool).

b. Conclusions and Recommendations

To date, RPM has been a strong and effective collaborator. RPM's comparative advantage in technical assistance, tools development, and operations research related to drug management and rational use have served to inform decision-making and improve the effectiveness of child survival and reproductive health projects.

At the country level, RPM has been responsive to USAID's and host countries' needs by communicating closely with donors, NGOs, and bilateral programs and by jointly financing and sponsoring a variety of activities. RPM has successfully utilized collaboration as a means to disseminate information and tools.

RPM should continue to focus on collaborating with other projects, organizations and donors, in order to coordinate activities, broaden the stakeholders in country projects, and leverage scarce resources. To these ends, RPM should disseminate information regarding technical services provided by RPM and the contributions of RPM activities to child survival and reproductive health interventions, to USAID missions, NGOs, USAID global programs, and bilateral and multilateral donors. Information dissemination will stimulate increased awareness of drug issues as related to health services delivery and outcomes, improve understanding of RPM, and create future opportunities for collaboration.

In light of WHO/DAP's technical experience and leadership role in worldwide national drug policy and essential drug program development, and multilateral/ bilateral donor support for drug procurement, RPM should continue to provide the

needed on-the-ground technical assistance that is not being provided by other donors. RPM should advocate the establishment of country working groups on essential drug management and use as a means to improve collaboration and coordination of activities, identify opportunities for leveraging of resources, and build consensus on policy and program strategies and recommendations.

V. Organization and Management

The evaluation team reviewed organization and management issues relating to both of the cooperating agencies, as well as USAID. Because rational pharmaceutical management is a new area for USAID and because of the different areas of expertise of the cooperating agencies, the team felt this issue was important for understanding the best approaches for implementation.

A. Cooperating Agencies

The team's principal goal in evaluating organization and management issues regarding the cooperating agencies was to examine the overall organizational structure and financial management strategies, in order to reach conclusions regarding the effectiveness of these strategies in achieving the goals of the project. The team did not attempt to evaluate internal management strategies at the cooperating agencies.

1. Organizational Structure

As described above, the RPM Project is administered by two cooperating agencies: MSH and USP. Each of these organizations is discussed in turn.

a. MSH

Within MSH, the personnel dedicated to the RPM Project are located in MSH's Drug Management Program (DMP). Although MSH is based in Boston, the DMP elected to move its operations to Rosslyn, Virginia, in December 1992, in order to facilitate collaboration with USAID for implementation of the RPM Project and to allow greater proximity to other clients such as the World Bank.

Currently, the DMP is comprised of about 24 staff members (including 19 professionals), of which 13 full-time equivalent staff members administer the RPM Project. The group of 13 can be divided into two subgroups, corresponding to those staff members working under the USAID–Worldwide cooperating agreement (CA) and those under the USAID–Russia CA. Five are assigned full-time to the Worldwide CA, and four are assigned full-time to the Russia CA. The remainder split their time between the two CAs.

Within DMP, RPM Project personnel ultimately report to DMP Director James Rankin. Under Mr. Rankin, James Bates is the Director of the RPM-Worldwide Project and Anthony Savelli is the Director of the RPM-Russia Project. Messrs. Bates and Savelli are responsible for overall management of their respective projects.

At present under the RPM-Worldwide Project, there are about eight full-time professionals involved in the implementation of country programs, supplemented by input from other MSH DMP staff, staff from MSH Boston, and a cadre of expert consultants. These full-time professionals are based in MSH's Rosslyn, Virginia, office. The responsibilities associated with overseeing these programs, combined with heavy travel schedules and administrative demands, has produced significant work loads for the professional staff. This current staffing level is a significant increase over at the start of the project. In 1992, the Worldwide Project had three professionals, an office manager, and two support staff.

Under the Russia Project, there are four professionals involved with the implementation of the country program. Three of these four — Anthony Savelli, Andrei Zagorski, and Olga Solovieva — are assigned full-time to the project. Mr. Savelli is based in Rosslyn, Virginia; Mr. Zagorski and Ms. Solovieva are based in Moscow, along with one staff member providing support services. The Moscow office was opened in 1995, and has provided an extremely useful presence for MSH in Russia.

b. USP

At USP, the personnel dedicated to the RPM Project currently number three full-time professionals, a part-time computer programmer, and additional drug and medical information specialists as needed for development of drug monographs. The three full-time professionals are:

- Keith Johnson, Director of the USP Drug Information Division and RPM Project Director
- Nancy Blum, Coordinator of International Programs
- Kirill Burimski, Russia Program Manager.

Ms. Blum oversees USP's activities in Mozambique and Nepal under the Worldwide CA, and Dr. Burimski oversees USP's activities under the CA for Russia. Both Ms. Blum and Dr.Burimski report to Mr. Johnson. All are based at USP's headquarters in Rockville, Maryland. The placement of Ms. Blum in the post of Coordinator of International Programs in 1996 was widely acknowledged as an important step forward. However, given the scope of project activities, USP staff members remain stretched beyond their capacities. USP needs to either increase its in-house staff or use consultants more often to fill gaps in areas such as monitoring and evaluation, field-testing, and institution-building.

The USP staff expressed concern about the ability of USP to meet all of the project objectives in Russia at the current level of staffing. The team observed that an in-country presence for USP would assist in implementing activities to better disseminate information from the current and planned drug information centers in Russia. Other country programs also would benefit from an in-country presence from MSH and USP.

2. Financial Management

As a preliminary matter, it is important to note that the team did not conduct a comprehensive analysis of the project'sxpenditures and accounting. Rather, the team evaluated the cooperating agencies' budgeting and strategic planning of USAID's overall allocation of resources, and the ability of the cooperating agencies to mobilize additional resources in order to achieve the project's objectives. These subjects are discussed below.

a. Budgeting and Strategic Planning

USAID allocated approximately (US)$11 million to the Worldwide Project and approximately $3.5 million to the Russia Project. For the Worldwide Project, $8.9 million was allocated to MSH, and about $1.3 million was allocated to USP. For Russia, about $2.4 million was allocated to MSH, and about $1.1 million was allocated to USP.

Both cooperating agencies manage their procurements and expenditures in accordance with Standard Operating Procedures. These procedures include the use of open, competitive procurements and the requirement that expenditures receive appropriate approval by the project manager. The team did not learn of any problems caused from the use of these procedures, nor did the team learn of any terms of the cooperative agreements that cause problems for the cooperating agencies' financial resource management.

As of March 1997, both cooperating agencies had obligated nearly all of their allocated amounts. MSH had received obligations totaling 89 percent of its worldwide ceiling,[13] and 100 percent of the funds for Russia. USP had obligated over 99 percent of the worldwide funds and 100 percent of the funds for Russia. Given the short time frame for the project, these levels of obligations and expenditures demonstrate commendable budgeting and planning.

Generally speaking, given the ambitious work plans of the country programs, the team found that these levels of expenditure were appropriate and were matched, at least under the team's qualitative analysis, in terms of project activities and accomplishments at country level. Only in a few limited areas (discussed in Section IV of this report) did the team feel that interventions could have been more useful (and expenditures better spent) if activities had been delayed until country programs were more mature.

b. Resource Mobilization

The cooperating agencies have been successful in mobilizing other USAID resources and in leveraging funds from other donors. On the subject of mobilizing other USAID resources, changes in the structure of USAID funding required the cooperating agencies to adjust their focus to USAID missions' Strategic

13 MSH had spent about 63 percent of the total, leaving an unobligated balance of about $963,000 and an unexpended balance of about $3.2 million.

Objectives (and the new "field support"" funding mechanism) in order to achieve RPM Project goals (as discussed previously in this report). By all accounts, MSH and USP have been extremely successful in ensuring the project's survival in this changing environment. MSH and USP have succeeded in explaining the goals and value of the RPM Project to several USAID missions, as evidenced by the increase in field support to RPM. In this revised structure, the cooperating agencies have been very successful in collaborating with other USAID projects and leveraging their expenditures. For example, in Nepal, the RPM Project has worked closely with the LSIP/FPLM and the AIDSCAP Projects and, in Mozambique, the PHC/URC Project has provided logistical support and sent 30 participants from the project provinces to be trained at the workshops.

Second, the cooperating agencies have succeeded in leveraging funds of other donors to achieve the project's objectives. Again, in Nepal, the project is working closely with the German aid agency (GTZ) in a project jointly funded by GTZ to strengthening drug management at the district levels. In Mozambique, UNICEF has agreed to fund costs for workshops, and the Swiss Development Cooperation has supported translation of training materials into Portuguese and covered fees for local trainers. Also, in Russia, the project has collaborated with the pharmaceutical industry to help cover the costs associated with recent national drug information workshops with AIHA to conduct a formulary development workshop and with WHO to conduct a rational prescribing workshop.

3. Cooperation and Collaboration

Cooperation and collaboration between and among USAID personnel and the cooperating agencies appears to have been strong, at both the central and country levels. Personnel at the cooperating agencies expressed satisfaction with the level and openness of communication with USAID personnel. Likewise, USAID personnel, both in Washington and in the field, generally expressed satisfaction with their level of communication with the cooperating agencies. Whenever any dissatisfaction with information flow was voiced (e.g., concerning the possible failing of MSH to send reports to the local mission), the team discovered the root of the dissatisfaction was typically a misunderstanding (e.g., regarding the frequency with which such reports were issued). The team did not find any systemic or significant communication or collaboration problems between USAID and the cooperating agencies.

Similarly, cooperation and collaboration between MSH and USP appears strong. Though communication between MSH and USP in Washington was not highly

structured in the early days of the project, regular meetings are now scheduled to coordinate the activities of the two. Both MSH and USP acknowledged that the addition of staff at USP has increased coordination between the two organizations. It can fairly be said that both organizations hold each other in high esteem and treat one another with respect.

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 is a real strength in cooperating agency collaboration. For example, in Russia, MSH and USP activities and staff are for the most part extremely well integrated. Indeed, as discussed above, MSH and USP have discussed combining operations into a single field office in Moscow. In countries that are less advanced than Russia, USP could benefit from a closer relationship with MSH due to MSH's extensive field support experience in less developed countries.

4. Conclusions and Recommendations

Overall, expectations for the project, particularly regarding the drug information component, were too ambitious given the organizational and management constraints. It would have been better to scale down expectations and develop more realistic work plans. In this regard, the team observed that the short-term technical visits on the part of RPM staff had been generally effective, particularly in situations where there were strong host-country nationals in place and when there was strong collaboration between RPM and other local collaborating entities. Having said this, it must also be recognized that it is apparent in some settings that the mode of short-term visits has reached the limit of its effectiveness. In Mozambique, Nepal, and Zambia, the evolving situations all argue for a long-term presence. The evaluation team is aware that RPM has in the past requested funding for resident advisors, which has not been forthcoming. RPM should, however, continue its dialogue with these missions and attempt to secure the required resources.

The expanding portfolio of RPM country programs and the leveraged resources of other donors and programs are evidence of increasing demand for RPM's services. The team expects that this demand will accelerate as missions recognize the role of essential drugs to support most of their health interventions. The fact that the project has expended nearly all of its funds on worthwhile activities and

has a few months left with more to do indicate to the team that the project has been underfunded.

Recommendations

- Given the critical and integral role of essential drugs in USAID programs, USAID should allocate more resources to essential drugs activities through and in collaboration with RPM. Likewise, RPM should make all necessary efforts to ensure that it has sufficient capacity to conduct its operations within such an expanded framework.

- USP has not been able to provide adequate personnel support to implement activities according to their work plan(s). USP should re-evaluate their program structure, objectives, "parachute" approach, and staffing to determine how to produce the proposed outcomes. In particular, USP needs to place a manager or coordinator in Nepal. Furthermore, a manager would be necessary in Russia (at least temporarily) if the All Russia Drug Information Network is to be established and function, as planned. USP should consider hiring short-term consultants to assist in development and implementation of technically specialized activities (i.e., organizational development, patient education, etc.), in order to avoid diverting necessary staff attention from project management and monitoring.

- The cooperating agencies should develop joint work plans (at the country level), to the extent possible, to ensure that activities under development by one CA continue to be technically coordinated with activities supported by the other CA.

B. USAID

Both cooperating agencies were complementary of USAID management, although personnel within the cooperating agencies did cite periodic instances where differences of opinion were encountered regarding administrative priorities and management processes. By all accounts, these differences of opinion have been successfully managed. In light of the overall success and rapid expansion of the project, the team believes that USAID management and the cooperative agreement structure have served the project well. Indeed, it appears that the

USAID CTO has been a very effective advocate for drug management issues at the global level and has been effective in providing project support.

1. Management of Cooperating Agreements

The team found that USAID's choice of cooperative agreements to implement the RPM Project was appropriate. It appears to the team that the goals and objectives of the project are being met with the necessary flexibility allowed under a cooperating agreement. Also, the team did not encounter any management concerns regarding the existence of two cooperating agreements, one each for MSH and USP. Cooperation between the two agencies (as described above) has been good and there has been little or no confusion regarding division of responsibilities at the field level.

In conjunction with our review, the team analyzed the issue of whether there should be one, or two, cooperating agreements in the future. This issue is not clear cut. On the one hand, a single cooperative agreement (with possible subagreements) has the potential to simplify management at the central level and, perhaps more importantly, at the field level. On the other hand, given the distinct areas of expertise (and histories) of MSH and USP, it is not clear that a single cooperative agreement would have streamlined management of the project to date.[14] Indeed, given the respect that each organization has for the work of the other and their effective collaboration "as equals," it is likely that the use of two cooperating agreements has been the most effective arrangement possible. Thus, to the extent that the design of the project in the future should parallel the activities currently undertaken (the team's recommendation is that the project should be so designed), the team believes that cooperating agreements separated to reflect the distinctions between the development of unbiased drug information and the implementation of drug sector reforms would be the most effective format.

- The "Substantial Involvement" Clause: Notwithstanding USAID's use of cooperative agreements with MSH and USP to implement the RPM Project, USAID has, by the terms of the cooperating agreements, been "substantially involved" with the project's implementation. In general, both the cooperating agencies and USAID appeared satisfied with the level

14 Tellingly, nobody that the team spoke to, either in Washington or the field, argued for the consolidation of these cooperative agreements.

and type of communications occurring within the project. Given the successful record of management to date, the team believes that this level of involvement is warranted and should be continued.

One area of dissatisfaction voiced by the cooperating agencies regarding USAID management of the agreements concerned general USAID restrictions — not specific to the project — regarding the funding of certain types of costs. For example, project personnel in Russia expressed concern that USAID restrictions against funding recurring costs prevented the use of project funds for the maintenance of phone lines for e-mail accounts. This, project personnel explained, was impeding the development of effective communication channels for the drug information centers.

2. Conclusions and Recommendations

On the whole, the cooperating agencies and field counterparts are pleased with the quality of USAID/Global management and support for the project. The current structure and style of USAID management has served the project well.

Recommendations

- In future RPM Projects, USAID should follow a similar approach to that used to manage the current RPM Project (i.e., use of cooperating agreements, with a "substantial involvement" clause).

- Both the CAs and the CTO recognize that in some circumstances long-term advisors are preferable, and sometimes essential, in order to make substantial progress with country level technical assistance programs. However, given the current field support mechanisms for project funding, missions must make sufficient funding available in order to provide long-term advisors. The team recommends that USAID should encourage missions to make funding available for long-term advisors when circumstances warrant their use.

- USAID should continue its dialogue with the cooperating agencies to identify government regulations that have impeded, or have the potential to impede, project initiatives (e.g., prohibitions against the use of USAID funds for certain recurring costs) and, if appropriate, USAID/Global staff

should initiate discussions with USAID management regarding the impediments and any possible solutions.

- USAID/Global staff may need, in the future, to resist temptation to expand the project too broadly. Pressure to do so may come as a result of new opportunities at either the central or country levels. It should be recognized, however, that both CAs are already operating at the limits of their current capacities. Expansion into new activities should only occur to the extent that both adequate funding is made available and the CAs engage enough additional qualified staff members to manage them.

VI. Future Directions

A. General Recommendations

1. Use of Project Resources to Support USAID Strategic Objectives

- The Global Center should develop an Intermediate Result (IR) for "Improved availability and rational use of necessary (STI drugs, ARI drugs, RH drugs, etc)," as well as the related performance indicator, to be incorporated into the strategic plan under relevant SOs. RPM should provide guidance to USAID missions in identification and inclusion of performance indicator(s) in missions' strategic plans that will serve to monitor RPM contributions related to program outcomes.

- Given the vital role that availability and rational use of essential drugs play in achieving strategic objectives in health and the increasing attention to treatment interventions within USAID–supported health programs, the Global Center should initiate a stock-taking exercise (with existing available data) that will examine the current situation of drug supply in countries with existing USAID health programs. Findings from this exercise will serve to inform USAID Global programs and missions about gaps that exist in drug supply, management, and rational use, and where these gaps present a constraint to the achievement of program outcomes in health.

- Given the opportunity presented by the new edition of *Managing Drug Supply* (MDS 2) and RPM's track record in providing effective training courses and workshops in Ecuador, the Eastern Caribbean, Mozambique, and Russia, RPM should collaborate with the World Health Organization to develop and apply training courses based on MDS 2 during any extension period.

- RPM should design and present a state-of-the-art training course on components of drug management and their relationship to achieving improved health outcomes. Such a training will provide USAID PHN officers with a knowledge base from which to incorporate drug management interventions into program planning. Providing "illustrative case studies" or "model programs" would be a good start.

- RPM/USP drug information interventions to date have focused on the provider side, without specific attention given to the patients and/or consumers. RPM/USP should undertake pilot activities in patient education related to drug use in one or two countries. This activity would likely include or build upon previous training for host-country counterparts in knowledge, attitudes, and best practices survey design, methodologies and analysis, and design and testing of patient education materials and counseling messages based on survey findings.

2. Configuration and Context of USAID Cooperative Agreements

- In future RPM Projects, USAID should follow a similar approach to that used to manage the current RPM Project (i.e., use of cooperating agreements, with a "substantial involvement" clause).

- If feasible, USAID should continue to allocate responsibilities for drug information to one cooperating agency and responsibilities, more broadly, for drug management to another cooperating agency. Given distinctions in subject areas, separate cooperating agreements seems appropriate.

B. SPECIFIC PROJECT RECOMMENDATIONS

1. Technical Priorities

a. Short-Term

(1) Country Programs

- RPM should "stay the course" in terms of the types of country support provided. The assessment-based approaches, followed by support in the areas of improving drug management, promoting rational use, and increasing access to drug information have served the countries, and the project, well.

- MSH and USP should undertake consistent consensus-building activities as part of the country program's implementation strategies.

- Sharing and documenting experience of countries that have received RPM support in similar areas could be beneficial, particularly in relation to the development and use of indicators.

More specifically, the project should consider the following activities and interventions in the areas of drug management and rational use:

- RPM should continue to support procurement and supply management at the central level through installation/training for INVEC-2 and through technical assistance in procurement methods and management. RPM also should proceed with the promising work of district logistics management support and capacity-building. In this latter area, RPM should gain experience and assess this work after a year, before introducing it in other countries.

- Indicator harmonization is another area where RPM and WHO should agree at least to introduce, in the short-term, a core set of indicators for testing and pilot trials. A meeting to address this issue was scheduled for mid-October 1997 in Geneva.

- RPM should identify potential country programs for implementation of DUR-type activities, as well as short proposals for how these activities would be carried out.

- RPM should explore the potential of providing support for INRUD core activities and for development of a Latin American rational use network allied with INRUD.

- RPM should undertake pilot activities in patient information. By initiating patient information development, the drug information component will be positioned to more directly contribute to improved health outcomes, particularly to improve compliance and begin to address key issues related to antimicrobial resistance.

Also, the project should consider the following activities and interventions in the area of drug information:

- The value and appropriateness of computer-based drug information technology versus drug reference books should be evaluated on a country-by-country basis. Mechanisms to provide in-country technical support in computer maintenance, troubleshooting, and ongoing training should be in place before computer and database installation takes place. Formal agreements and work plans that address USP DI database adaptation must be established as expeditiously as possible.

- The advantages and disadvantages of supporting the establishment of drug information centers versus a drug information network should be evaluated on a country-by-country basis. In countries where the network approach is appropriate and feasible, the potential DI network sites should develop a consensus and written work plan that includes the network mission, objectives, and activities.

- The organizational and technical capacity of existing DICs and drug information networks should be assessed. Based on the findings of this assessment, training should be provided in organizational development, including the development of DIC standard procedures, work plans, marketing plans, and financial sustainability.

(2) Core Activities

- RPM should continue its ongoing core activities in the areas of tools development and should finish the pending operational research regarding drug supply costs of reproductive health programs. Major new research, publications, or software development should be undertaken cautiously and only after close coordination with and endorsement by USAID.

- To address current needs, the project should consider the development of generic guidelines or a procedure manual for management and marketing of a DIC. Such guidelines shouls emphasize integration of drug information services into activities such as development of formularies and drug use review.

- RPM should continue its efforts to disseminate and demonstrate drug information and management tools to local officials and developing country decision-makers through articles, presentations, and lectures. RPM should increase its efforts, however, in disseminating such information to other USAID global programs, CAs, NGOs, and bilateral and multilateral organizations affiliated with USAID programs. In this regard, dissemination methods might include "brown bag" presentations, fact sheets, the Internet, or exhibition booths at conferences (e.g., NCIH). Dissemination should include how the tools can be adapted to be used in a variety of programs.

b. Long-Term

(1) Country Programs

- The project should limit its growth to other countries (and regions in countries in which the project currently is working) during an extension period. Much work remains to be done in the countries (and regions) in which the project is currently operating. Absent increased resources and staffing, rapid expansion could compromise the effectiveness of current project interventions.

- To assist in addressing needs beyond areas in which the project is operating directly, the project should consider using national/local stakeholders to be project "ambassadors," with due consideration of regional sensitivities. This recommendation is particularly appropriate for

countries such as Russia, where the capacity of local counterparts is extremely strong and the allure of being project "ambassadors" may increase interest in participating in the project and build inter-country collaboration.

- For the foreseeable future, the project should continue to focus on the current technical areas (i.e., improving drug management, promoting rational use, and increasing access to unbiased drug information). RPM should prioritize activities to develop strategies that bridge the gap between improved drug management systems and improved health outcomes. RPM should continue to collaborate with other CAs, NGOs, multilaterals, and host country institutions and should develop complementary activities and synchronized work plans.

- Indicator-based assessments should continue to be key in the design of country programs. RPM should complement the information gathered through these assessments with political mapping and stakeholder analysis. These additional assessment methodologies will allow RPM to more comprehensively analyze the pharmaceutical situation within the macro and micro political environment, design appropriate strategies, and identify viable counterparts. Priority areas to keep in mind in these assessments:

  - Health reform and the decentralization process: This would include integrating public health logistics, drug management and supplies, training, and research on cost-effective purchasing, storage, delivery, and use for programs such as family health care, child survival initiatives, reproductive health care, STDs, HIV/AIDS, tuberculosis, and polio. Within this context, RPM should target capacity-building in drug management, rational use, and supervision at the provincial and district level.
  - Private sector collaboration: This would include exploring, researching, and establishing mechanisms to work with the private sector in satisfying public health goals in the procurement and distribution of drugs and in promoting the rational use of drugs.
  - Cost-sharing: This would include evaluating cost-sharing mechanisms and assisting in applying successful mechanisms in a few countries.

- Focused, short-term technical assistance provided by RPM is valued by USAID missions, other cooperating agencies, and host-country

counterparts. This assistance should continue. However, it should be recognized that drug management involves complex and inter-related issues, which creates a need for close collaboration at the country level. Accordingly, RPM, MSH, and the CTO should continue and intensify efforts, on a country-by-country basis, to persuade USAID missions to fund the presence of resident advisors.

(2) Core Activities

- Regarding operations research, RPM should continue to engage and collaborate in operations research, focusing project resources on country-specific studies that would directly benefit country programs. Studies of general applicability should be chosen carefully and should be undertaken only in close coordination with other international entities, such as WHO, that may be engaged or interested in similar studies.

- Regarding tools development, the project should continue to develop documents and manuals, both for specific countries and for general applicability. As with operations research, the project should continue to closely coordinate its plans for producing materials of general applicability with other international entities, such as WHO, before embarking on a certain activity. This will ensure the production of materials that will find a receptive audience and distribution network, such as *Managing Drug Supply.*

- Regarding the development of software, the project should approach this very cautiously. Any investment in software products area should be done with the clear support of other international entities (e.g., WHO and other donors involved in software development).

2. Project Management

a. Short-Term

- MSH and USP should work more closely in coordinating work plans and activities in order to ensure that the interventions and timing of activities of each CA support the evolution of the interventions of the other CA.

- Assuming that RPM is extended, and that increased funding is provided, both cooperating agencies should increase staffing, expand the use of existing consultants, and identify new consultants in order to provide services to existing and new programs. Additional human resources appeared necessary to satisfy current demands on the project and would certainly be necessary in times of project expansion. Staffing at USP, in particular, has been inadequate to carry out the activities in the workplan within the original time frame. There has been only one program manager for Mozambique, Nepal, and other activities under the worldwide agreement. This person has been responsible for programming nearly $1.3 million with no designated administrative support and limited assistance from technical consultants.

b. Long-Term

- The cooperating agencies should develop a monitoring and evaluation plan for RPM. As such, emphasis should be placed on monitoring (which can be more cost-effective and relevant than large project evaluations). RPM should determine the feasibility of conducting follow-up indicator-based assessments in countries where baseline assessments were conducted during the preliminary stages of project development, as a means to determine project outcomes as related to stated objectives.

- RPM should design and carry out a study to document the outcomes and, to the extent possible, the impact of program interventions. This might include outcomes such as:

  - money saved through tender procurement
  - money saved from curtailing antimicrobial resistance through use of first-line antibiotics (e.g., sulfas, tetracyclines, and penicillins) rather than newer, more expensive, and unnecessarily broad-spectrum antibiotics
  - decreased occurrence of drug stock-outs
  - improved patient care due to improved drug selection.

- USAID should allocate project resources and shape project priorities to focus on longer-term technical assistance, particularly through in-country advisers.

Annex A. Country Report — Mozambique

BACKGROUND: HEALTH SECTOR AND PHARMACEUTICALS

Mozambique's young democracy has continued to grow in a climate of relative peace since the multiparty elections in October 1994. The long-term challenges for the government are to stimulate economic growth and fight poverty. The economy continues to be heavily dependent on foreign assistance and remains among the world's poorest, with a per capita income of only $90.

As a result of the economic and political policies of post-independence FRELIMO (ruling political party), compounded by war and drought, 60 percent to 70 percent of the population is absolutely poor, and Mozambique's social indicators are among the worst in the world. Between 70 and 80 percent of the population of 16.5 million live in rural areas. Households living in absolute poverty and or destitution amount to 60 percent in rural areas and 50 percent in urban centers.

Much of the rural infrastructure was neglected or devastated during more than 16 years of civil war. A third of all health units and half of the primary schools were destroyed. Many of the remaining services networks were inoperative or barely furnished.

The current health status of Mozambicans is worse than in 1980 and worse than in almost all other countries in Sub-Saharan Africa. Over the past 15 years, the life expectancy of newborns fell and is now 13 years less than that of newborns in other developing countries. The infant mortality rate is estimated to range from 140 to 170 per 1000 live births. The under-five mortality rate is 280/1000.

At all levels of the health care system, the health sector lacks the institutional, human, and financial resources to deliver quality services as well as an adequate information base upon which to make decisions and set priorities. These structural constraints make it difficult for the MOH to translate health care policies into operational programs or services and for provincial governments and concerned NGOs to effectively implement programs at the provincial, district, and community levels.

Although the MOH adopted a public health sector plan, it has never developed a sector-wide health policy document. The following principles and strategies have been stated, however, in numerous documents and are regarded as de facto policies:

- Access to primary health care as a basic right
- Nationwide coverage of health care to be achieved through an expanded network of Level I primary health care facilities
- Preventive primary health care to be emphasized
- Primary health care to be emphasized over tertiary and above- level care
- Program planning, budgeting, and health care delivery to be decentralized
- A national drug policy to be formulated to give priority to the importation and availability of essential drugs within the health context of Mozambique
- Family planning, principally through an active program of child spacing, to be included within the broader MCH program.

In 1992, Mozambique spent 6 percent of its total budget on health and 2 percent of its health expenditures on pharmaceuticals. When the value of donations are included, 25 percent of health expenditures are for pharmaceuticals. This amounted to $0.62 per capita on pharmaceuticals, well below the internationally recommended range of $1.00 to $3.00.

From 1992 until 1995, USAID was the only financier of the essential drug program (EDP). USAID contributed $11,018,696 through a UNICEF grant to Mozambique's EDP. Important additional donations of $1,260,000 was provided by USAID for emergency procurement of EDP kits and antimalarial drugs, and more recently in 1995 $327,982.08 for the extension of the grant until December 1996. Current donors funding the EDP are The Swiss Cooperation ($7M), The Dutch Embassy ($5M), NORAD ($6.5M) and Denmark ($3.5M).

Mozambique has a policy to limit public sector procurement to items on the National Formulary. An estimated 91 percent of government purchases are made through a competitive procurement process. MEDIMOC is a central parastatal company responsible for procurement of drugs and medical supplies for the entire

country, and for their distribution to provincial medical stores. Distribution from the provincial stores to district pharmacies and health facilities is the responsibility of the MOH. In 1993, the accuracy of MEDIMOC inventory control procedures was assessed and found to be lacking.

The problem of inventory control has persisted and is a source of concern among drug donors. Drug losses as high as 50 percent were reported to the team. A working group consisting of the MOH, USAID, The Swiss Cooperation, The Dutch Embassy, NORAD, UNICEF, WHO, The World Bank, and the EU has been formed, and an audit/tracer drug study of the EDP will begin in September to determine the scope of the problem. The recent appointment of Dr. J. Durao as Director of Pharmaceutical Services is viewed as a positive development by USAID and other donors.

Mozambique does not have a formal National Drug Policy. Laws exist concerning the National Formulary, prescribing and dispensing of drugs, and the importation and export of drugs. Therefore components of drug legislation can be said to exist.

There are estimated to be 20 private and 40 FARMAC (parastatal company) pharmacies, thus for a population of 16 million people, access to private sector pharmacies is very low. The pharmacy inspection system has not been fully developed due to a lack of trained inspectors (only two for the entire country).

In Mozambique, there are only seven university trained pharmacists. The MOH has determined that the best strategy for providing pharmacy manpower is to train pharmacy technicians rather than degree-holding pharmacists. In practice, the primary work of pharmacy technicians is dispensing drugs in clinical facilities and managing drugs in the storage and distribution system. This system is composed of two elements: the system for essential drug kits, and the "via classica" (i.e., the traditional, pull) system.

The main objective of the EDP is to promote health through the provision of cost-effective treatment for the most common diseases. Specific objectives include training for health workers and public education in drug use, effective procurement, storage, and distribution of drugs and associated supplies, and the development of policy and management systems to support rational, cost-effective, and consistent drug distribution, financing and use.

RPM activities in Mozambique support USAID Strategic Objective 3, "increase the use of essential MCH/FP services," directly and in collaboration with the Primary Health Care Project (PHC/URC) and the EDP (UNICEF), two important USAID-funded projects. Specifically, RPM contributes to IRs 3.11, " increased supply or quality of MCH/FP services;" 3.12, "more health facilities are equipped to provide essential services;" and 3.13, " more health facilities with trained

staff." The primary focus of RPM's work in Mozambique is training of MOH staff at the national, regional, and provincial levels in logistics management for drug supplies, rational use of these essential products, and the development and dissemination of unbiased drug information.

In 1995, USAID Mozambique provided a total of $390,000 to RPM to design and implement a country program. The Global Bureau allocated $290,000 to the MSH cooperative agreement, and $100,000 to the USP cooperative agreement.

ASSESSMENTS USED IN DESIGN OF PROGRAMS

A formal assessment of the Mozambique pharmaceutical sector was conducted from 10 October to 4 November 1993 by a team of MSH technical advisors and local counterparts with USAID mission funding. The assessment was carried out using the indicator-based approach and included an extensive review of the UNICEF EDP Kit program. The objectives of the Mozambique assessment were: first, an evaluation of EDP, in order to assess the impact of the program and make recommendations for further improvement; and second, to identify opportunities for RPM for possible future work in Mozambique.

This assessment found numerous problems with the pharmaceutical system and several positive factors, one being that the provision of pharmaceuticals to public health facilities is the top priority of the Ministry of Health. In addition, a national formulary system exists and has reduced the number of imported non-formulary drugs. A policy requiring generic prescribing has resulted in virtual elimination of brand-name prescribing.

The accuracy of MEDIMOC inventory control procedures was a problem. The average recorded figure on control cards in storage facilities was 128.85 higher than the actual count. Cards kept at the administrative offices indicated recorded inventory 159.3 percent of the actual. Monitoring and supervision of drug ordering, storage, and distribution by warehouses and health facilities at the provincial and district levels was lacking.

The kit system in Mozambique has been the main mechanism for the distribution of essential medications at the primary health care level. However, information is not readily available on the distribution of kits and on stock levels at these facilities.

In 1994, Mozambique had no formal National Drug Policy, although laws did exist concerning the National Formulary, the prescribing and dispensing of drugs, and the importation and export of drugs.

Following this assessment and per USAID request, a MSH team visited Mozambique in April 1995, and developed a plan to assist the Ministry of Health improve the management of pharmaceutical resources in three technical areas: procurement and inventory management; drug information and rational drug use; and drug product registration.

ASSISTANCE STRATEGIES

Assistance Strategies Used

RPM assistance did not begin until the last quarter of 1995. This delay from the 1993 assessment was due to both bureaucratic difficulties and RPM's other commitments. In mid-1995 a work plan was drafted and approved by the USAID mission and the MOH. MSH and USP are the USAID cooperating agencies conducting this work. RPM focuses on three priority technical areas:

- Establishing and automating drug registration systems
- Rationalizing procurement and inventory management in the public sector
- Expanding drug information resources and promoting rational drug use.

In light of the critical manpower shortage and the poor skills in the area of drug management, the MOH placed highest priority on training pharmacy technicians (rather than degree-holding pharmacists) and on improving the drug management skill of the existing MOH personnel.

In April 1995, the RPM/MOH team agreed that priority be given to improving the skills of prescribers, pharmacists, and pharmacy technicians in the areas of drug procurement, inventory management, and rational use. This was to be done through national, regional, and provincial training workshops with the development of Mozambique-specific materials.

Using the Managing Drug Supply training series developed by the MSH Drug Management Program as a basis, and with RPM technical assistance, MOH staff adapted and translated 16 sessions and the trainer's guide into Portuguese. RPM staff subsequently updated and revised this material, which is now available as "Gestao e Use Racional de Medicamentos."

RPM conducted a two-week national-level workshop in Maputo (June 1995). Participants included 28 physicians, pharmacists, pharmacy and medical technicians, and pharmacy agents. All provinces were represented. Subsequent two-week workshops were held in three regions: 22 participants completed the workshop in Manica (central region) in November 1995; 23 in Chokas Mar. (northern region) in April 1996; and 31 in Namaacha (southern region) in October 1996. Between June 1995 and May 1997, a total of 120 participants received training.

Eleven MOH personnel who attended the national-level workshop completed a training of trainers (TOT) workshop held during the week following this course. The Mozambican trainers (representing all provinces), formed the Nucleus for Rational Drug Use in the Pharmaceutical Department and have been heavily involved in organizing and conducting the regional workshops. It is important to note that by the third and last regional workshop, the Nucleus had gained sufficient experience to independently conduct future workshops with the course materials.

The "Drug Management and Rational Drug Use" (DMRU) courses were organized by the MOH and received technical and financial support from UNICEF, The Swiss Cooperation, and the PHC/URC. Specifically the various organizations provided the following:

- The Pharmacy Department of the MOH provided administrative and logistical support in identifying participants and trainers, the venues, providing local transportation,etc.

- The UNICEF EDP paid for all local costs for each workshop including logistical support, per diem, and lodging and travel expenses, at a value of approximately $50,000

- The Swiss Cooperation contributed to RPM training efforts by supporting the initial translation of the training materials into Portuguese and later by providing the funding (to cover per diem expenses) for the local trainers who were employees of the Ministry of Health

- The USAID-funded PHC/URC Project has been supportive of RPM training activities, providing logistical support and funding 30 participants from the URC's three project provinces to attend the workshops. URC hired a pharmacy technician, Ms. Isaura Possolo, to continue training and provide follow up in the URC Project provinces. She is currently adapting

training materials for use at the district level. The estimated value of this support is $22,140.

The DMRU course conducted in May 1997 in Gaza was the first provincial level course and represented a new course format agreed upon by the MOH and RPM. The shorter one-week didactic portion still provides 16 theoretical sessions, but reduces the amount of theory to allow group and individual work in class and to incorporate MOH drug policies and procedures. The second week of the course consisted of facilitator visits to participants' work sites in order to consolidate the new material. Sixteen participants from eight district health facilities attended the course, including a clinician and pharmacy staff member for each facility. This interprofessional setting proved to be a great advantage in facilitating the understanding of the material and will contribute to the application of acquired skills at the work sites.

The "Drug Use Review" (DUR) course was given to all participants of the DMRU course in May 1997 who are prescribers and two of the EDP physicians from Maputo. Additionally, hospital and health center staff were trained in DUR. This is viewed as a preparatory step to a broader program for promoting rational use, now in the planning stage.

In the area of drug information, USP has supported the establishment of a drug information center (DIC) located at the Library and Documentation Center of the National Institute of Health, a department of the MOH in Maputo. The translation of the USP DI database into Portuguese was completed (through an agreement outside of RPM), the database was installed and is operating smoothly, and three staff members have been trained in its use. RPM provided a computer with CD ROM and a laser printer that will give the center the capability to produce drug information bulletins and educational materials. A qualified MOH counterpart has been identified to adapt the Portuguese USP DI to include Mozambique specific drugs, however, the adaptation has not yet begun, nor has a formal agreement been reached to allow the counterpart to carry out this work. USP has also provided drug information reference books and periodicals. Future USP supported activities will include a September 1997 drug information workshop, at which time the DIC will be "officially" launched. Following the workshop, four people will participate in a drug information study tour to South Africa.

Appropriateness of these strategies

As stated above, the main strategy followed by RPM was that of training and this was based on the major interest and recommendation of the MOH. The MOH has been pleased with the training conducted to date and now wishes to see it

continued at the provincial level in order to involve health staff at the district level. It is hoped that this approach will guarantee the continuity of service delivery improvements.

The work of USP in the provision of drug information appears to be most relevant and supportive of the needs of the medical community. When the adaptation of the USP DI database is completed, the database will provide valuable information to support activities in rational use. If and when the pharmaceutical market is more "open," the availability of information to inform decision-making will be even more vital. The decision to locate the DIC in the Library and Documentation Center of the National Institute of Health, appears to have been an appropriate choice due to the fact that practitioners are accustomed to using the center, and the staff are available, capable, and enthusiastic.

Results from these strategies

Since April 1994, RPM/MSH with MOH and URC support has trained a total of 104 MOH staff members at the national and regional levels. RPM has developed, translated into Portuguese, tested, and revised course materials in drug management and rational use. RPM has taken care to train a cadre of trainers at the national and provincial level, thus promoting the sustainability of this work. The project has developed two training manuals, one for trainers and the second for participants. Finally, RPM conducted a workshop on DUR and developed and translated related training materials.

USP has provided the USP DI database in Portuguese to the Library and Documentation Center of the National Institute of Health, and created the first drug information center in Mozambique. USP is currently negotiating the assignment of a high-level staff person with the MOH to manage the database adaptation process.

USAID believes that RPM's work serves as a platform which other USAID projects and CAs can use to the advantage of their own programs. For example, the URC Project is in the process of adapting the materials developed by RPM for its own district and facility level training activities.

PROJECT IMPACTS

In many ways it is too early to talk about the impacts of this project. Also, lack of formal testing/evaluation of the training conducted makes it difficult to say how effective the training has been. However, all interviewed indicate that to date they

are very satisfied with the work of RPM and USP and have observed some positive changes. In addition, contracts were signed by participants and facilitators at the May 1997 DMRU course promising to continue the learned activities.

A potential and significant impact of the project will be the finalization and adoption of The National Drug Policy planned for March 1998. This will be a significant development, as it defines the new structure of the MOH Pharmacy Department, and the responsibilities of the various programs and departments. Similarly, implementation of a new drug registration system is pending the publication of a new drug registration policy.

In the future objectively verifiable indicators should be identified and used to evaluate the impact of this project.

OBSTACLES AND CONSTRAINTS IN MEETING OBJECTIVES

The successful completion of activities in Mozambique is due to the support and enthusiasm of the MOH, the USAID mission, EDP/UNICEF, the PHC/URC Project, and various donor agencies. Due to a high degree of cooperation there have been minimal constraints to carrying out the training activities as planned. However, RPM has been slow to move beyond training due several constraints.

RPM had intended to support the establishment and automation of a drug registration system. The MOH will utilize the WHO drug registration computer software and has assigned a person to receive training in use of the software. However, the assigned person has not yet completed the training, and a clear role for RPM support has not been defined by the MOH.

The decentralization of many management functions to the provinces implies that there should be a system in place at both central and peripheral levels capable of providing the needed information to support all management activities. RPM and the Pharmaceutical Department agreed to collaborate in assessing the types of information needed and to make recommendations on the type of system that should be implemented. This activity was scheduled to take place in early December 1996, but was canceled due to scheduling conflicts. It remains to be rescheduled.

Skills in estimation of drug requirements remains a weak point of the supply system. It is essential to strengthen this aspect of drug management in order for the MOH to optimize the use of the limited resources available and to increase their credibility among donors. Improved skills in this area should assist the MOH to identify priority products, appropriate quantities, and the amount of funds

needed to cover the treatment of the most prevalent and critical diseases. For this purpose, a national quantification exercise using consumption and morbidity data has been proposed by RPM. However, this activity was postponed by the MOH.

The Pharmacy Department and the public sector supply system need to establish more credibility among the donors so that the MOH does not lose a significant amount of funds and support. Pooling resources at the central level in various areas has been discussed as one mechanism. RPM/MSH, EDP/UNICEF, and the PHC/URC Project originally agreed to create a document that specifies activities that would support the Mozambican EDP. However, it was later determined that it would be better to have the MOH as the focal point of all activities, and the three organizations would work through normal communication channels, and their own work plans to further the Mozambican EDP activities.

Until a National Drug Policy is adopted, activities will continue to be postponed. Similarly, implementation of a new drug registration system is pending the publication of a new drug registration policy.

Progress has also been slow perhaps due to the limited number of personnel at the MOH, which can create a competition for time. Planned activities have been frequently postponed and rescheduled, and therefore the recommendations made in the original assessment were often slow to be adopted or not adopted, and completion of work plans is behind schedule. Sustainability is a concern due a shortage of trained MOH personnel and weak supervisory systems.

Poor communication infrastructure have hindered planning and execution of activities in a timely manner. MSH and USP have both reported unreliable internet e-mail and fax communication.

RPM training activities in drug management include an activity which requires the participants to design an activity or project for their facility. Participants have submitted these activity proposals to their provincial MOH departments. However, due to financial constraints these activities, have not been implemented. This may create frustration and discourage participants from following through with application of skills and knowledge acquired through the training.

The MOH has developed a formulary, but the formulary has not been approved by the Minister of Health. USP DI database drug monographs will be a valuable resource for upgrading and production of the formulary. The planned adaptation of the USP DI to include Mozambique-specific drugs will greatly assist this effort.

VIEWS OF USAID MISSION STAFF AND LOCAL COUNTERPARTS

Through RPM, USAID has become recognized by other donors as a leader in strengthening drug management in Mozambique. The Swiss Cooperation, for example is urging USAID through RPM, to provide a full time advisor to assist MOH with implementation of its new national drug policy.

In addition to meetings with USAID, interviews were conducted with the pharmacists at the Maputo Central Hospital and the Health Sciences Institute, pharmacy technicians at Mavalane Hospital, the newly appointed director of the Department of Pharmacy as well as his predecessor, the pharmacist at the MOH Department of Pharmacy, the medical librarian, the head of the National Institute of Health, the WHO Country Representative, UNICEF National Health Officer, the representative in charge of pharmaceuticals at NORAD, and the staff of PHC/URC. The representatives from the other two major donor partners, the Swiss and the Dutch, were on home leave.

All consulted had high regard for the training conducted by RPM and for the work of USP. A concern expressed by the Norwegian representative was that RPM has no national counterpart. While trainers were being trained and had successfully conducted one course, she felt that at the MOH level there was not an identified person to continue this training and therefore there may be a lost value to this training. This however was not the belief held by the previous director of pharmacy at the MOH. He felt that because of the TOT and adaptation of RPM training materials to the Mozambique situation, the MOH will be able to sustain the program upon completion of the RPM Project. He also stated that drug management and rational use training go hand-in-hand and should continue.

While no follow-up assessment has been conducted to determine the results of RPM training, all persons interviewed believed the training has produced improvements in drug management. The host country nationals in the department of pharmacy also communicated their opinion that they have observed "some improvement" in skills, etc., but could not provide specifics.

Parties interviewed by the team expressed their opinion that the RPM should provide technical assistance to address the problem of drug loss. The donors in particular are hopeful that the findings of the tracer drug study will identify specific weaknesses in the drug management and logistics system that need to be addressed.

CONCLUSIONS AND RECOMMENDATIONS

The RPM Project has made progress despite many schedule delays. All interviewed have great respect for what has been accomplished to date and the technical assistance provided. All expressed interest in seeing this activity continue and expand to other areas aside from training.

In the next year more emphasis on the training of provincial level staff was viewed as necessary. In addition, the length and type of courses might need to be reviewed. Dr. Durao indicated that he felt the courses may be too short, training should emphasize practical skills over theory, and refresher training will likely be necessary.

Inadequate supervision by the MOH and inadequate skills in supervision of drug management is a major area of concern by all parties. Future training should include drug management supervision, and RPM should coordinate with the MOH department of human resources to ensure continuity in this regard.

Because of known problems in drug use, RPM is studying the best use of DUR practices with EDP physicians in Mozambique. It has been suggested that the introduction of DUR concepts take place at the Medical Institute, followed by implementation of DUR programs at larger tertiary care hospitals and clinics in metropolitan areas. In the DUR process, actual drug use is compared with predetermined criteria, allowing detection of inappropriate prescribing practices and/or costly drug therapy.

Other important areas which RPM has planned in its 1997 work plan include: drug management (selection and quantification); health system financing/recurrent costs of drugs; and installation and training in various software programs and information systems for drug selection, inventory management, rational drug use, and management information systems. Given the past history with repeated delays and the current drug problem, this work plan appears to be very ambitious. Without a long-term presence to move activities along, it is doubtful that this plan can be completely implemented. The evaluation team is aware that RPM has requested funding for a resident advisor, but due to limitation of available resources, the Mission has so far been unable to provide such funding. In addition, it would appear to be important to evaluate the outcome of the training that has been conducted, prior to proceeding with additional training activities.

Recommendations

- The results of the audit/tracer study will likely have implications for improved drug management and supervision, revised procedures, etc.

RPM should be prepared to offer technical assistance and training to address the needs identified by the audit.

- As mentioned in the original assessment and throughout this visit, supervision is an important element currently not being adequately addressed. RPM should assess (if it has not already done so) the supervisory capability and training of MOH staff in the area of drug management supervision. RPM should provide technical assistance in drug management supervision and/or adapt the current training program to integrate supervisory skills.

- RPM, with the Department of Pharmacy, should identify mechanisms to fund small projects initiated by the newly trained personnel. Possible funding sources might be the EDP donors or NGOs implementing MCH projects in the various provinces.

- If and when the MOH moves toward decentralization, RPM should review drug supply management at the hospital level as they currently absorb 60 percent of the budget.

- RPM should review its future plans in terms of their relationship and support to the five-year strategic plan for the Department of Pharmacy.

- The sustainability of both the work of MSH and USP has been questioned; a review of the issues that might affect the sustainability of the work to date should be undertaken and adjustments made.

- Consideration should be given by the USAID mission and RPM of the placement of a long-term advisor in Mozambique. Placement of a long-term advisor would greatly assist RPM with carrying out its work plan as scheduled. This would require, and merits, extensive dialogue with the MOH Department of Pharmacy.

- USP should focus on supporting the activities of the existing DIC, adaptation of the drug information database, development of a marketing plan, operational procedures, etc. A specific need exists for drug information on contraceptives in Portuguese. This need should be addressed, with monographs translated and adapted, if needed, and incorporated into the adapted USP DI.

- WHO/DAP in Geneva reported that translation of the *WHO Guide To Good Prescribing* into Portuguese is underway. When the translation is completed and available, RPM should explore opportunities for introduction of this guide and incorporation of its use in Rational Drug Use training in Mozambique.

Annex B. Country Report — Nepal

Background: Health Sector and Pharmaceuticals

The Ministry of Health is responsible for providing drugs and medical supplies to the approximately 1,200 public sector health facilities (e.g., health posts, sub-health posts, health centers, and different level hospitals) located in Nepal's 75 districts. The government yearly drug budget of about (US)$1,000,000 is grossly inadequate for Nepal's population of 20 million. In recent years, donations (from the Nippon foundation, KfW, and UNICEF) of about $4,000,000 worth of medicines have helped to solve some, but not all, of the public sector shortages in Nepal.

Due in part to the public sector shortages, the private sector, which consists of about 8,000 drug retailers, plays a very important role in Nepal. It accounts for an estimated annual turnover of about $60,000,000.

In addition to inadequate financial resources for drugs, well-trained health professionals are scarce or lacking in Nepal in areas such as drug selection, management, procurement, and distribution and the use of medicines — areas for which strategies need to be developed to reduce wastage and increase availability and accessibility of essential drugs.

In the late 1980s and early 1990s, the government of Nepal started to address and systematically examine many of the problems in the pharmaceutical supply system, both public and private, under the umbrella of a prospective National Drug Policy. The Nepal Drug Policy, which was adopted and published in 1995, was intended as a guide for action but has, in fact, been followed only partly. The policy has not been translated into a comprehensive operational action plan for the whole pharmaceutical sector.

Assessments Used in Design of Programs

The RPM Project in Nepal consists of support from both MSH and the USP. In 1993, MSH was asked by the USAID mission in Nepal, in its response to the

government's request for donor assistance, to join a team from the WHO Action Program on Essential Drugs that was scheduled to review the pharmaceutical sector in Nepal. The resultant joint team from WHO and RPM assessed, over a three-week period, the pharmaceutical sector in Nepal and development of the National Drug Policy (NDP). From this assessment, the joint WHO/RPM team prepared an overall NDP plan that covered both the public and the private sectors. Participants on the team from RPM stayed on another two weeks to complete an RPM-specific country assessment [producing 23 of 33 RPM standard indicators].

The RPM assessment identified drug registration; drug management including procurement; inventory control and distribution; rational drug use and drug information as particularly weak areas that needed technical and managerial assistance. The most pressing problem identified in the assessment was the public sector logistics system. To further assess this problem, RPM became part of a multidisciplinary team that developed a structured questionnaire for data collection through interview and document review with key staff from the Ministry of Health and donor agencies. The team prepared a matrix summarizing issues and problems that were identified in the management of product selection, procurement, distribution, management information systems, human resources, and budget and finance. As part of this process, a workshop was held with Ministry of Health officials and donor agencies to get their input. After a final review by the team, a draft (three and a half year) collaborative work plan for Logistic System Improvement Plan (LSIP) Project under the lead of John Snow, Inc. (JSI) was submitted to, and later approved by, USAID.

Overall implementation strategies for Drug Information and Rational Use are described in the final October 1994 work plan, which covers activities in three areas:

- Establishment of a drug information network and creation of a capacity to develop and disseminate information
- Development and implementation of intervention strategies for rationalizing drug use
- Development of training materials.

The principal counterpart agency for implementation of the overall LSIP is the Logistics Management Division of the MOH. For the drug Information and rational drug use subcomponents of the LSIP, the principal counterpart agency is the DDA.

ASSISTANCE STRATEGIES

The RPM Project, in collaboration with USAID/Nepal, JSI, the MOH, and key NGO's working in drug-related areas, has developed activities that *directly respond* to all of the needs and priorities identified in the assessments.

- Drug registration: Under the auspices of this project, RPM made verbal arrangements with WHO in the spring of 1994 to provide technical assistance and computer software for automating drug registration data with the Nepal Department of Drug Administration (DDA). Later, in July and August 1994, a work plan for Drug Information and Rational Use was drafted after an assessment was conducted by a four-member joint MSH/USP team.

- Procurement and Inventory Management: The Logistics System Improvement Plan included a plan to clean out and reorganize all district and facility level storage facilities as well as assist with the design of a new logistics information system — MSH took the lead on developing the product coding system; developed a drug supplier information system and proposed appropriate procedures for managing competitive procurements of drugs and other supplies; developed an approach to track all drugs and contraceptives in the MOH services delivery system; and developed recommendations for improving cost-recovery at the community level.

- Drug Information and Rational Use: RPM, primarily USP, has worked with the Department of Drug Administration (DDA) to set up the Drug Information Network of Nepal (DINoN) which includes five drug information centers equipped with up-to-date publications and the USP DI Plus database for providing unbiased drug information; has begun the adaptation of the USP DI Plus database to include Nepal-specific information; and worked with drug information centers to increase the availability of drug information to their members and constituents through the use of periodic Bulletins.

  RPM, primarily with assistance from MSH, has collaborated with DDA and the Tribhuvan University's Health Learning Materials Center to produce a revised "Standard Drug Treatment Schedule"; and, in collaboration with GTZ, INRUD, and DDA, has begun to develop a strategy for promoting rational drug use within MOH services in two districts where GTZ has their primary health care projects.

PROJECT IMPACTS

Improving Allocation, Management, and Use of Resources

- Procurement and Inventory Management — the Logistics Management Information System: Over the past four years, RPM has — together with JSI — put a lot of effort in the areas of technical and managerial expertise into the new Logistics Management Information System (LMIS). Progress has been slow but meaningful. Progress has been slowed, in large part, because of the complexities inherent in working with Nepal's civil service, in which cultural and political differences abound and where technical and/or modern managerial skills are often lacking. In some instances, the government may not have responded adequately, or quickly enough, to take full advantage of RPM proposals (e.g., appointing a much-needed local counterpart in the LMD). Nonetheless, there should be no doubt that RPM inputs into the LSIP have had significant impacts, such as those described below. The team expects these impacts to be greater once the LSIP is fully implemented. RPM has developed, or has participated in the development of:

  - the product classification and coding system being implemented through LSIP
  - procedures for stores management and "dejunking" which has been completed through LSIP
  - routines for managing competitive procurements.[15]

  In the first part of 1995, RPM worked with LMD and produced the "Nepal MOH Pharmaceutical Supply Directory." This in-depth study developed an approach to tracking all drugs and contraceptive inputs into the overall MOH services delivery system. Analysis of data for 1994 on "who supplied what, from where, for whom and at what price and quantities" amongst the MOH, the UN agencies, and major donors showed that all drug inputs, for which data could be obtained, were valued at about $5 million, and 80 percent of this was provided by donors. It revealed 23

15 These include a supplier information data base, tendering and adjudication guidelines and a supplier pre-qualification system. Regarding the latter, the government is now using a book that was produced from RPM guidelines, which is sold to suppliers wishing to bid on contracts to provide certain drugs.

supply episodes, the presence of eight funding agents, seven procurement agents and over ten program implementers. It further drew attention to issues concerning drug quality assurance. The revelation of this state of affairs should have been of great concern to MOH decision-makers and donors. RPM staff have indicated that they shared the report with senior government officials as well as with staff at UNICEF and WHO. Regrettably, however, these efforts do not seem to have induced MOH to take steps to improve the situation. RPM was, however, able to make some significant use of this work by collaborating with FPLM and applying the findings to the implementation of the Logistics System Improvement Plan.

- Nepal Cost-Sharing in Pharmaceutical Distribution Study: In response to a request from UNICEF concerning the design and implementation of the MOH-sponsored Community Drug Program (CDP),[16] RPM carried out a major study to evaluate existing drug cost recovery activities in Nepal. This study, which involved MOH, DDA, USAID, UNICEF, and Valley Research Group (a local research team), was comprehensive and well executed.

  The study addressed the difficulties encountered by the CDP in the area of cost-sharing, and one of the major recommendations from this study was that

  > the MOH, with UNICEF support, [should] negotiate grant agreements with NGOs to assume the responsibility of establishing community drug cost-sharing in specific districts or part of districts. The MOH, UNICEF and the collaborating funding agencies should agree upon specific general characteristics and objectives that each participating drug outlet should achieve . . . .

  The intent of the RPM recommendation was that MOH should retain the leadership role and use NGOs with established track records in drug sales activities as its implementing agents. It is apparent in hindsight, however, that both MOH and UNICEF found the idea of allotting a significant and visible role to the NGOs to be politically unacceptable.

  It is apparent that RPM made attempts to discuss their findings and recommendations with key decision makers. For example, they organized a one-day workshop to present findings to important decision makers and gave a copy of the report to a member of the National Planning

16 UNICEF was the executing agency for the Community Drug Program, a program that was supported with drugs from KfW and the Nippon Foundation.

Commission. In addition, RPM provided copies of the report to UNICEF, KfW and the Nippon Foundation. (One staff member even visited Tokyo to consult with Nippon directly after completing the study and another participated in Nippon's annual program review several months later.) RPM staff also discussed the study in CDP working group meetings. Regrettably, however, these efforts did not persuade any of these parties to support the strategy advocated by the study. Nonetheless, the findings of the study remain extremely important and should be widely discussed (again) at the policy level. (Indeed, the findings are of international interest and should be published.) The findings are also of renewed interest in the RPM/GTZ collaborative activities in strengthening drug management at the district level (discussed below).

- Strengthening of Drug Management at the District Level (SDMD); GTZ Collaboration: RPM, through DDA, started collaboration with GTZ in the fall of 1996. RPM had approached GTZ for funding for:

  > the local costs of the development and demonstration, within two districts, of a practical strategy for promoting rational drug use, that is suitable for widespread implementation within the Ministry of Health's services delivery system.

  GTZ felt however that any joint activity could not be carried out in isolation and that it could not be limited only to rational drug use. In response to GTZ concerns, the scope of RPM/DDA activity was expanded to include needs estimation, storage and distribution, and rational use. GTZ agreed to provide the requested $40,000 for the project, which was to be carried out under the responsibility of DDA.

  An indicator based assessment was carried out by DDA (in cooperation with GTZ Primary Health Care Project) in the two districts wherein GTZ is working (i.e., Dhading and Sirah). The principal investigators for the assessment were Dr. K. K. Kafle, head of INRUD in Nepal, and Dr.B. Santoso, RPM technical adviser. Following initial input from RPM concerning design issues, the study was produced by the local team. The good quality report, which included a considerable amount of data, represents a successful transfer of the RPM indicator-based assessment technology.

  A workshop was held in June 1997 to review findings and prepare a one-year work plan. Although there was some concern expressed at GTZ about the outcome of the June work shop, it is obviously too early to assess any impact from this work. It is, however, important now to state

clearly the scope of RPM drug management support and to plan carefully the work so that the strategy is clearly understood and shared by all stakeholders. Such planning will be critical so that the work to be done in these two districts will have a future impact that can be replicated in other districts. In the start-up phase of collaboration in an important project such as this one, RPM must ensure that technical and managerial assistance is available on a continuous basis, and that the person who will provide this is familiar with, among other issues, the process of decentralization that is now taking place in Nepal.

In this work, the need to include support and capacity building at district level in drug procurement must not be overlooked, and should be re-emphasized in the project. This is because the rapid assessment study found, for example, that local acquisition prices varied between 20 percent to 248 percent of MOH acquisition prices, being, on average, much more expensive. Unfortunately the rapid assessment study, carried out prior to the June 1997 workshop, missed looking into the private sector and patient purchasing of prescribed medicines from the drug retailers/chemists.

Promoting the Rational Use of Drugs

- Development of Revised Standard Treatment Guidelines: From INRUD-supported drug use interventions studies and research, carried out in Nepal by the same group that undertook the rapid assessment study mentioned above, it is clear that presence and use of standard treatment guidelines in health facilities are low. The revised guidelines (developed with RPM input) are about to be printed in Nepalese and in English by the Health Learning Materials Center. Their impact can only be measured once they have been actively promoted (not just passively distributed), made part of educational curricula (currently they are not in Nepal), and made part of an integrated training program addressing key health problems, as envisaged in the GTZ Project.

  The development process of revising the standard treatment guidelines helped to draw attention to the need for more serious attention to the rational drug use issue in Nepal. The majority of the Nepalese population, particularly in rural areas, seek advice from drug retailers, who could therefore play a very important role in promoting rational drug use for a few widespread and important diseases. For such public health strategies to be accepted it is essential to have the medical profession and disease managers closely involved. Much can be learned from AIDSCAP's successful efforts working with the medical profession, the National

Chemist and Druggists Association (NCDA) and the DDA to prevent and treat sexually transmitted diseases. In this regard, RPM should work to support the introduction of the revised standard treatment guidelines into the regularly held training courses for the drug retailers.

- Studies and Operations Research: Through various support from INRUD, RPM and WHO, several studies on drug use and pharmaceutical management have been conducted in Nepal since the early 1990s.

  DDA undertook a quantification study with WHO support in 1992 to find out the top ten drugs consumed in Nepal. Dr. Kafle and INRUD members investigated in 1995 prescribing practices of medical professionals in the private sector. DDA with WHO support carried out a similar study in the Kathmandu Municipality in 1994.

  Prescribing and dispensing practices have been investigated mostly at the primary health care level at health posts and sub-health posts, and in some central hospitals.

  In 1995, RPM supported a study on intervention tests for improving prescribing and dispensing practices. In 1997, an indicator-based rapid assessment survey (see above) was carried out by a five-member team from DDA and INRUD/Nepal, Dr. K. K. Kafle. Technical assistance for this stream of activities was provided by RPM advisors, Dr. B. Santoso of INRUD/Indonesia and Dr. Dennis Ross-Degnan of Harvard University. The findings were discussed at the June 1997 workshop mentioned earlier. The study had been intended to cover indicators for the private sector but did not. It covered aspects of district pharmaceutical budget and procurement, availability of official manuals (National Essential Drug List and Standard Treatment Schedules), pharmaceutical logistics, and drug use. The study concluded that training of health care providers and consumer education are very much needed, as well as supervision and monitoring, and that official manuals must be provided and used. The baseline data gathered in this survey will be used for intervention and for development of evaluation strategies for training, including the tracing of major health problems such as ARI, diarrhoea, fever and skin conditions.

  In April 1997, USP signed a subagreement with a recently established NGO, the Pharmaceutical Horizon of Nepal (PHON) led by Dr. K.K. Kafle and including colleagues from DDA. PHON's main focus was reported to be on provision of information to consumers and womens' groups.

The scope of the USP/PHON subagreement covers two parts. Under one, the "Drug Information Study," PHON will collect and examine academic and non-academic curricula with regard to coverage on rational prescribing and drug use information (with focus on drugs included in the Nepal National List of Essential Drugs). In the second part, the "Health Care Study," PHON will examine prescribing practice of qualified and unqualified prescribers at different levels of health care (central, regional, zonal, and district levels including hospitals, primary health care facilities, and the private sector). The specific objectives of this study are to find out the use of priority drugs; the use of inappropriate, harmful, ineffective or needlessly expensive drugs; and the use of drugs in diarrhoea and ARI in infants and children and anemia, pregnancy, and STDs in adults.

The evaluation team feels that there now is a need to gather all the studies and operations research on rational drug use, drug management, cost recovery, etc. The methodologies used, the findings, the applications, etc., need to be reviewed by an advisory or reference group familiar with the public and private health services systems in Nepal. A clear analysis of each study should be done and presented in a standardized and tabular format and recommendations for future studies and operations research should be given by the proposed advisory/reference group.

Improving Level of Drug Information

Generally speaking, the 1994 RPM/USP mission's work plan for drug information and rational drug use was, in the view of the evaluators, too ambitious. Nepal's institutional capacity could not handle or absorb all activities set out in the work plan, particularly not within the proposed time frame.[17]

- Drug Information Dissemination: Nonetheless, progress has been made regarding the overall objective of improving access in Nepal to independent and evaluated drug information for providers and consumers. Under the USP contractual agreement the five centers have received up-to-date books (including, but not limited to, the *USP Drug Information),* which are regularly used. The centers have also received computers and printers under the RPM Project, including the USP DI Plus CD-Rom database. On the whole, the latter has not yet found regular use. One reason for this has been technical difficulties with the CD-Rom itself.

17 For purposes of this evaluation, it would also have been helpful if the original work plan of 1994 could have been updated in such a format that planned and actual achievements could have been easily compared.

Another reason may be that the Nepal-specific adaptation of the data base is not yet ready.

The effectiveness of these centers in disseminating information varies significantly between the designated drug information centers: those at the Teaching Hospital and the Resource Centre for Primary Health Care (RECPHEC, an NGO) are very active, the one at the NCDA not yet fully functioning, and the one at the DDA in between these two extremes. (The center at the National Council on Health Research (NHRC) is just starting up.)

At the Teaching Hospital, which is part of the Institute of Medicine (IOM), an excellent Drug and Therapeutics letter is produced for health care providers (without financial support from RPM). This information will now become a permanent feature in the Journal of the Nepal Medical Association. The USP and IOM are also discussing a subagreement for IOM to conduct a three-day training seminar for new physicians in the Kathmandu valley, on the principles of rational drug use. There are further plans for IOM support under this subagreement to enhance the one-page consumer information page ("Consumer Sheet") intended for patients and providers in this University hospital.

RECPHEC produces an excellent newsletter with a circulation of 10,000. RPM funds the costs of this publication and provides technical assistance for a drug information column, which is a regular feature of the publication. RECPHEC also has an impressive documentation center. Under the RPM Project, a "Bibliography on Drugs" was produced and is now being updated under a USP subagreement. DDA also prepares its own Drug Bulletin (DBN) concerning mainly regulatory matters and NCDA its monthly bulletin for drug retailers, wholesalers and importers. Under another USP subagreement, the NCDA Bulletin will be further expanded in content and in quality in order to reach all of the 8,000 drug retailers and wholesalers registered in Nepal. Through the above-mentioned mechanisms practically all target groups are covered. However, it would be useful for Nepal to have an umbrella NDP implementation plan to bring together all the ongoing work under the different administrative and technical components in the public and private pharmaceutical sector.

One lesson learned from the evaluation mission is that clear operating procedures and operative work plans, including purpose and use of expected products and interim products, must be jointly prepared by MSH and USP, together with those who are going to implement the work. This is particularly true for the DDA work on the drug registration package, the

Nepal version of the USP drug information data base and the use of USP CD-Rom. This will require some longer-term presence of technical and computer assistance until the programs are up and running.

- DINoN: Drug Information Network of Nepal: DINoN, the network of the five drug information centers mentioned above, was officially inaugurated at a two-day meeting on Drug Information in September 1996. This was an important achievement for Nepal: the meeting received attention in the media, and health professionals and the general public are getting to know of the existence of drug information centers. An informative pamphlet has been prepared which spells out the aims of DINoN (i.e., "to provide unbiased and accurate information to a wide range of audiences"). The main activities, features and audience for each center are also described in the DINoN pamphlet.

  The evaluation team encountered significant concerns from individuals within the network regarding DINoN's structure and ability to function as a network. For example, the Steering Committee with DDA as focal point has only met once and the working group of the network has met infrequently. No standard operating procedures have been developed for the network. Unfortunately, there are also some personality problems within the network that threaten to impede DINoN's functioning as a true collaborative network. The evaluation team discussed these problems at length, and feels that instead of forcing the network to prepare a joint work plan, each group should prepare its own with technical assistance from RPM as required. Nevertheless a common set of goals, an overall strategy, and working procedures should be developed by the Steering Committee that should meet once a year and then also prepare for the annual drug information meeting.

  Plans to extend the current drug information network to two regional outposts of the DDA were mentioned several times during the team's visit to Nepal. The evaluation team appreciates the need for having up-to-date drug information available at the DDA offices close to the Indian border (where a lot of drugs enter Nepal). Nonetheless, this extension to the regions should not be undertaken before the main DDA office (with RPM assistance) has developed appropriate standard operating procedures for running a drug information center.

  It was difficult to assess the impact of the study tour organized by USP to the United States and Malaysia. The observation of the work of Hospital Therapeutic Committees was mentioned as very useful. It was no doubt also useful to visit USP and FDA. The evaluation team feels that it may be

appropriate to plan future study tours so that more "hands on " experience can be gained and that such tours could include visits to neighboring or other developing countries.

- Drug registration: The entering of data for drug registration into the computer data base is still ongoing. The fact that 75 percent of the data now is automated is a partial achievement, recognizing that data selection, data "clean-up" and entry is a time-consuming process that has been further slowed down by change of Directors of the DDA, the absence of an operational plan, problems with the WHO software, and lack of technical and computer support when it was most needed. A detailed review of the current situation is needed and RPM should help to prepare an operational plan.

OBSTACLES AND CONSTRAINTS IN MEETING OBJECTIVES

One of the major constraints of the RPM work was the lack of an assigned counterpart in the LMD. The leadership of LMD was not responsive to the substantial amount of work produced by RPM in 1995. The changing, and charged, political environment, the rigid administrative civil service system that does not give much leeway for bringing in new personnel, the lack of appreciation of the magnitude of problems, the political juggling of the MOH with powerful donors supplying drugs for the design and implementation of the Community Drug Program (CDP) were probably some of the reasons why the MOH did not immediately follow up on RPM's recommendations. Some of the RPM work produced in the LMD was therefore "put on ice." But as mentioned earlier, this work was not lost and was revitalized later and became an important, if indirect, input to the development of the Logistics Implementation Plan.

Another constraint was the lack of response to the RPM work carried out with UNICEF in 1995-96. RPM had hoped to play a major role in influencing the design and implementation of the CDP, having been invited by UNICEF in April 1995 to assist with this troubled program. The subsequent cost-sharing study, carried out under RPM leadership, was circulated to MOH, international organizations, and donors. But in the view of the RPM evaluation team, it appears that it was not really "planted" and brought up for in-depth discussion at the policy level. While it is clear that RPM did attempt to engage MOH and concerned donors in a policy dialog based on this study, in the view of the evaluation team these efforts were not successful. Thus the opportunity presented by this important study has not yet been realized.

A common constraint, particularly for the work carried out in DDA in drug registration and in the drug information centers is the lack of recognition by both RPM and counterparts for process support. That is, the need for more and longer "hands-on" support, analytical status reports, operational plans, and checklists developed in collaboration with the nationals. Both MSH and USP have annual work plans but these are, by design, of more general nature.

An obstacle, particularly in the development and use of the Nepal Drug Information data base and use of the USP DI database has been the absence of longer term technical and computer assistance.

VIEWS OF USAID MISSION STAFF AND LOCAL COUNTERPARTS

The USAID mission and others that the evaluation team met in Nepal had very positive comments regarding the work and the staff of the RPM Project.

In 1993 when RPM first visited Nepal together with the WHO team, the mission was then mainly involved with family planning and logistics, knew little of national drug policy development, drug management, promoting rational drug use, and the need for unbiased drug information. The mission felt that RPM's presence has provided a great educational process for the mission that had been extremely important to the country and to the USAID mission's strategic plan. It felt that a future role for RPM, more broadly, is "to come in and help countries to pose questions and solve problems" and that "RPM's great flexibility was most important" in doing so in Nepal.

The mission suggested that RPM market their technical and managerial expertise, and that they produce a leaflet on its activities which can include brief scenarios. It was felt that such a pamphlet would be useful for USAID missions and also for Washington.

The mission, as well as all others, felt strongly that more long-term presence of RPM is needed, particularly now in the start-up phase of the GTZ Project on the strengthening of drug management at district level.

Since 1993, the USAID mission in Nepal has provided RPM with a total of $724,000. This activity contributes to the mission's Strategic Objective 2 (SO2), "Reduction of Fertility and Improvement in Maternal Child Health" by developing systems to assure commodities essential to MCH programs can be handled appropriately from the central level to the district level. This level of funding is expected to continue, unless the mission's overall PHN budget is drastically reduced. This level of commitment is an indication of the value of the RPM

Project given the shift in the RPM Project from funding through core funds to a field-support mechanism.

JSI/FPLM, with whom RPM collaborates very closely in Nepal, was very complimentary and places high esteem on RPM's technical and managerial knowledge and skills in drug management and logistics. This was reiterated by GTZ, where in the absence of the Director who was on annual leave, the logistics management director however felt that some important policy issues regarding support to procurement at district level had to be sorted out.

All DINoN centers were very pleased with the support they had received under the RPM Project and said that the RPM Project had strengthened their own institutions and work.

DDA is still very much dependent on RPM technical and managerial support. They stated that they need more RPM presence in Nepal to help with the day-to-day (i.e., process work with the data base developments and procedures). They also said that due to RPM and the WHO software, the DDA has been able to slowly enter a modern drug regulatory environment.

UNICEF said that they need the technical and managerial expertise of the RPM Project and also recognized that they had failed in their initially too simplistic approach to the Community Drug Program. They had scaled down their activities and was now about to start work in a few districts and welcomed anew RPM's expertise.

A visit to the WHO, where the Representative was on annual leave, confirmed the need for renewed NDP discussions and activation of the National Drug Policy draft implementation plan, developed by the WHO/DAP/SEARO team in November 1995. RPM Project close involvement and team work in this was seen as most important.

Personnel at AIDSCAP, who had put RPM in contact with the NCDA, felt that the private sector and NCDA could play an important role in new strategies for promoting rational drug use and that RPM had an important role to play in this area.

CONCLUSIONS AND RECOMMENDATIONS

The RPM work in Nepal has contributed toward improved logistics management of drugs and other supplies. It may not have proceeded as quickly as RPM had foreseen or would have hoped. But this work is slowly starting to bear fruit at the central and district level, through the introduction of the Logistics Management

Implementation Plan developed by LMD, with JSI as lead and with RPM's technical and managerial input. Collaboration with GTZ in two districts is promising, but the scope of RPM support needs to be clarified and firmly set within the MOH policy framework. This will initially require RPM senior staff presence, followed by long-term presence of technical and managerial support of a person familiar with the Nepal environment and decentralization process.

The road to rational drug use is long. The RPM Project has taken important steps to assist in promoting such use, by assisting in the revision of standard treatment guidelines and in the dissemination of unbiased drug information. Five drug information centers have been established plus the Drug Information Network of Nepal, DINoN. This network requires assistance with general strategic plans and procedures. Further support has been given to the centers for publication of important drug bulletins for different target groups including consumers. Studies and operations research have been, and are being, conducted as a basis for developing strategies for training in rational drug use for providers and consumers; there is now a need to review and analyze these various studies for future strategies and activities.

The planned adaptation of the USP DI Plus database for Nepal is still not available; due partly to delays in the input to the drug registration data base and partly to unrealistic time schedules where the need for considerable process support and periodical status analysis was not recognized, or underestimated. The same applies to use of the computer and the USP DI Plus CD-Rom application.

Recommendations

Short-term:

- For the MOH, GTZ, JSI, and RPM implementation of the Strengthening Drug Management at District level (SDMD) it is recommended that RPM quickly places a competent person *in* Nepal to work as part of a team in this important project. In this context a visit by the RPM Director to Nepal is recommended, to discuss RPM district and other work as part of support to the country's policy framework and decentralization process.

- It is recommended that RPM provide support to mechanisms for effective procurement of drugs at the two GTZ supported districts.

- In order to provide needed process support, it is recommended that MSH and USP, jointly with DDA, analyze the status of the drug registration data

base (with WHO as required), prepare an operational plan for finalizing this data base, and prepare a second plan/checklist/procedures for application and use of the Nepal Drug Information data base. USP needs to do the same for the CD-Rom, plus plan for its evaluation in a year's time. An overall Nepal, possibly joint and standardized MSH/USP work plan should also be considered for ease in monitoring and evaluation of all RPM activities in Nepal.

- RPM is recommended to prepare a small pamphlet of its activities with possible scenarios, intended primarily for USAID missions and Washington, showing how RPM can assist in providing technical and managerial assistance.

- There is clearly a need for ongoing RPM, especially USP, support for the individual DINON members. For each of the members there needs to be increased focus in five areas: improving the organizational capacity to manage a DIC and disseminate drug information; improving computer competency; expanding the awareness and use of the DIC with a good marketing strategy and bringing in new constituents; using the information in the databases and reference materials to improve the quality of their own training/teaching/courses; and developing, testing, monitoring, and evaluating the effectiveness of their activities and materials. These areas were uniformally weak for all members, but improvement should be possible with targeted technical assistance.

- IMCI is being introduced by WHO into two pilot district in Nepal. RPM/MSH, should engage in a discussion with the MOH and USAID to see if there is a role for drug assessment etc in the introduction process. Wherever possible, RPM should look for ways to demonstrate the link between essential drugs and health outcomes. The software developed for the reproductive health costing activity could be very useful in guiding and monitoring IMCI implementation.

- RPM should support the creation of a multi-disciplinary research advisory or reference group to analyze and summarize past studies, surveys and operations research, and to give advice on future studies, particularly in cross-cutting programs where pharmaceuticals play a major role.

Long-term:

- It is recommended that RPM explore and develop different strategies with appropriate institutions for involving the private sector in different mechanisms for drug procurement at the district level, and for promoting the rational use of drug with the help of NCDA and consumer support groups like RECPHEC.

- It is recommended that apart from the current areas, long-term support should include support to educational and training curricula, development of hospital and district therapeutic committees, formularies, and drug utilization review research.

Annex C. Country Report — Russia

BACKGROUND: HEALTH SECTOR AND PHARMACEUTICALS

In the Soviet health system, drug procurement, production, and distribution were highly centralized. Complex arrangements were created between the Soviet and East Bloc countries, including bartering and the allocation of specific roles for different parties (production of raw materials, manufacturing of finished products, etc). The collapse of the Soviet Union left the health care system in a state of economic and managerial chaos. Initially, the collapse of the production and distribution led to severe shortages of drugs throughout the New Independent States. In 1990, the national Ministry of Health devolved the responsibility for financing and delivery of health care services to the oblast (local) level. Local health officials, who lacked managerial training and expertise, were suddenly responsible for fiscal management, purchasing, planning, and policy development. The opening of markets resulted in an influx of foreign drugs into an environment devoid of the information necessary to make drug selection decisions. Physicians found a new sense of freedom in being able to prescribe almost any drug they desired. Also, private pharmacies were unprepared for the challenges of self-management. These factors contributed to an unstable situation in the area of drug supply and management.

As the Russian economy evolved from a command-driven to a market-oriented system, the gross domestic product of the country plummeted. Consequently, funding for the health sector has been adversely affected along with other social programs. Prior to the collapse of the Soviet Union, approximately 6 percent of GDP was allocated to health services. Currently, less than 3 percent of GDP is spent on health. The lack of financing has left many facilities unable to pay for the three "protected" budget line items, including physician and staff salaries, food, and medicines.

The health sector is also encumbered by federal requirements to provide drugs free of charge to large "special" populations including pensioners, veterans, children, Chernobyl victims, and individuals with certain diseases such as AIDS or TB. Approximately 40 percent of the population receives some type of drug subsidy. While the government entitlements were perhaps well-intentioned

attempts by the political structures to preserve the social safety net, these federal mandates have not been funded by the central government. The financial burden of these entitlements has fallen upon the oblasts. Given the deterioration of the economies in most regions, the local governments and facilities are indebted to drug suppliers for provision of free pharmaceuticals to exempt populations or unable to provide the drugs.

- Drug Supply: Prior to the collapse of the Soviet Union, chronic drug shortages were common. Drug shortages continued post independence as former trade relations with East Bloc countries (i.e.,. drug manufacturers in these countries), broke down. As trade relations with other countries improved, and local manufacturing capacity has increased, drug availability has improved considerably. Currently, there are 10,000 drugs registered in Russia, with 60 to 70 percent of drugs imported and 30 to 40 percent manufactured domestically. The team found no evidence of chronic shortages in supply availability.

  Drug shortages still occur at the hospital level, however this is due to the lack of adequate financing for the health sector. Health facilities pharmaceutical budgets have declined dramatically, resulting in huge debts to pharmacies and suppliers. In addition to debt, there are some cases of shortages; frequently, hospital patients are forced to supply their own drugs out of pocket.

- Drug Information: For thirty years, the Russian Center for Pharmaceutical and Medical Technical Information (Pharmedinfo), has been the leading central source for drug information and has published and disseminated information to MOH centers across the former Soviet Union. The organization served as a central archive and reference library for information dissemination until the breakup of the republics.

  The RPM assessments in the three RPM oblasts all indicated that there was no source of continuously updated, unbiased, and accessible drug information. Administrators, physicians and pharmacists received the bulk of their knowledge from the single domestic text by Academician Mashkovsky, pharmaceutical sales representatives or unregulated company produced literature which may not contain vital information such as side effects, interactions, or relative costs.

- Drug Quality: The opening of the Russian market to foreign manufacturers, led to the importation of many unfamiliar drugs, some of low quality. Concern for product quality escalated justifiably and the

laboratories were not equipped to test all new drugs. Quality testing laboratories exist in each oblast. These labs perform analyses of drugs (samples) to determine whether the drugs shipped into the oblast meet quality standards. Approximately 30 percent of all imported drugs are tested for quality. If a product fails it is retested. If findings are validated the shipment is rejected. Rejects occur in 2–5 percent of tested products. The FDA has provided technical assistance to develop a memorandum of understanding with the MOH to streamline the registration and importation of U.S. pharmaceuticals and in good manufacturing processes with support from USAID.

- Procurement: Development of effective procurement mechanisms has been impaired by several factors. These include lack of health sector funding discussed previously; lack of appropriate and transparent procurement policies and procedures; lack of management capacity to conduct tenders at the local level; and lack of appropriate and necessary drug information. The lack of financing and history of nonpayment on the part of health facilities has led to inefficiencies in procurement. In some cases suppliers will not grant facilities credit, forcing the facilities to place smaller drug orders with more suppliers. In one example, the oblast hospital purchases drugs from 36 suppliers.

  As previously discussed, drug procurement was highly centralized. Rather than conducting competitive tenders, drug purchases were most often made through negotiations with drug distributors and manufacturers. Standard formulas were not utilized to determine drug needs and quantities, impeding rational procurement decisions. Finally, the lack of appropriate and necessary drug information has hampered drug procurement. Decision-makers often use information provided by pharmaceutical companies, which is brand specific and inappropriate for cost or quality comparisons.

ASSESSMENTS USED IN DESIGN OF PROGRAMS

One of the initial activities RPM undertook was an assessment of the pharmaceutical sector in the target oblasts. RPM involved Russian counterparts in each step of the process including the adaptation of standard indicators developed by MSH for worldwide use, the development of a data collection instrument, and data collection and analysis. The assessment served to provide information about the public sector drug supply system, finance, procurement,

quality and distribution; private sector pharmacy network; drug control legislation; drug selection and utilization; and disease patterns in the oblasts. Counterparts also made substantial contributions to final assessment reports, and helped decide on work plans for each RPM technical area.

The findings of the assessment pointed to several key areas in need of urgent attention, and common across the three oblasts.

- Systems did not exist at the health administration or facility levels for rationally selecting drugs for procurement and use. Moreover, cost-effectiveness was not generally considered when selecting drugs.

- The availability of funds for drug procurement was extremely limited.

- An increase in drug suppliers in the oblasts had led to increased availability of therapeutic alternatives and drug products, many of them previously unknown to practitioners. Unbiased drug information about many of these products was not available.

- Ongoing systematic activities for reviewing drug prescribing and use for in- and out-patients did not exist.

- In the area of procurement, there was a lack of appropriate and transparent policies and procedures, a lack of management capacity to conduct tenders at the local level, and standard formulas were not being used to determine drug needs and quantities.

- Financial and legal (tax) structures contributed to financial difficulties of community pharmacies.

- Community pharmacy managers often lacked the managerial skills necessary to survive in a competitive business environment.

- Some Standard Treatment Guidelines (STGs) were in effect in public health facilities, but they did not adequately address drug use. Explicit recommendations for drug therapy were rarely included in STGs.

- Prescribing was reported as excessive for patients eligible to receive drugs free of charge or at reduced prices.

- There was a shortage of professionals with the clinical pharmacology training needed to rationally select drugs.

The assessments accomplished two important outcomes. The first was the systematic collection and analysis of baseline data heretofore never carried out in these oblasts previously. This empirically-derived data enabled Russian counterparts to understand the problems and issues of pharmaceutical management. The second was to create stakeholders and generate consensus-building among Russian counterparts as to priorities and interventions needed to improve the pharmaceutical sector.

ASSISTANCE STRATEGIES

RPM conducted two initial visits to Russia to establish relationships with the Ministry of Health and the mission, establish criteria for selection of the pilot site, and select a Russian collaborating organization. On the recommendation of the Ministry of Health, Pharmedinfo was selected as the chief technical partner for drug information, and to provide logistical and limited technical support to MSH. During the second visit, in January 1994, Ryazan Oblast was selected as the chief pilot site. Ryazan, located south of Moscow, has a population of 1.3 million, with 600,000 in the city. There are 137 health facilities (22 in city). Novgorod and Pskov Oblasts, both located in the northwestern region of Russia, were selected as roll-out sites in April 1995. Novgorod has an oblast population of 742,000 with 260,000 in the city. There are 121 health facilities, including 21 in Novgorod. Pskov Oblast has a population of 839,500, with 300,000 in the city. Pskov has 100 health facilities oblast wide.

In accordance with the findings put forth by the assessments and the consensus arrived among Russian counterparts, RPM proposed that primary attention be given to the following pharmaceutical assistance:

- to improve the allocation, management, and use of resources, including the selection, procurement, distribution and management of pharmaceuticals

- to promote the rational use of drugs, including rational prescribing and drug utilization review.

These major areas would be addressed through the following activities:

- formulary development/product selection

- procurement and tender management
- community pharmacy management
- rational drug use
- drug use review
- drug information development.

Assistance in these technical areas was carried out through policy options workshops, training, study tours, on-site short-term technical assistance, tools development, and collaboration and dissemination.

Formulary Development/Product Selection

In the three oblasts, 59 facilities have developed and implemented formularies. Formulary committees were established in each hospital and meet regularly. One of their functions is to periodically review and revise the formularies. All three oblasts plan to require that all hospitals develop and implement formularies by the end of the year. Two oblasts, Novgorod and Pskov have created an oblast-level formulary based on the work done at the hospital level. The Ryazan Oblast Hospital, the recipient of the most hands-on assistance from RPM, has developed a formulary manual that includes basic drug monographs for each drug on the list. The manual for the Novgorod Oblast Formulary is currently under development, with the support of Pharmedinfo. In Ryazan and St. Petersburg, lectures on formulary development and drug selection have been incorporated into medical, nursing, management, and pharmacy curricula and into continuing education programs for existing providers. The Manual for Development and Maintenance of Hospital Formularies was developed as part of the Russia project. It has been adapted for use in other RPM countries. A formulary software program, Formulary-R, was also developed as part of the RPM-Russia project to support implementation efforts.

Procurement/Tender Management

All three oblasts have established drug tender committees and have conducted "trial" competitive procurements with training and technical assistance from RPM. Training has been supported by the adaptation and translation of MSH

pharmaceutical management training materials, including the Managing the Drug Supply training series. The INVEC-2 software package was adapted and translated into Russian, but has not been installed because during the implementation process the oblast underwent severe financial and legal difficulties. Additionally, Pharmacia became a private company, resulting in decreased interest in this activity by oblast public health officials.

Community Pharmacy Management

Directors of community-based pharmacies in the three oblasts participated in advanced training and a U.S. study tour to improve financial, management, and networking skills. RPM supported the development of individual business plans and produced a how-to manual for the community pharmacies.

Rational Drug Use

RPM promoted rational drug use through training in clinical pharmacology, technical assistance, and the adaptation and translation into Russian of the WHO's Guide to Good Prescribing. RPM and WHO collaboratively held an NIS-wide workshop to integrate rational drug use concepts into undergraduate medical school curricula.

Drug Utilization Review

All three oblasts have received training and technical assistance in DUR. The Prescribing Analysis Software System (PASS) which analyzes physician prescribing practices was adapted and used to analyze drug use in two facilities as a way of introducing the DUR process. Most facilities in Ryazan, Novgorod, and Pskov have conducted at least a trial DUR.

Drug Information

The RPM/US Pharmacopeia drug information assistance strategy had multiple targets—the first was to strengthen capacity of the counterpart drug information agency, Pharmedinfo. USP also concluded a separate agreement with Pharmedinfo to adapt and translate the USP Drug Information manuals into Russian, which will be a major resource for Russian health professionals. Pharmedinfo is instrumental in sponsoring the annual Man and Drugs conference, the chief forum for dissemination of drug information and activities throughout

Russia and the NIS. Pharmedinfo also serves as a coordinator for regional drug information efforts and is leading the development of the All-Russia Drug Information Network.

Secondly, RPM/USP's provided assistance to develop oblast-level drug information centers. The drug information centers were to serve a variety of purposes and functions. The DI centers were involved in varied tasks including formulary management, drug use review, provision of drug information to health care practitioners and the public, publications of hospital newsletters for the medical staff, and education of physicians and pharmacists — both current students and as continuing postgraduate education. As of the team's visit, nine centers had been established, two in Ryazan oblast, two in Novgorod, two in Pskov, two in Moscow (including Pharmedinfo), and one in St. Petersburg. Most centers visited had only recently begun operation and outreach; the two DICs in Ryazan oblast were the oldest.

Thirdly, RPM/USP and Pharmedinfo are supporting the development of an All-Russia Drug Information Network, based at five electronic university or hospital "hubs" — St. Petersburg, Moscow, Tomsk, Vladivostok, Ekaterinburg. A site in southern Russia may be included in the future. In addition to dissemination of drug information, the Network could disseminate RPM technical information on formulary development, DUR, community pharmacy management, rational prescribing and Russian literature to a nationwide network. As of June 1997, the Tomsk, Saint Petersburg, and Moscow sites had been set us and two others have been confirmed.

ASSISTANCE STRATEGIES USED

The RPM used specific implementation strategies, which contributed to the success of the program.

Oblast Level Focus

RPM, USAID/Washington, and USAID/Moscow decided to concentrate the bulk of its resources and efforts at the oblast level. USAID had several reasons for wanting RPM to focus on the oblast level, including (1) the desire to empower and encourage policy and decision-making at the grassroots level; (2) the absence of a clear-cut policy from the national level; (3) responding to the federal mandate to decentralize decision-making and financing of social sector activities to the oblast-level; and (4) the receptivity of the oblast level to supporting new

and innovations. Many professionals had been active in health reform prior to the RPM Project and were very receptive to participating in the project.

Site Selection

RPM sought a demonstration site and rollout oblasts that could serve to assist the development of RPM concepts throughout Russia. Sites were selected based on proximity to Moscow, the willingness of the political powers to support the program, and the willingness and ability of the key personnel who were to be involved to work with this project. The presence of both Medical and Pharmacy Schools was an important factor in selecting Ryazan Oblast as the pilot site. Due to the long history of Moscow domination (and, presumably, resentment on the part of rural Russia) it was felt best to develop sites outside of Moscow for the project. RPM also sought sites which were within reasonable travel distance to facilitate support from the Moscow-based personnel and expatriate staff. The selection of sites for the project was well done. Clearly, the individuals with whom the project has worked are competent and dedicated. The individuals with whom the team interacted were not only successful in their adaptation of knowledge gained to their practice site but willing to share information so that others may benefit from the lessons learned of these representative oblasts.

Roll-Out at Local Level

Although the initial agreement called for RPM to roll out the activities to up to five additional sites, this was subsequently cut back to two sites, given the need to target limited resources and the Mission's desire to deepen reform in existing oblasts and emphasize dissemination efforts. However, the RPM Project reaped unanticipated benefits from dissemination of the project information at all-Russia conferences and from networking among Russian collaborators, and aspects of the RPM Project have been rolled out to several sites which did not directly benefit from RPM technical assistance, both within demonstration oblasts and in St. Petersburg.

Health authorities from many other Russian oblasts have started formulary development on their own after attending an RPM seminar, receiving written information, or attending the annual "Man and Drugs Conference." According to MSH, formulary development is proceeding in Arkhangelsk, Altai, Urals– Cheliabinsk and Ekaterinburg; Siberia– Chita, Krasnoyarsk, Novosibirsk; Volgograd, Tver, Yaroslavl, and Voronezh. The Ryazan State Medical University's active networking and continuing education courses (available to a wide range of oblasts) have also disseminated drug management and rational use

concepts throughout Russia. In addition to the ones described above, the RSMU has disseminated information to Khabarovsk, Saratov, Kurgan, Magnitogorsk. RPM dissemination has extended interest in drug management and information beyond Russia. In August, 1997, the director of the Moldova Pharmacia Institute, who attended an RPM-WHO workshop, hosted a conference on improving the rational use of drugs in Moldova. Over 40 participants supported the "ground-up" implementation of hospital formulary systems.

"Bottom-Up" Policy Change

According to the cooperative agreement and input from USAID/Moscow, the RPM Project was to concentrate first on one site (Ryazan) as a "local laboratory" to develop a set of tools and informational products which then could be used to roll out to up to five additional oblasts. It was anticipated that the concrete results from local pilot sites could then be generalized to promote policy dialogue on issues of rational drug use, selection, and management at the national level. The local pilots would be "models" which the Ministry could observe and incorporate into national-level policy. Given the higher-risk strategy to focus on a few sites, the choice of the sites became critical.

Consensus-Building Activities

The project conducted policy options workshops in each of its three oblasts which were attended by many project participants, by way of introducing the concepts and possible approaches to rational drug use, selection, and management. Ryazan specialists were heavily utilized as presenters and advocates at the workshops conducted for Novgorod and Pskov. Counterparts stated that the non-prescriptive presentation of the subject and the inclusion of approaches not only from the U.S. but other European countries as well contributed to the credibility of the project and reduced suspicions that the U.S. project was promoting an exclusively "American" agenda. The assessments (described above) were also successful at gaining widespread support from Russian counterparts.

Flexible Strategy for an Evolving Health Care System

The RPM strategy was designed to be flexible to respond the realities of limited financing and to the evolving nature of the health sector. The incremental and adaptive approach was able to demonstrate immediate and concrete gains in efficiency and effectiveness and helped to cement counterpart support. For example, RPM helped counterparts to implement rationally derived limited lists of

drugs as a way of maximizing the benefit from limited funds, while improving therapy at the same time. Once formularies were established, the project also ensures that the drugs chosen for formularies are being used properly through the ongoing programs for monitoring and evaluation (DUR) of the use of the most critical, expensive drugs, against pre-established criteria. Concomitantly, the project is focussing on rational prescribing, while introducing elements of pharmacoeconomics to the formulary development process. This process helped to link into a continuous "triumvirate" the processes of formularies, DUR, and rational prescribing.

Beginning one hospital at a time, the project also helped to harmonize and standardize the formularies being developed in order to create an oblast-level drug formulary. The involvement of tender committees in formulary development spurred planning for eventual pooled procurement activities. Counterparts were able to conceptualize the positive benefits of lower drug prices and improving access to drugs by conducting large tender purchases of formulary drugs for participating hospitals. By emphasizing the process of formulary development at each facility, RPM has managed to create a critical mass of supporters for formulary systems; develop the technical cadres required for the more sophisticated work of DUR; build stakeholders for a standardized oblast formulary which each hospital was involved in formulating; and to establish the foundation for pooled procurement activities. This also demonstrates the success of the decentralized approached adopted by RPM.

Use of U.S. Study Tours

RPM conducted U.S. study tours for a wide variety of Russian collaborators on health insurance, pharmaceutical policy, community pharmacy management, drug information, and drug use review and management. The team found that the tours had been judiciously apportioned throughout RPM collaborators in each oblast and a representative of almost every RPM counterpart facility participated in a study tour. As other USAID projects have demonstrated, properly targeted study tours to the U.S. and elsewhere can accelerate learning and motivation to pursue reforms. The team found that Russian collaborators viewed their exposure to U.S. systems as very helpful to understanding how pharmaceutical management is used and how to adapt relevant components to their own practice. Clearly, significant good will and positive outcomes were fostered through this investment.

Networking and Information Exchange

The RPM Project encouraged Russian collaborators to use all available fora in which to present and disseminate the results from the oblasts. RPM collaborators regularly made presentations at the "Man and Drugs" conference, which is the annual Pharmedinfo-sponsored national forum for drug issues with NIS-wide attendance. RPM built upon preexisting connections to initiate and facilitate dialogue among an increasingly growing network of parties. For instance, RPM and Pharmedinfo cultivated high-ranking academicians who were well-known throughout Russia, to support work in drug monograph development. Large academic institutions (Moscow Medical Academy, St. Petersburg Medical Academy) were cultivated and engaged in curricula development for rational drug management and use. The Russian Federation's state medical university system of fourteen major institutions (including Moscow and St. Petersburg) will be discussing incorporation of a series of courses in drug management and use.

In addition, RPM supported contact between RPM-participant oblasts. Many RPM seminars deliberately included participants from all three pilot sites. RPM counterparts from Novgorod, Pskov and St. Petersburg have visited Ryazan and mentioned exposure to Ryazan activities as one of the most valuable services provided by the project, second only to the training. Novgorod and Pskov had consulted each other on legislation development. Novgorod and Pskov Veteran's Hospital Chief Physicians have consulted on developing formulary lists for their elderly populations. St. Petersburg Department of Pharmacy is working with Ryazan to develop a model rural hospital formulary to be used in the northwestern region.

THE APPROPRIATENESS OF THESE STRATEGIES

The greatest testimonial to the appropriateness of the strategies employed by RPM Russia is found in the resulting success of the program as detailed in this report. The team found striking appreciation for the program and genuine enthusiasm for the improvements which have been achieved through utilizing the tools and expertise which RPM provided the local counterparts.

Nature and Quality of Tools Used

Reference material for procurement, tendering, and inventory management are contained in the comprehensive publication, *Managing Drug Supply,* 2nd ed., which was produced by RPM contractor Management Sciences for Health in

collaboration with the World Health Organization. This reference is of high quality and was seen during the site visits.

The formulary development and drug use review reference manuals appear useful and user friendly. These materials had been utilized in Russia in the demonstration sites and in rollout facilities. The manuals have been widely distributed in Russia and the NIS via workshops, seminars, conferences, and mailings. The rollout facilities using the materials included hospitals in rural areas which were affiliated with the demonstration hospitals. The materials were also used, along with information presented at the Man and Drugs conference by St. Petersburg Medical University to develop a formulary and drug use review program. The fact that the St. Petersburg effort was done without direct hands-on assistance of MSH is indicative of the quality of the reference materials.

Assessment of the INVEC-2 program showed it to be sufficiently logical and comprehensive to facilitate tracking of inventory and utilization. As mentioned previously in the report, INVEC-2 is not in use in Russia.

Tools developed and used for formulary development included a manual for formulary development (translated into Russian) and seminars. Tools used for the Drug Use Review portion included seminars and a DUR manual translated into Russia. All facilities questioned indicated they had performed an ABC-VEN analysis in beginning the formulary development process, demonstrating that counterparts are following the procedures outlined in the formulary development manual. This exercise, in which each drug used at a facility is given a designation of either "Vital," "Essential," or "Non-Essential," and then ranked by value, is explained in the formulary development manual. It is a valuable tool for understanding how drug funds are being spent.

Drug information

There is a high demand among Russian health professionals for updated and appropriate information and an sincere interest to adapt what is useful to improve the health sector. RPM has addressed the information deficit through the creation of drug information centers and production, adaptation, and dissemination of technical assistance tools. The drug information centers (DICs) will test the effectiveness of a variety of models. This "experimentalism" enabled the project to adapt to the cultural and environmental needs and to support the needs for drug information voiced by counterparts.

Several DIC facilities were visited. Facilities visited were stand alone (not within a library), with adequate space to perform basic drug information services. All facilities visited had the two volumes of USPDI which have been published to

date. The Russian translation of the Merck Manual, a high quality unbiased therapeutics text published by the Merck Company, had been distributed to Man and Drugs Conference participants and was present in the DI Centers visited. The DI Centers were each equipped with modern U.S. manufactured computers and printers. Also present were other leading English language publications including Meyler's Side Effects of Drugs, Goodman and Gilman (pharmacology text), and American Hospital Formulary Service which is a comprehensive drug information text. The usefulness of the English language publications was a concern as few of the individuals in the center were conversant in English. When asked, the DI personnel indicated they were able to understand the material with their own limited knowledge of English and the use of dictionaries or, as needed, the assistance of English-speaking colleagues.

RESULTS FROM THESE STRATEGIES

RPM Project assistance, and how it was provided, had a profound impact on the management culture and the broader decision-making process within facilities and oblasts. While these changes do not directly impact on the technical areas addressed, they are critical to the sustainability of RPM activities in the target oblasts and to the replication of the technical activities to other parts of Russia. The following impacts were reported by RPM counterparts.

A significant result was to alter mindsets of decision makers regarding drug use, selection, and management. The RPM tools enabled counterparts to analyze (for the first time) physician prescribing patterns and to consider what drugs were actually being used and to critically evaluate drug use with reference to objective information about efficacy. The ABC/VEN analyses performed with RPM assistance helped the Russian collaborators to critically assess drugs being used. This led to procedural and policy changes for drug selection and use. For instance, in Ryazan, the process of developing the formulary was key to counterpart's awareness of how examining comparative cost effectiveness of drugs may improve decision-making about procurement.

Impact of the project was also noted in the acceptance of a broader based approach to assessing information and making decisions. The RPM training helped Russian collaborators to enhance decision making in drug management, enlisting all participants (physicians, suppliers, pharmacies) in the process. All three oblasts had engaged cross-sectoral teams to work on critical health issues, including pharmaceutical sector management. In Ryazan, major health facilities and learning institutions worked in a highly collaborative and coordinated fashion to implement RPM activities. In Novgorod, all major players in the health sector

(including the Oblast Health care Administration, Territorial Health Insurance Fund, ASCO, Pharmacia, health facilities, etc.) were engaged in drug management activities.

RPM assistance was designed to foster collaboration between all three pilot sites and to encourage maximum dissemination of preliminary results to other non-RPM sites through national and regional conferences and through existing continuing education mechanisms for providers. Cooperation between sites has occurred. Novgorod and Pskov benefitted from experiences gained and shared by Ryazan. As for dissemination to non-RPM sites, this has been accomplished through the (national) Man and Drugs Conference and through regional seminars. Dissemination has also been achieved through collaboration with other projects, such as the USAID-funded Zdrav Reform and AIHA Hospital Partnerships Projects, and the WHO Pharmaceutical Project in Russia. It was through these mechanisms that St. Petersburg became active in formulary and DUR activities. Chief physicians from Novgorod and Pskov Veteran's Hospitals presented their drug management projects at a recent conference on Health for the Elderly which was sponsored by UNICEF and the European Union which included delegates from many other regions in Russia. These presentations helped to disseminate RPM information and there was great interest in the activities from other oblasts.

PROJECT IMPACTS

While the RPM Project in Russia has only been in operation for less than three years and empirical data are not yet available for a comparative "before" and "after" analysis, the project has a wealth of directly observable and anecdotally reportable intermediate results and accomplishments. The project has achieved results not only in its technical activities but also in influencing decision-making, capabilities, and mindsets of RPM participants.

Skills acquired in formulary development and DUR have strengthened the capacity of the oblast health officials in the areas of pharmaceutical management and rational drug use in Ryazan, Novgorod and Pskov. Hospital formulary committees are functioning in all three oblasts (a total of 59 hospitals have developed formularies), and oblast formularies have been developed in Novgorod and Pskov). In addition to formulary development, both Novgorod and Pskov have passed laws that integrate formulary development and DUR into oblast health policy. DUR activities have also been initiated, and the findings of DUR have resulted in follow-up physician inservices to improve prescribing practices. The implementation of formulary development has resulted in the removal of

costly, unsafe, and ineffective drug products. DUR and improved prescribing practices have contributed to improved patient care and treatment outcomes.

The project has also created ten DICs, three of which (Pharmedinfo, St. Petersburg Medical Academy and Tomsk Cardiology Institute) will be hubs for the All-Russia Drug Information Network. These centers have been equipped with modern computer technology and updated drug information in text and electronic media. Most DICs have begun to serve their target populations. RPM has disseminated project information through conferences, requests, and other USAID-funded project dissemination efforts. Two volumes of the USPDI, with expanded and adapted monographs in cardiology and psychotropic drugs, have been published. Three DICs have begun development of drug management, rational prescribing and clinical pharmacology curricula for medical and pharmacy students. The DICs have already demonstrated several unanticipated benefits, including one of these was the coordinated education model in Ryazan State Medical University, the private sector approach of the DIC managed by ASCO the health insurance company that will focus on patient education, and the dual foci of hospital-based DICs, which participate in competitive tendering, formulary development and DUR.

In its less than three years of operation, the project has produced impressive results in formulary development, and the development and dissemination of unbiased drug information. Russian colleagues strongly support the RPM approaches and have incorporated them into significant legislative, policy, and curricula reforms.

Improving Allocation, Management and Use of Resources (e.g., Selection, Procurement, Distribution, and Management)

Procurement Assistance

The project was to improve efficiency of procurement through tendering. This activity is just getting underway. Training has been provided but most facilities and oblasts have not fully implemented tendering to reduce their costs. However, counterparts from all three oblasts pointed to the significant savings gained from pilot tenders conducted recently. For example, Ryazan counterparts stated that a tender for insulin had been conducted in Ryazan with a savings of $585,000.

In 1996, the Pskov Oblast Health Care Administration conducted a "trial" competitive tender for cardiovascular drugs, antibiotics, and antispasmodics for oblast health facilities, and achieved a savings of approximately 10 percent. The Governor of the Oblast has issued a decree mandating competitive procurement for drugs and medical supplies.

In 1997, Novgorod oblast issued tenders for insulin, antituberculosis drugs, oncologics, and anesthetics. They reported savings of 20 percent (anesthetics) to 50 percent (TB drugs) in acquisition prices with net savings of $200,000 as a result of the tender. Plans are underway to develop a more comprehensive tender.

Reasons that the practice of tendering had not developed further include the financial situation (don't have money to pay for drugs), the dependence of some hospitals on the pharmacies to whom they are indebted (financially and ethically), and what seems to be a hesitancy on the part of the hospital and oblast officials to perform the function. Technical assistance has been provided in the form of a manual (a chapter in Managing Drug Supply) and a seminar. This is an area where follow up training is needed in either the "simulated" tender as was specifically mentioned in Pskov or by actually walking prospective purchasing agents through the process.

Administrative Structure/Legislation

A significant, though unanticipated benefit to the project, has been the adoption of legislation and implementing documents (decrees and orders) which codify RPM activities in the oblasts. Without legal support to foster the concepts being developed and to restrict activities which run counter to the program, the sustainability of efforts such as RPM will be impaired. Additionally, the fact that each oblast has formalized RPM activities in formal decrees and Memoranda of Understanding exemplifies the strong support which the activities have generated from Russian counterparts and their institutions.

An excellent model of legislative reform exists 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," and competitive procurement is codified in the Oblast Decree "On State Guarantees on Drug and Medical Supplies Procurement." Generic substitution is mandated and the sale of antibiotics without a prescription is prohibited. Alliances have been formed with the tax police, tax inspection unit, police agencies, and "counter-intelligence" to exert control over licensing and the business practices of health care providers.

Novgorod has taken a centralized approach to RPM. An oblast formulary was developed and hospitals are required to work within the oblast formulary. Enforcement of the formulary is made through restricting payment for the exempt prescriptions (paid for by oblast and adjudicated through ASCO) to formulary items only.

In Pskov, RPM drug management activities and annual workplans have been formalized through decrees signed by the Head of the Oblast Health Care Administration. Formulary drugs are codified in the newly-developed standard treatment guidelines by the oblast health care administration.

Promoting the Rational Use of Drugs

Formulary development and management

This is an area of strong achievement. Given that the project has been working less than three years, the production of a formulary manual in Ryazan Oblast Hospital, formulary lists in many other hospitals throughout the oblasts and even an oblast formulary in Novgorod speak well for the efforts of MSH and their Russian shareholders. The processes established in the facilities appear sound, as exemplified by the multi-departmental representation on formulary committees. Membership of the formulary committee included the section chiefs as well as the director of pharmacy (where one existed), and in Ryazan, a representative from the DIC. A process exists to allow for the use of non-formulary drugs when necessary. Approval is required by the section chief and head or deputy head physician and is based upon assessment of individual cases. Such instances are reportedly reviewed by the formulary committee at a later date.

A very positive finding in the hospitals visited was in the reduction in the overall number of antibiotics used (one third to one half were removed from use) and in particular the changes in which antibiotics are prescribed. Questions regarding the antibiotic use patterns revealed the use of older, generically available, and cost effective drugs such as doxycycline, gentamicin, co-trimoxazole, and ampicillin. It was noteworthy that prior to the project, streptomycin, tetracycline, and a combination of ampicillin with oxacillin were the most commonly used.

With RPM assistance, antibiotic selection and use has improved. The influence was also evident with surgical prophylaxis. The most commonly used antibiotic for surgical prophylaxis was cefazolin, which is the drug of choice for this indication in the U.S. and other western countries. However, in two of the facilities visited, the most used drug for post-surgical antimicrobial prophylaxis was cefotaxime. Cefotaxime is a very effective drug, but contemporary practice would dictate reserving cefotaxime for treating serious infection (not prophylaxis) in order to maintain the antimicrobial sensitivities of cefotaxime and other related compounds. The move to more standard drug selection will be enhanced with DUR activities and drug information.

Several hospitals reported early impacts as a result of RPM management tools. Decreased length of stay (LOS) was reported for hospital admissions due to

pneumonia. In one hospital the LOS decreased from 18 to 12 days. This could be attributable to using more efficacious antibiotics, could be fostered by cost constraints, or purely circumstantial. However, the hospital staff attributed the improvement to better selection and use of pharmaceuticals.

The Novgorod Veteran's hospital has already seen a positive impact of the formulary and reported that combatting polypharmacy was relatively easy once physicians were trained and given information about drug interactions, which did not exist before. The Deputy Head Physician calculated that the formulary has saved them approximately 10,000 to 20,000 rubles per prescription. In the past two-three months, the staff estimates a hospital-wide cost-savings of 2-3 percent on drugs. Also, they attribute decrease in average length of stay (June-December 1996: 21.4 days, and January-June 1997: 19.4) directly to more appropriate use of more effective drugs.

The Pskov oblast formulary will be used as the basis for pooled drug procurement in the future. Formularies have been introduced in eight key pilot facilities and by 12/97, OHCA estimated that all health care facilities would be operating under a formulary. With RPM technical assistance, the Oblast Clinical Hospital formulary committee has managed to reduce the number of drugs commonly prescribed from 1,500 at the beginning of the exercise to 482.

The number of drugs maintained on the formulary and in use at the hospitals has been reduced. It was reported that the proportion of non-essential (per VEN analysis) drugs also had been reduced. This is beneficial due to the deletion of inferior drug products, increased cost-effectiveness, and improved efficiency in inventory management.

A need for follow up exists to make certain the formulary process continues following the publication of the formulary manual or list. However, counterparts have stated the need to continually revise the formulary with time and experience. DUR results should be incorporated into the formulary assessment process.

It is unclear how formularies will be managed at hospitals which have no in-house pharmacies. At Scopin Central Rayon hospital, the contract retail pharmacist indicated the pharmacy would provide any drug ordered. This would indicate that formulary management is not being conducted prospectively and is a problem which needs to be addressed. The contract pharmacies need to be brought into the process to effectively manage the formularies which have been developed. This could be done through contracting whereby (as with U.S. HMO provider pharmacies) hospitals pay the pharmacy based upon what is on the formulary and pharmacy be financially responsible for any non-formulary drugs dispensed.

Retail pharmacies will operate with a formulary system for prescriptions filled for exempt patients. Centralized reimbursement mechanisms are in various stages of development whereby edits for eligibility of patient and drug can be performed before payment is made.

Drug Utilization Review

The tools and techniques of drug utilization review, a new concept for Russia, was introduced by RPM early in the project. The first formal seminar in DUR was conducted in September, 1996 in Ryazan. A few studies have been done on particular drugs (gentamicin, theophylline, cazar (antidepressant), enalapril, and others) and one review by medical diagnosis (asthma). Results have (predictably) shown deficiencies in drug prescribing and use although this information was difficult to obtain from the facility staff.

The process of DUR is understood by the Russian stakeholders. Most DUR activities are conducted under the auspices of the formulary committee. The MSH-developed DUR manual, and drug information provided by U.S.P. are being utilized in developing the methods and criteria for the institutions conducting DUR. Members of the DUR committee articulated the process of criteria development, data collection and analysis, problem identification, intervention design and implementation, dissemination of information (to individual prescribers and through "newsletters"), and reevaluation.

In some instances there existed knowledge of the process but a hesitancy to commence activities. This was reportedly due to lack of personnel, lack of a computer, and lack of sufficient purchase history (stated need for 2-3 years' history). In one instance, DUR was ongoing but no report had been formalized because counterparts felt since reports are done as percentages, they must have 100 cases. While this makes for an unnecessarily long process, interim reviews had been conducted with feedback to the prescribers. This indicated the process is working but some misinterpretation has occurred in how to conduct and report findings of DUR.

Some of the reasons given for not starting DUR activities in certain settings was more a function of lack of confidence and the need to be jump-started in conducting an analysis. However, the task of conducting a DUR, finding faults in one's processes, identifying deficiencies in a physician's prescribing (and inevitably confronting the physician) is an imposing task and one that for many Americans (and Russians) can be put off.

Efforts are needed to further educate the facilities' staffs on the process and stimulate action. This will be facilitated by disclosure of the results of those studies conducted along with improvements documented in the follow up.

Community pharmacy program

Assistance was provided to community pharmacy owners in the form of seminars on developing business plans and with general material on pharmacy management. Several community pharmacists participated in a U.S. study tours to Michigan. The investment in pharmacies was well placed, as community pharmacists play a key role in drug use management in the outpatient setting and in many instances provide pharmaceuticals for hospital inpatients. The need to improve financial and management capacity for community pharmacies is critical, especially as many were on the brink of bankruptcy from unpaid orders. The retail pharmacists visited by the team attributed their financial survival to the technical assistance in business planning and financial management received through RPM. Based on the assistance provided, pharmacies have made significant and rapid structural modifications, by reducing in-house production and expanding more profitable retail sales. In addition, pharmacists adapted lessons learned from the visits to U.S. pharmacists associations and have expanded local association activities.

Improving Level of Drug Information

The successes attained in the demonstration sites have been facilitated by the drug information component provided through RPM/USP. As the facilities become more sophisticated in drug use management, the DICs will play an increasingly important role in the management of pharmaceutical use.

Oblast activities

The DICs are involved in varied tasks including formulary management, drug use review, provision of drug information to health care practitioners and the public, publications of hospital newsletters for the medical staff, and education of physicians and pharmacists - both current students and as continuing post-graduate education.

The DICs are strategically located to test the applicability and potential of different approaches and target populations for drug information. Three DICs (Ryazan, Moscow, St. Petersburg) were located in the departments of

pharmacology within leading medical universities and developed drug management curricula for undergraduates and continuing education for providers.

A major accomplishment of the Ryazan State Medical University DIC has been the introduction of drug management and rational prescribing issues into the curricula of the pharmacy, medical, dentistry, nursing, and health management schools. The Ryazan SMU DIC has coopted the majority of faculty members of the medical and pharmacy faculties and in 1996 developed an Inter-institutional Pharmacy Training program, in which all faculties participate. While individual faculties do not cross-train students, the DIC is considering approaching training "health care teams" of future physicians, nurses, pharmacists built around rational prescribing and drug management. Ryazan SMU DIC has also adapted courses to teach locally through professional associations and to many oblasts in Russia through continuing medical education. Members of the Ryazan SMU DIC and Oblast Clinical Hospital DIC closely coordinate activities. Representatives from both institutions participate in formulary development, DUR, and preparation for tenders.

The St. Petersburg DIC located at the Department of Pharmacology in St. Petersburg Medical University, targets physicians in training for the city of St. Petersburg. The DIC's website will incorporate RPM and other relevant pharmaceutical materials available to anyone with internet access. They eventually plan to serve as a central DIC for physicians practicing in the northwest region. The staff at the Department of Pharmacology developed a formulary list, using RPM tools, but without direct RPM assistance and have co-taught clinical pharmacology courses for RPM counterparts.

Four DICs were located within major oblast-level facilities (Ryazan, Pskov, Novgorod) and provided drug information to health care providers, some in-person, by telephone, and drug management newsletters. Many centers were heavily utilized by the public via telephone. These centers were dual function and also assisted in RPM formulary development, DUR, and tendering. In Novgorod, a DIC is managed by ASCO, the health insurance company, and will target patients with special education programs. The ASCO DIC is located in a large, inter-facility pharmacy which also serves patients. The DIC will provide medication and disease management counseling at time of service.

The Novgorod Oblast Clinical Hospital DIC is a good example of the dual purposes of the hospital DICs created under RPM. The DIC provides drug information to physicians and will eventually serve as the oblast-wide reference facility for physicians and pharmacists. Their initial outreach conducted through newspapers, TV, radio, and direct mail campaigns through the oblast was disappointing primarily because of poor communication infrastructure in the rural areas and calls to date have been few. However, the oblast is mailing printed

materials, including a drug management newsletter they produce and mail them directly to the rayon hospitals. They are considering asking interested physicians to contribute minimal costs for subscriptions. The DIC is actively involved in formulary development, hospital DUR (the hospital has conducted studies on antibiotic use), and provision of information for oblast competitive procurements.

Pharmedinfo

Pharmedinfo, a commercial organization which receives no financial support from the government, appears crucial to the effort to promote drug information in Russia. Pharmedinfo is well connected politically and has a number of leading Russian physicians in its employ or serving as consultants. Pharmedinfo maintains a registry of manufacturers and a comprehensive file of drugs marketed in Russia. The Director, Ms. Galina Shashkova, indicated that USP has been excellent to work with and has been flexible in adapting the database to the Russian health care culture.

A concern with Pharmedinfo is the seemingly long time required to complete the translation and adaptation of the USP DI to Russian. Adaptation and translation of the USP DI is funded under a separate agreement concluded USP and Pharmedinfo, not under RPM. To date, two volumes of monographs on cardiology and psychotropic drugs, have been completed. Ms. Shashkova indicated this would be completed by the end of the year (1997). The delays in translation of the USPDI does complicate the smooth operation of the centers at a most critical time as they strive to establish credibility and gain support for their activities. Once the USPDI has been completed, Pharmedinfo will have a powerful tool to assist in formulary development. Production of future formulary manuals will be facilitated by the USP DI Plus database in "electronic book" format, which will allow extraction of selected monographs adapted to the Russian context to compile a published formulary.

It appears that the project with USP has provided a major boost to Pharmedinfo. The sale of publications (and advertising in them) is an additional source of revenue. Ms. Shashkova indicated she is working to obtain permission from USP to place manufacturer-developed product information in the Russian version of the USPDI (for fees) in order to offset the cost of the publication and thereby make their distribution more widespread. The status of Pharmedinfo and its ability to develop an extensive network would be impaired without the USP Project. Sustainability of the Pharmedinfo component and the continuation of drug information centers following discontinuation of the USP/RPM is questionable.

All-Russia Drug Information Network

The All Russia Drug Information Network will consist of regional sites in Moscow (Pharmedinfo as central contact), St. Petersburg, Tomsk, Ekaterinburg, and Vladivostok. Sites have been established in Moscow, St. Petersburg, and Tomsk. This network has great potential for additional roll-out of RPM activities and has sparked the interest of Russian counterparts both in university and hospital settings. The next step will be to bring the parties together from these sites for a meeting at which goals, objectives, mission, work plan etc. of the network will be established. The network regional sites will collaborate in DI dissemination to the regions of Russia, and in their respective regions, each center will disseminate information.

OBSTACLES AND CONSTRAINTS IN MEETING OBJECTIVES

The RPM project faced a number of constraints, some unique to the environment, some of a management nature, which have hampered the project in meeting objectives. Many of these constraints have been addressed by the project through adaptation to the environment and actively building consensus and partnerships among Russian counterparts. Some are worth briefly mentioning below:

- The poor financial conditions inhibited more extensive assistance and impact in procurement activities. As described previously, soaring inflation and unpaid debts rendered facilities unable to conduct tenders, let alone purchase needed drugs in anything but small lots. Pharmacies and suppliers are floating facilities and carrying an unsustainable amount of debt.

- DICs and possibly Pharmedinfo have been constrained by a nationwide lack of effective communications infrastructure. DICs which were placed in relatively sophisticated environments with resources, such as universities and major hospitals, do have the capability to communicate with other, similarly equipped sites. However, many DICs in the oblasts plan to serve as oblast-wide facilities and experience difficulty in serving areas without even a reliable phone line. Most centers are very new and to date have received the bulk of inquiries from within the hospital or city in which they are located. Lack of effective communication will hamper both provider and patient information. These centers have resorted to mailing information to outlying areas. "Real time" communication may be a ways off yet.

- The high cost of operating laboratories, and lack of capacity to perform antibiotic culture/sensitivity tests, and drug blood level monitoring, has greatly hindered efforts to promote rational prescribing and prevent antimicrobial resistance. In the past, physicians did not regularly culture to assess their antibiotic prescribing or did not read results of cultures they ordered. It was reported that physicians, lacking access to adequate laboratory capacity, have no way to monitor a patient's blood drug levels. Many drug reactions or interactions were misdiagnosed as a new symptom of a disease and were subsequently treated with yet another drug, a problem common in other countries as well. Such harmful provider practices have been aggravated by severe financial constraints.

- Exposure to high-technology solutions can overshadow more appropriate lower-tech strategies. In the case of DUR, many Russian counterparts were hesitant to begin regular DUR activities without a computer. While their concerns about devoting salaried staff (when these staff may be needed elsewhere) are real, many counterparts expressed the belief that DUR would not be possible without such assistance. By offering certain sites a modicum of technology and resources, the project may have inadvertently stimulated a preoccupation with and dependence on computer equipment and technology, where such equipment is not necessarily warranted. The team also concedes that counterparts may have reported a dire need for computers in the hope that the evaluation team would issue a recommendation that RPM purchase additional computers for their facilities.

- The program encountered some resistance from physicians, who were being asked to modify prescribing practices under drug management activities. Such resistance from major stakeholders would be enough to halt project implementation. However, RPM and Russian counterparts were able to coopt physicians through the assessment process and the formulary development process.

- RPM also encountered an environment in which authority for critical health sector decisions had been suddenly devolved to the oblast level but little guidance from the national government could inform the oblast undertakings. Major health sector laws either languished in conference or were passed without implementing regulations. The environment presented opportunities and challenges for the project. The oblasts were at once targets for sweeping operational and policy change and vulnerable to

adopting changes which could eventually contradict national policy, when adopted. Russian counterparts and RPM were able to garner substantial local political support for their activities and counterpart activities did not seem to be hampered by fears that the work would be overturned or resisted.

- There is a lack of coordination among in-patient and out-patient providers in prescribing drug therapy for the same patient. Neither physician may know what the other has prescribed, leading to unnecessary changes in treatment of chronic conditions and possible overmedication and drug interactions.

- While there is a demand for patient education related to drug use, the lack of a tradition of patient education and differing cultural attitudes towards the physician-patient relationship in Russia should be considered in any pilot patient education effort. Traditionally, health care was managed exclusively by physicians and not consumer-oriented. The physician relationship to the patient is authoritarian. Patients may not be expected to ask questions or to take an active role in their treatment. Many physicians consider it acceptable to withhold information about conditions from the patient in order to ensure compliance or reduce stress and suffering by patient or family.

VIEWS OF USAID MISSION STAFF AND LOCAL COUNTERPARTS

USAID representatives interviewed in Russia and Washington DC were highly supportive of the project. In Russia, the RPM project was originally designed to build institutional capacities to manage drug supply and to complement other activities under the USAID strategy to promote security of pharmaceuticals. (These other activities included promoting US investment in the Russian pharmaceutical sector and advising on policy regarding the registration of foreign drugs and good manufacturing practices.)

Drug management is a critical component of any dialogue on health sector reform. As supply issues (as opposed to access) became less important, the RPM activities were used to support the current Mission objective of improved effectiveness of selected social benefits and services. This objective attempts to promote systemic efficiency and cost-effectiveness of the health sector during the transition to a market-oriented economy. The RPM activities complement and enhance on-going financing and service delivery reform efforts by Abt Associates (focussed on

systemic reform through local payment, quality, and management information system models), the American International Health Alliance's Hospital Partnerships (updating delivery of medical care in hospitals) and Boston University (policy and legal assistance to oblasts to promote systemic health reform) at the local level.

Most USAID representatives stressed that the process involved in RPM activities, such as formulary development, creation of drug information and monographs, etc., was just as important as the results of these activities. Russian counterparts were encouraged to build consensus and coordinate among different actors, not just impose management decisions hierarchically and to base decisions on empirical financial and utilization information, not on "norms" as in the past. These processes have improved institutional capacity in the oblasts to better manage the health sector.

Like many other health programs in the NIS, RPM had to (1) identify and take advantage of targets of opportunity within the changing environment of Russia and (2) to position themselves to meet Mission strategic objectives in the health sector. USAID management trends and the Russian environment have influenced and will no doubt influence RPM management, strategy and promotion in the future. For example, USAID priorities in ENI have always focussed on economic restructuring and democracy building. Programs to improve the social sector (with the exception of the funding in 1994) has steadily declined as a percentage of USAID ENI expenditures. Health earmarks have also reduced the level of discretionary funding for such activities as RPM. USAID Mission Directors are now receiving budgets based on the fulfillment of strategic objectives. This has driven projects to show measurable results for continued funding. As stated by Mission representatives, RPM will need to document and demonstrate measurable results and impacts in the future.

Collaborators: At the national level, RPM has established collaborative relationships with the following key Russian counterpart organizations at the central level - Pharmedinfo, The Moscow Medical Academy, The Russian State Medical University, and the Academy of Sciences. RPM has cultivated the support of key Russian physicians and academics. The support of Academician Chuchalin of the Academy of Sciences, Academician Belousov of the Russian State Medical University, Academic Lepkhin of the Friendship University, and Academician Mashkovsky has been instrumental in promoting the key components of RPM such as formulary and monograph development and drug utilization and review essentially unknown in Russia prior to RPM. The participation of these and other key Russian physicians in RPM training workshops, study tours, and high level technical meetings has resulted in the development of a cadre of respected supporters of RPM. The recently established

DIC at The Moscow Medical Academy will provide the opportunity for integration of RPM concepts into the curriculum of the pharmacy program.

Pharmedinfo, as the official RPM counterpart organization, has collaborated in RPM training workshops and in adaptation and translation of the USP DI. The organization has also supported formulary development by providing technical assistance to the oblasts in the development of Russia specific drug monographs. The annual Man and Drugs Congress sponsored by Pharmedinfo has provided RPM the opportunity to disseminate materials and methodology throughout Russia and the NIS.

At the oblast level, oblast health officials have been both the beneficiaries of RPM training and the disseminators of RPM methodologies. Officials in Ryazan, the first site of RPM interventions, have hosted visitors from other oblasts interested in drug management and information activities. Communication and exchange of information between the Ryazan, Novgorod and Pskov have fostered the roll out of RPM to the oblasts.

Other Organizations Working in Russia: RPM has established collaborative relationships with other organizations and USAID funded projects. These relationships have generally consisted of training and reproduction of RPM materials; both activities contributed to the dissemination of RPM materials, and implementation of RPM concepts throughout Russia. Specific organizations and collaborative activities have included:

The American International Health Alliance manages 22 hospital partnerships between US and NIS institutions to improve delivery of medical care. RPM conducted a formulary development workshop for 21 participants from AIHA partnerships hospitals in Russia, Georgia and Armenia and a seminar on rational drug selection at the AIHA Partnership Conference. AIHA staff was complimentary of RPM for providing tools and motivation for rational drug use. Collaboration between AIHA and RPM should continue in information exchange and training. Several future areas of collaboration have suggested themselves: AIHA has expressed interest in RPM conducting a procurement workshop for some of its hospitals to introduce the concepts of tendering and pooled procurement. Another opportunity suggested by AIHA would be to disseminate RPM materials in the national learning resources center in Russia. AIHA also supports an infection control initiative in partnership hospitals and is advising national infection control policy and upgrading the diagnostic capacity of reference labs in major NIS cities, including Russia. This may be another point of information-sharing, as RPM activities in the future may increasingly focus on prevention of antimicrobial resistance.

The ZdravReform Program, run by Abt Associates, created models of financing, quality and management reform in target oblasts. Abt and RPM collaboration began as the ZdravReform program was ending in Russia in 1996. The collaboration was a series of exchanges. First, RPM conducted a one-day meeting on RPM concepts in the Abt offices in Novosibirsk, for about 15 officials involved with ZdravReform. Secondly, participants from four ZdravReform oblasts--Tomsk, Kaluga, Tver, and Novosibirsk, attended an RPM formulary development workshop. In turn several RPM participants attended the USAID/Moscow ZdravReform conference on Health Reform in Russia in November 1996. RPM drug management materials are included in ZdravReform's CD-ROM of health and management products and these CD-ROMs have been distributed throughout Russia. ZdravReform was to provide funds to reproduce 3,000 copies each of the RPM-Russia manuals; however, this did not take place due to a lack of funds.

USAID/Moscow supported Boston University to provide assistance in legal and regulatory reform for the health sector. The BU program assisted Novgorod Oblast in the drafting of the oblast health care law, in which drug management concepts were incorporated. This is an optimal collaboration to ensure that policy reform accomplished by Russian counterparts and RPM is supported by legislation.

RPM collaborated with WHO to adapt the *WHO Guide to Good Prescribing* for use in Russia. Abt Associates provided funding for the reproduction of the guide. RPM and WHO co-sponsored workshop on Integration of Rational Prescribing Practice in Medical Undergraduate Curricula in the NIS.

CONCLUSIONS

RPM has been active in Russia for less than three years. In this relatively short time, the concepts of formulary development and management has been not only communicated by MSH, but embraced by the influential stakeholders with whom RPM has partnered. This project's task to promote rational use of drugs is formidable and its accomplishments over only two years of activity are laudable, especially when one considers the U.S. experience, where formulary management evolved much more slowly. In the case of Russia, the sheer lack of health financing clearly contributed to the support for and speed of the work. Many counterparts emphasized that "they had no choice" but to pursue more efficient drug selection, management and use policies. Drug costs typically comprise 10-12 percent of a hospital's operating budget and is one of three protected categories (the others are staff salaries and food). While staff costs can comprise up to 70

percent of a hospital's operating budget and they are difficult to reduce for bureaucratic and political reasons, given already widespread unemployment in oblasts. Therefore, it is very attractive to use the opportunity to maximize drugs procured given scarce resources.

Rational use activities may be more difficult and lengthy than formulary development. Rational prescribing and use are sensitive as they may appear to threaten physician sovereignty and the efficacy of traditional clinical practice, which is not always evidence-based. However, RPM has been successful in building consensus among physicians by producing persuasive empirical information about prescribing practices and their impact on cost and effectiveness.

The development of formulary systems is most promising. The oblast hospital in Ryazan, which was the initial demonstration site and the recipient of the greatest amount of hands-on assistance has produced a sophisticated formulary manual. It is notable that the knowledge gained in this facility through the greater time and attention paid by MSH has been shared with other facilities throughout Ryazan as well as with key players in Novgorod, Pskov, and St. Petersburg.

Despite some delays with the publication of the USPDI, USP has provided critical assistance to Pharmedinfo and created promising pilots for drug information at the oblast level. While most sites are relatively new, the high level of enthusiasm and commitment of Russian counterparts should ensure that the sites will fulfill their mandates. A promising new activity, the All-Russia Drug Information Network, could serve to disseminate RPM and USP information to a critical mass of drug information centers nationwide. The project has also stimulated the development of modern drug management, rational use and clinical pharmacology curricula at target universities.

A key aspect of the RPM project has been the fact that local people have been trained to function at a higher level in assuring rational and appropriate use of pharmaceuticals and other health care resources. The Russian people who have been touched by this program are learning skills which will make the health sector more efficient and sustainable in the future.

Based upon the excellent results achieved to date, it appears the effort and resources have been well spent. The project merits the proposed two-year extension. Expansion of the program should be considered as outlined in the Future Needs Section. The Russian economy is in a shambles. Assistance of the quality and type provided by RPM will better enable the new democracy to withstand the challenges imposed upon their social programs. It is clearly evident that help is needed and that the assistance provided to date has achieved superior results.

FUTURE NEEDS

Specific areas which need to be addressed in the future include:

- Further assistance in implementing tendering and, in order to maximize the benefit of tendering, facilitating development of a "consortium" to combine purchasing power.

- Further assistance in conducting drug use review programs. Additional technical assistance is warranted to assist the counterparts to adapt DUR in a way that makes the task more manageable.

- Assist oblasts in efforts to ensure continuity in drug therapy between in-patient and out-patient care, since frequently a different prescriber follows a patient upon discharge from the hospital.

- Apply the hospital formulary concept to out-patient care by assisting oblasts to review and refine lists of drugs provided to the population free of charge or at subsidized prices.

- A communication strategy is needed for dissemination of experiences in Formulary development, DUR and rational use, between the oblasts.

- Reference materials and instruction in basic pharmacoeconomics.

- Documentation of outcomes and impacts achieved as a result of the project. Development of "marketing" tools and materials to disseminate findings.

- Dissemination of methodology and materials on curricular reform, as has been implemented in Ryazan, is needed to improve training in pharmacology, drug information, and drug use management for physicians and pharmacists. Improved communication and collaboration is needed between Moscow Medical Academy, Ryazan State Medical University, and St. Petersburg Medical University.

- Rational antibiotic use - to address the issue of emerging antimicrobial resistance. There is a need to assess the level of knowledge regarding rational antibiotic use and current prescribing practices.

- Development of Russia specific patient education materials and counseling methodologies.

- Development of a Mission Statement and management plan for the All Russia Drug Information Network.

- Development of procedure manual for operation of a DIC. Additional training in DI dissemination skills.

Recommendations

Based on the future needs identified and conclusions from the team, the following steps are recommended:

- RPM should provide additional technical assistance and training in tendering. The feasibility of developing a "consortium" or purchasing group may be worth exploring.

- RPM should provide additional technical assistance and training in DUR. Attention should be given to assisting counterparts to adapt or "scale down" DUR to make the task more manageable. Computer methods to assist DUR should not be introduced unless computer equipment, software, and trained personnel are available.

- RPM should assist counterparts in improving continuity of prescribing between in-patient and out-patient settings. Out-patient formularies should be developed and joint monitoring of the in-patient and out-patient care systems tested.

- RPM should undertake activities to document project outcomes and impacts, and disseminate these findings, as soon as possible. Marketing tools should be developed to demonstrate the impact of RPM interventions in terms of improved resource management and health outcomes, and activities undertaken to project findings to the national level.

- RPM should continue to collaborate with AIHA and other organizations in training and dissemination of RPM practices. Some AIHA partners have established National Learning Resource Centers which could serve to assist in dissemination, or as sites for future DICs.

- RPM should assist counterparts to develop an inter-oblast communication strategy for dissemination of experiences in formulary development, DUR and rational use. This should include strategies for on-going formulary refinement and management.

- Pharmedinfo should be encouraged to complete the translation and adaptation of the USP DI in both printed and electronic versions as soon as possible, followed by provision of the database to the DICs.

- Member DICs of the All Russia Drug Information Network should develop a network mission statement, management and work plan, and communication strategy as soon as possible.

- RPM should promote collaboration and communication between the institutions and DICs engaged in curriculum reform activities. Training in clinical pharmacology should be continued by RPM if possible, or institutions should be assisted to develop and expand training in clinical pharmacology.

- MSH and USP should explore the feasibility and capability of the DICs within the All Russia Drug Information Network to serve as regional technical resource centers for formulary development, DUR, rational use, and dissemination of RPM manuals.

- Given adequate funding and mission support, RPM should initiate activities to support the development of counterparts capabilities in patient education. This might consist of needs assessment related to patient information, training in KABP survey techniques, identification of host country counterparts or other organizations with experience in patient education, etc. These initial activities will serve to guide the design of future activities in patient education, and identify resources and constraints to carrying out these activities. RPM may consider adapting the USP disease management monographs for use in Russia.

- The project may be interested in incorporating drug therapy into "Standard Treatment Guidelines" or protocols. Should this occur, RPM should explore opportunities to work with other health projects in Russia which have or may develop clinical "best practices," continuous quality improvement and critical pathways.

Annex D. Country Report — Zambia

BACKGROUND: HEALTH SECTOR AND PHARMACEUTICALS

The Government of the Republic of Zambia is implementing an ambitious program of Health Sector Reform. A new Central Board of Health was formed in 1996 in order to provide technical and managerial support to the health services through district and hospital management boards and teams. The functions of the restructured Ministry of Health cover policy, planning, financing, budgeting, legal and advocacy matters.

The National Health Policy and Strategies document of 1991 proposes a series of health policy reforms characterized by a move from a highly centralized system to a more decentralized system in which the center provides only support and national guidance. The government committed itself to provide "equity access to cost-effective, quality care as close to the family as possible" and to build effective "leadership, accountability, and partnership".

The National Strategic Health Plan of 1995 (covering 1995 to 1999) describes strategies and implementation plans for priority areas. These include: essential health care packages; human resources; drug supply and policy; medical equipment, transport and communication equipment; infrastructure; organization of the MOH; partnership; financial administrative and management system (FAMS); monitoring and evaluation/health information management system (HMIS); and financing.

In June 1996, the Department of Pharmacy, with institutional support from the Karolinska Institute, Stockholm, held a National Drug Policy Consensus Workshop reviewing eight background papers describing the situation and analyzing the problems in the public and private pharmaceutical sector in Zambia. A comprehensive draft National Drug Policy (NDP), including recommendations or guidance for action, and a NDP Development Work Plan for 1997 resulted from the workshop. These documents broadly specify needed strategies and outputs for key NDP components, such as procurement, distribution and financing of essential drugs and medical supplies; local drug production; legislation and regulation; quality assurance; human resources development; rational drug use,

selection, research and development; traditional medicine; and international collaboration.

Shortage of drugs has been a recurrent problem for years in the Zambia public sector in spite of major donor supplies (e.g., kits for health centers) and government support of essential and supplementary drugs and supplies. The reasons are many and complex. Insufficient public sector drug financing is a major one; lack of appropriate drug management systems, skills, and knowledge, and irrational prescribing and use are some others. These are analyzed and described in the comprehensive background papers prepared for the National Drug Policy workshop.

In 1996 the government's procurement, storage, and distribution institution then called Medical Stores Limited (MSL), in 1997 renamed Essential Drug and Medical Supplies Store (EDMSS) faced bankruptcy. A consultant team, including RPM, visited Zambia in late 1996 and recommended drastic downsizing of staff, renaming and restructuring of MSL. The team gave various options for pursuing these tasks within the context of the overall health and national drug policy reforms and the decentralization process. Implementation of the recommended option for EDMSS has now started. So has the capacity building and support to hospital and districts with training, supervision and monitoring of selected drug management practices also recommended by the team. To coordinate this and other work related to strengthening management capacity of drugs and other areas of pharmaceuticals, the Central Board of Health appointed a Pharmaceutical Manager Services Support Expert on July 1, 1997, in the Directorate of Health Services Commissioning of the Central Board of Health.

ASSESSMENTS USED IN DESIGN OF PROGRAMS

At the request of USAID Zambia, RPM Project director paid a two day visit to the country in 1995 to establish contact with the Ministry of Health, which was then in the beginning of its restructuring phase.

Problems in drug procurement, distribution, logistics, management, and rational drug use were well documented in the NDP background papers as mentioned above. Furthermore, with support from the WHO Action Programme on Essential Drugs, MOH staff was carrying out an indicator-based study of achievements of NDP, as part of a comparative analysis of national drug policies in 12 countries. Given the high baseline of existing information, RPM did not carry out its own separate country assessment.

Funded by BASICS, and on request of MOH, RPM then participated in the June 1996 National Drug Policy consensus workshop. At that time the MOH also requested RPM to assist the Department of Pharmaceutical Services and the MSL with preparation of an emergency restricted tender for procurement ($3.8 million was provided by DANIDA, DGIS, NORAD, and SIDA) of the most critical essential drugs and medical supplies for the district and general hospitals. In August 1996, RPM's assistance was again requested. This time it was in computerization of the analysis of the bids for essential drugs and medical supplies under a World Bank loan ($6 million).

RPM started to define a work plan in June 1996. In August 1996, RPM produced a work plan based on needs expressed in the June NDP workshop and the follow up meetings of MOH counterparts. The August work plan outlined a number of activities for RPM support, at a total estimated cost of $566,000. The plan emphasized development and implementation of MIS at the central level, in particular, at Medical Stores Limited. It did not respond to the problems at the district level. This had become a priority in the Zambia transitional health reform environment where frequent changes in policy decision were taking place and where the government and donors were probing for solutions to organize the decentralization process to support district level care. BASICS, which manages the Zambia Child Health Project, expressed these concerns and stressed the need for RPM to focus on capacity building, and support to training in drug management and logistics at district level.

In response to BASICS's concern, RPM developed a second plan in November 1996, which did not yet specify details, but tried to clarify RPM's role and support at the district level. In December 1996, RPM then participated as a member of the international team that was evaluating options for restructuring Medical Stores Limited. RPM's role in the team was to evaluate the capacity of the newly formed District Health Boards to relate effectively to an improved MSL and to manage stocks once they reached the district and facility levels.

According to BASICS/Zambia, the RPM participation in the MSL assessment helped to further clarify the needs at district level. It also helped RPM to understand how to work within the new structure of the Central Board of Health, to work towards integration and decentralization, and to determine its own role in program implementation assisting primarily district, but eventually also hospital, boards, teams, and health services. These, the main clients of the new EDMSS, need institutional support and capacity building to make use of a new and improved drug procurement and distribution operation. They need to be able to estimate drug and medical supplies, to prepare financial plans and procurement orders, to manage and monitor storage and inventory control, to carry out

supervisory functions, and to tackle the widespread problems of irrational drug prescribing and dispensing.

Immediately after the MSL assessment in December 1996, the RPM Director followed up on the now more clearly-identified needs and prepared an important concept paper, "Strengthening Public Health Logistics in Zambia." He proposed a collaborative effort for upgrading public health logistics services, covering drugs, contraceptives and laboratory supplies and discussed this concept with major donors in Zambia. It proposes many activities for which technical assistance would be given by a team of RPM (responsible for drugs), FPLM (family planning and supplies), and Irish Aid (laboratory supplies). In January 1997, the plan was jointly launched by the technical assistance team and the MOH Department of Pharmaceutical Services and the Central Board of Health.

With USAID BASICS and Zambia Family Planning focusing their work in Lusaka Urban district where 15 percent of Zambia's population live, it was decided that RPM, in collaboration with these two programs and with Irish Aid's MedLabs Project, should start the public health logistics strengthening activity in Lusaka district, in 1997.

ASSISTANCE STRATEGIES

Assistance Strategies Used

RPM's first two visits to Zambia were mainly exploratory. No long-term strategies were, nor could have been, developed. RPM had to become familiar with the complex and changing environment in Zambia. The USAID mission, the government and the many donors also had to get to know RPM's specific expertise in drug management and rational use of drugs. The opportunity to do so came at the National Drug Policy Consensus Workshop. There, RPM could share its experience and expertise and demonstrate its available tools and methodologies for selection, procurement, distribution, management and rational use of drugs. The government saw an immediate need for some of the tools. It asked RPM to help prepare the emergency drug tender and to provide assistance for the analysis of the bids for essential drugs under the World Bank loan. RPM automated this process by using the tender management module of the INVEC-2 inventory control software.

RPM then tried to identify other areas for USAID support in the pharmaceutical sector. But the elaborate set of proposed activities for an estimated cost of $566,000 never got off the ground as mentioned above. Instead, as a result of RPM participation in the MSL assessment and the follow up discussion with

stakeholders, RPM proposed the collaborative strategy to support strengthening drug and logistics management in an integrated program at the district level. RPM would also support automation of inventory management at the EDMSS.

Appropriateness of These Strategies

RPM gave needed and timely technical and managerial assistance in the NDP development and national consensus workshop, in the emergency drug tender, and in analysis of the bids for the drugs under the World Bank loan.

RPM had been groping to identify its long-term role and strategy. The opportunity came as an outgrowth of the work on restructuring MSL. RPM responded to the development needs under the health sector reform and to BASICS' request and took the lead to support the integration and decentralization efforts at the district level. The strategy to team up with FPLM and Irish Medlabs and to bring together management of drugs, contraceptives, vaccines, and laboratory supplies through cost-sharing and participatory development of appropriate tools and training is sound.

The first draft of the District Integrated Logistics Self Assessment Tool or DILSAT was developed in March 1997 with staff of Lusaka Urban District. It was further tested in Petauke Rural District (Eastern Region) in a workshop 7-10 May 1997. DILSAT consists of an indicator based district integrated self-assessment tool and a practical problem solving tool locally adapted from RPM indicator assessment manual.

A consultation process with the Central Board of Health, the Department of Pharmaceutical Services, donors, and district health management team is in place as an integral part of the DILSAT development.

Results from These Strategies

The technical support and use of INVEC-2 for the $6 million World Bank tender bid analysis helped to organize and shorten this otherwise cumbersome and very time consuming work. The ultimate results were successful procurement of the much needed drugs.

The draft development of DILSAT, its testing and phased introduction is now in full process. This includes training of trainers and planning for large scale workshops in quantification methods in August 1997. Prospective trainers from all of Zambia's 72 district will attend the August meeting. DILSAT is produced in two versions, one for district facilities and another one for the district health

management team. At the RPM evaluation visit, the Director General, directors and senior staff of the Central Board of Health stressed the urgency for rapid DILSAT introduction and use as the new decentralized budget, finance, and monitoring system will be introduced in January 1998.

PROJECT IMPACTS

Improving Allocation, Management and Use of Resources

The appreciation of RPM's technical and managerial assistance is evident in Zambia.

Quantitative data are not yet available to measure the improved allocation, management and use of resources. But qualitatively RPM's support to automate a massive amount of data for the emergency tender and the World Bank procurement process had an important impact on drug selection, procurement, distribution, and management. With the help of INVEC-2 software, and the RPM technical expertise, the data could be organized (e.g., through ABC analysis, price comparisons, drug classification systems) and analyzed and informed decisions could be made.

The above was clearly expressed by the new Managing Director of EDMSS and the new Pharmaceutical Manager in the Central Board of Health. Both, now senior officials in decision making positions (earlier working in the now shrinking Department of Pharmaceutical Services) were RPM counterparts and benefitted from the collaborative experience. As a consequence of their familiarity with the INVEC-2 software and its specific design for drug management and supplies, they strongly support its urgent installation in EDMSS, and its integration into the new district management system.

Since DILSAT only started in February-March 1997, was tested in two districts and is about to roll out in 6 additional districts before national introduction, it is yet too early to evaluate its impact. Its real impact will be known in the forthcoming development of the District Action Plans. But at Lusaka district, the Director and staff informed the evaluation team that they already now use DILSAT as a monitoring and supervisory tool at visits to the district health facilities. The Director also told that some health workers' behavior had started to change with regard to losses of drugs, that those trained in DILSAT had improved drug storage and record keeping, and that DILSAT had "replaced the earlier fragmented approach."

Promoting the Rational Use of Drugs

RPM is indirectly involved in Zambia in promoting the rational use of drugs, both at the central and district level. It is too early to assess any impact but the process, exemplified below, is sound and should help to develop suitable strategies.

The DILSAT package is assessing if district health facilities have a functional Hospital and Health Centre Drug and Therapeutics Committee; a recognized mean to promote the rational use of drugs. Most do not, but need such committees and mechanisms, identified as priorities in the NDP. Strategies are now being developed to introduce such committees. SIDA is one of the major supporters in this work.

DILSAT is also assessing if staff has taken part in training in promoting rational drug use. This is another area where much work is needed and where little so far has been done in Zambia. Tools such as revised standard treatment guidelines are under way with support from SIDA and the Central Board of Health has just published its first edition of "Integrated Technical Guidelines for Front line Health workers." This booklet concentrates on cost-effective interventions, which includes drug treatments, for the essential health care package.

A revised version of the Zambia essential drug list, another tool for promoting the rational use of drugs, is about to be published. Its impact will be seen through DILSAT training and evaluation of the selection of drugs at the district level.

Other examples of RPM staff promoting the rational use of drugs have been presentations and lectures. These included a lecture given for pharmacy technicians at Evelyn Hone College, and the RPM Director's lecture at the annual "Pharmacy Awareness Week" on the topic of educating the public in drug purchasing and use. Both were mentioned as having created much interest in the area of promoting rational drug use.

Improving Level of Drug Information

Objective, evaluated and targeted drug information is not available in Zambia. Typically, of course, national formulary committees, drug information centers or drug regulatory bodies would be the provider or such information, but in Zambia it is the responsibility of the Department of Pharmaceutical Services. This Department is however in the process of change and regulatory activities will most likely become the responsibility of a proposed new autonomous body. SIDA has just sponsored a study on the creation of such a body.

With an expanding private sector, the need for independent drug information becomes even more important. But until a proper central framework is in place RPM will likely have a greater impact conveying appropriate messages at the district level.

OBSTACLES AND CONSTRAINTS IN MEETING OBJECTIVES

In the changing Zambian health reform environment with major restructuring and heavy donor support from major donors, obstacles and constraints become challenges. The major RPM challenge was to find its role and identify more long-term technical and managerial assistance acceptable to the stakeholders and in support of the decentralization process.

VIEWS OF USAID MISSION STAFF AND LOCAL COUNTERPARTS

The RPM evaluation team received positive feedback on the work of RPM. Apart from what is already mentioned above, both USAID and other donors felt that the RPM Concept Paper and the visit of Director RPM to the various stakeholders were most important.

RPM collaborators in the development of DILSAT also gave very favorable comments. Those working closely with RPM in the government expressed a special "kinship" and appreciated the fact that they could call on — and receive — RPM technical and managerial expertise on short notice. One donor felt that close linkage with RPM systems and mission hospital systems was needed and also cautioned against possible diversion of DILSAT from the Health Management Information System (HMIS) of the Central Board of Health. The evaluation team has been assured that DILSAT has been developed in collaboration with the Central Board of Health and that RPM is cognizant of the importance of ensuring that this activity remains consistent and compatible with the HMIS.

CONCLUSIONS AND RECOMMENDATIONS

After some initial searching and timely technical support in drug tendering and procurement, RPM has created an important role to strengthen district level logistics management in Zambia. This has brought together management of drugs, contraceptives, vaccines and laboratory supplies in an integrated approach. RPM has worked in a team with BASICS (who also put in $74.000 for local costs for

workshops), FPLM and MedLabs and in consultation with the District Health Management Team, the Central Board of Health, the Department of Pharmacy and donors. The result is an indicator-based District Integrated Logistic's Self Assessment Tool or DILSAT for district health facilities and district health management teams to be used in district health planning, supervision and monitoring.

Training of trainers has started in Lusaka Urban District and Petauke Rural District and will be quickly extended to all of Zambia's 72 district. The impact of DILSAT is yet too early to assess and will likely not be known until the new district action plans for 1998 are developed. But current feedback from Lusaka District Health Team is favorable and DILSAT is already appreciated and used in supervision as a monitoring tool.

Recommendations

- RPM should continue to limit its technical and managerial support to a maximum of four areas. The evaluation team recommends:
  - district logistics management support and capacity building/training
  - management support to EDMSS including installation of INVEC-2, training and modern computer equipment
  - technical assistance in procurement methods and management
  - analysis of needs regarding drug information and, if appropriate, limited "start-up" activities.
- To provide effective support in the areas of management support to EDMSS and technical assistance in procurement, a continuous presence for RPM in Zambia will be required, at least until local counterparts are totally familiar with the systems.

Annex E. Report on Meetings with WHO and UNAIDS

The scope of the RPM project evaluation was not intended to review the RPM grants to WHO/DAP. However, in light of the fact that RPM has undertaken collaborative activities with DAP at both the global and country level, and the leadership role that DAP plays in essential drugs and policy development, the input of WHO was deemed important in order to assess the relevance, effectiveness, and comparative advantage of RPM initiatives. Furthermore, the input of officials and technical officers at DAP and other WHO programs is relevant to the design of the proposed follow-on RPM project, and to identify potential opportunities for future collaboration.

RPM support to WHO/DAP is carried out under two grants. The first grant consists of two activities — harmonization and promotion of indicator-based systems, and the development of a strategy for drug management information exchange. The harmonization and promotion of indicator-based systems activity is designed to foster collaboration among major donors active in drug issues in developing countries by promoting a standardized method for assessing drug policies and management using indicator-based assessment approaches and other methods. The second activity — development of a strategy for drug management information exchange — will create an efficient communication infrastructure, and foster a continuous communication process among donor countries, institutions and international organizations. As the first step in this activity, WHO/DAP is carrying out a feasibility study which shall lead to the proposal of a model for information exchange that will allow donor agencies, countries and WHO/DAP to exchange data on drug and health management information in various countries.

The Rational Pharmaceutical Management in the New Independent States grant will support activities that complement interventions of the RPM/USAID project and activities being undertaken by other organizations. Specifically, the project intervention areas are the promotion of indicator-based methodologies for assessing the pharmaceutical sector, promotion and development of essential

drugs list and formulary, and improvement of drug prescribing through the strengthening of drug utilization review.

At the global and regional level, RPM and WHO have collaborated in several activities. In July 1996, RPM, PAHO, USAID and BASICS conducted a joint planning meeting that resulted in the Latin American and Carribean Regional IMCI Initiative. For their part in this initiative, RPM proposed collaboration in the development and testing of an IMCI Drug Management Assessment Module to complement other tools being developed by the initiative. In May 1997, USAID coordinated an IMCI joint operations research meeting attended by WHO/CHD, UNICEF, CDC, BASICS, and several other USAID funded CAs. Drug supply and management were identified as one of the priority areas for operations research in order to inform the implementation of IMCI, and the health system improvement interventions necessary for IMCI. The result of these collaborative activities is that the development of the ICMI Drug Management Assessment Tool is underway, and field testing of this tool is anticipated in the coming months.

The First International Conference on Improving Use of Medicines (ICIUM) was held in Chiang Mai, Thailand April 1997. International co-sponsors included WHO/DAP, INRUD, USP, and the Applied Research on Child Health Project (ARCH). The objective of the conference was to synthesize what is known about the effectiveness of different strategies to improve the use of medicines in developing countries, to develop policy guidelines for implementing proven strategies, and to identify important directions for future research. The conference was attended by 272 health manager, policy makers and researchers from 46 countries. Over 120 contributed papers were presented on improving pharmaceutical practice by health professionals, improving community drug use, and assessing economic and policy interventions of the use of drugs.

RPM input and experience contributed significantly to the revision of *Managing Drug Supply*, undertaken by MSH-DMP and WHO, and published in April 1997. (RPM and MSH-DMP will also produce revised training materials based on MDS-2). Currently, RPM and WHO/DAP are collaborating in the harmonization of indicator-based-assessment tools. The resulting product will be a state of the art drug management assessment tool which combines the expertise and experience of RPM, MSH-DMP and WHO/DAP.

At the country level, WHO and RPM have collaborated on numerous occasions. In Ecuador, RPM's work with several donors, including PAHO, in the development of a decentralized drug management plan facilitated consensus on

the model developed, coordination of technical assistance inputs, and local cost sharing. RPM activities in Nepal began with collaboration with WHO/DAP in an evaluation of the Essential Drug Program. RPM facilitated the installation of the WHO Drug Management and Policy Program's drug registration software at the DDA. In Russia, RPM collaborated in the adaptation and translation of the *WHO Guide to Good Prescribing*, and co-sponsored a workshop on Rational Drug Use in May 1997.

SUMMARY OF MEETINGS

WHO/DAP

The team met with DAP staff members from the following program areas: National Drug Policy, Rational Drug Use, Drug Regulation and Quality Assurance Capacity, and country and regional programme development for the Americas (AMRO), Africa (AFRO), Eastern Mediterranean (EMRO), Europe (EURO), South-East Asia (SEARO), and Western Pacific (WPRO).

Dr. Jonathan Quick, director of DAP, reviewed the organizational and programming structure of DAP. DAP recently adopted a revised strategy as a result of careful review of current programs by a Management Advisory Committee. The revised strategy consists of activities that fall under two general programming areas— policy and technical development and country programme development. The focus will be increasingly on policy and technical development activities at the global level, as a means to address specific needs at the country level. Activities included under the scope of policy and technical development include national drug policy, health economics and drug financing, drug management and supply strategies, rational drug use, regulation and quality assurance capacity and traditional medicines. Country programme development begins with a needs assessment followed with the design of an action plan consisting of interventions at one of three levels of technical and financial support: long term policy and strategy development; intensified support in a limited number of countries; and implementation of specific technical activities.. Country program development will remain a priority, but with greater focus, efficiency and impact.

In terms of global level activities in the area of policy and technical development, WHO will convene its WHO Expert Committee for review and update of the *WHO Essential Drug List* in December 1997. DAP plans to undertake a multi

country study of logistics and management systems, and in September a regional meeting of countries in East and South Africa is planned. The harmonization of indicators is also being undertaken under the rubric of global level activities.

Dr. Quick spoke positively of RPM's activities in Nepal. The RPM participation in the WHO led review of the essential drug program served to kick-start RPM activities. WHO/DMP, with RPM support, is implementing a computerized drug registration system in Nepal. Dr. Quick complimented RPM's use of technical consultants from the region as an important mechanism for the development and implementation of country appropriate interventions. Finally, the activities of RPM have facilitated networking among professionals in Nepal.

Dr. Quick recognizes the technical expertise offered by RPM in on-the-ground program implementation. He suggested that one way to foster closer collaboration between RPM and WHO/DAP would be for MSH to become a WHO Collaborating Center. As such, the two organizations could develop joint work plans and improve technical collaboration.

In relation to general drug issues, Dr. Quick believes that essential drugs could serve to be a strong integrating issue around which to focus policy makers and program managers. Decentralization also has potential to be an integrating issue. As drug management and supply programs, as well as vertical programs with a drug component, are decentralized, it will be important to analyze to what level these programs can be sensibly decentralized. How to combine public and private sectors in relation to distribution and supply present additional challenges.

The Interagency Pharmaceutical Coordination Committee consists of WHO, The World Bank, UNICEF and The European Union. The committee is not open to bilateral organizations. The key issues the committee is focusing on are pharmaceutical procurement, registration of drugs from non-profit suppliers, procurement capacity building, pharmaceutical pricing and public sector drug supply. A joint effort is underway to develop standard guidelines for drug procurement, with RPM providing technical assistance in this effort.

The team also met with Dr. Hans Hogerzeil, coordinator of Country Program Development and also of Rational Drug Use, and Daphne Fresle, technical officer. Both spoke positively about the RPM publication *The International Drug Price Indicator Guide*, view the guide a very important source of information for drug management personnel in developing countries, and an information source that no

other organization provides. They agree with the inclusion of WHO and UNICEF drug prices, but questioned the relevance of inclusion of Zimbabwe Medical Store Prices. On the other hand, they acknowledged the fact that the listing of Zimbabwe prices provided a "reality check" in that the Zimbabwe prices provided a point of departure.

Dr. Hogerzeil and Ms. Fresle also complimented RPM's recent collaboration with WHO/EURO in the workshop on rational drug use held in Russia in May. In their words, the workshop was "well executed and brought together many participants who had never attended a WHO workshop before." The workshop's technical content was largely centered on the *WHO Guide to Good Prescribing*. Apparently, there are two Russian translations of this publication: the WHO/EURO supported translation (word for word, very simple language, more student oriented), and the RPM supported translation (more scientifically oriented, geared for the professors). RPM is developing *Training Materials Based on the WHO Guide to Good Prescribing*.

Mr. Hogerzeil and Ms. Fresle summarized the activities of INRUD. The jointly sponsored WHO/INRUD training courses (2 weeks) on Rational Drug Use have been a tremendous success. The regional courses have been held for 10 years, are generally over-subscribed, many participants are either willing or able to pay (of approx. 55 participants, WHO typically only pays for 3 or 4), and have become self-financing. They would like to see INRUD expanded to include 3 or 4 Latin American countries (Ecuador and Nicaragua were mentioned as possibilities). Should expansion to Latin America go forward, there will be a need for research training, and revision and translation of INRUD training materials into Spanish. Other specific activities mentioned as potential collaboration in the future were Spanish translation of the *WHO Guide to Good Prescribing*, and medical curriculum development in the area of rational drug use. A Portuguese translation of *WHO Guide to Good Prescribing* is underway.

In regards to consumer education related to drugs, Ms. Fresle stated that she believes there is a big gap in this area. She expressed concern that there is little known about communication and education messages related to drugs for the consumer. She expressed concern that since USP's experience in consumer education has historically been in the US, USP does not have sufficient IEC developing country experience to develop consumer education materials and messages that will be appropriate for developing countries. She emphasized that development of consumer and patient education information related to drugs will

require thorough assessments, country specific IEC program design, and careful pre-testing followed by revision of IEC messages.

The team met with Mrs. Kari Bremer, Coordinator, and Mr. Eshetu Wondemagegnehu, Technical Officer, both in the program area of Drug Regulation and Quality Assurance. Activities supported by this department of DAP include, at the country level— financial, technical and management support in quality assurance; regional activities— promoting the use of quality control labs by regional authorities; and global level activities including tools development (e.g., support for use of WHO certification scheme), and research. The DAP plans to undertake a multi-country study to assess effectiveness of drug regulation (this study will take place 1998-99). The findings of this study will guide the development of new and revised strategies.

WHO/DMP

The team met with Dr. Idanpaan-Heikkila, Director of DMP— Division of Drug Policies and Management, and Dr. El Griffiths, Chief of Biologicals. Dr. Idanpaan-Heikkila complimented the WHO-RPM collaboration on drug registration in Nepal. In the area of drug information, USP will need to incorporate the revised WHO essential drug list (the WHO Expert Committee on this will meet at the end of 1997) into the USP DI .

In relation to the area of regulation, Dr. Idanpaan-Heikkila believes there will be increasing regional cooperation driven by the lack of technical expertise to regulate drugs or biologicals at the country level. Specifically, this might consist of the development of regional approaches and harmonization of regulatory standards. Finally, Dr. Idanpaan-Heikkila indicated his continued interest in counterfeit drugs and would like to see some activity or dialogue on this issue.

WHO/EPI

Dr. Melgaard communicated his concern regarding the implications of health reform, particularly decentralization, for EPI. His opinion is that EPI should not be decentralized, but believes that operations research on this subject is warranted. WHO/EPI will be sending two consultants to Zambia in September to look at health reform and EPI.

In regards to essential drug logistics and management, Dr. Melgaard recommended that RPM should look to the experiences from EPI systems development to determine if there are lessons learned that have application for essential drugs. Tanzania has integrated EPI and Essential Drugs logistics and would be a worthwhile case study.

Finally, Dr. Melgaard communicated that there are vaccines entering Russia without Russian language package inserts. This is an area that warrants further investigation and possibly intervention on the part of USP. Russian language monographs for vaccines could be developed, disseminated, and included into the USP DI Russia adaptation.

WHO/CHD

Discussions with the staff of WHO/CHD largely focused around IMCI. Implementation of IMCI began in 1996. By the end of 1996, Tanzania, Uganda and Zambia had begun the training of health workers, and at least 18 other countries had initiated planning for IMCI, including adaptation of the case management guidelines for first-level facilities. IMCI is being undertaken through WHO/CHD collaboration with country ministries of health, and inclusion of IMCI as an intervention in child survival projects such as BASICS.

The staff communicated that introduction of IMCI must consider several drug related issues. At the national level, the existence of a national drug policy and essential drug list are important. Other key issues to be addressed are the inclusion of IMCI required drugs on the essential drug list, the existence of standard treatment guidelines, the existence of policies which permit the administration of IMCI drugs by first level health worker, the skills and training needs of the first level health worker, and finally the availability of necessary drugs at the first and referral level facilities. At a workshop of WHO/CHD, BASICS, USAID, and other organizations involved in IMCI initiatives, a consensus was reached that operations research should be undertaken to learn more about the availability and management of necessary drugs needed to implement IMCI.

A Drug Supply Management Course (DSM) and related training materials were developed by WHO/CHD, BASICS, and ACT International with technical direction provided by MSH. The course content includes standardized procedures for improving the ordering, organizing, storage, and dispensing of drugs, and prescribing practices, and was designed for health workers whose responsibilities

include drug management at first-level facilities. During July 1996, the DSM was field tested in South Africa. Based on the findings of the field test, the training materials were revised. During 1997 CHD plans to apply the course in three or four countries that have already implemented IMCI or are planning to do so.

UNAIDS

In response to the arrival of new combination drug therapies including protease inhibitors and increasing demand for antiretrovirals, developing countries are seeking assistance in all aspects related to AIDS/HIV drugs. A collaborative effort has been initiated by UNAIDS, ASD, DAP, and DMP to address access to these drugs and their rational use. The result of these activities will be the development of a strategy plan on access to HIV-Related Drugs.

At the global level, UNAIDS will take the lead in the development of global strategies on access to HIV-related drugs, global advocacy, and the formation of a European Commission, DG-12 Working Group on Access to Drugs for HIV in Africa and care of HIV-AIDS in Africa. UNAIDS will also be the primary focal point for the development of guidelines for local adaptation of clinical guidelines for the use of HIV-related drugs, and conduct an assessment of implementation of Brazil's ARV policy.

UNAIDS and WHO/DAP are collaborating in three specific areas: access to new drugs and drug development; improving in-country access to HIV/AIDS-related drugs through communities and health systems; and the establishment of a working group on access to drugs for HIV/AIDS and STDs (see annex). A significant effort will be undertaken to gather information on the current situation. Assessments (conducted by DAP) at the country level will look at what people expect in relation to AIDS/HIV related drugs, assessment of the current situation of access to drugs, mapping of what has been done, and identification of regional problems. Global issues such a monopolistic markets for these drugs, purchasing policies, black markets, and social and political factors will be examined as well.

UNAIDS anticipates that regional strategies to address the HIV related drug issue are a possible strategy worth pursuing. Within such regional strategies, group procurement, negotiation with industry, and standardization of treatment protocols hold promise as means to approach cost savings.

WHO/ASD

ASD provides overall coordination of WHO work in the area of HIV/AIDS and STDs, and serves as the focal point for collaboration with UNAIDS. With respect to STDs, activities supported or planned by ASD are updated STGs for STDs (in collaboration with CDC revised STGs will be released in 1999), integration of the new drugs for STDs (based on updated STGs) into the essential drugs list, and development of STGs for ARVs.

ASD was the lead organization in an ARV consultation held in April 1997. The consultation was held in response to requests from developing countries for information and technical guidance related to ARVs and other new drugs. The primary recommendation resulting from the consultation was that WHO provide technical assistance to developing countries on the use of ARVs. ASD is currently developing a manual on ARVs including modules on prescribing, laboratory tests and analysis, incorporation of ARV therapy into health systems (eg. training, and other issues), ethics, and maternal child transmission.

Maternal and Newborn Health/Safe Motherhood (MSM)

Key areas of concern related to maternal and newborn health and essential drugs are the availability of appropriate drugs at first level facilities, compliance to STGs, and over use of drugs. Priority areas of reproductive health care that rely on drug availability and appropriate use are Magnesium Sulfate for treatment of eclampsia and pre-eclampsia, oxytocin in the third stage of labor, and antibiotics for treatment of post-partum and post-abortion sepsis.

As part of the joint WHO activities in access to drugs for HIV/AIDS and STDs, MSM is looking at the integration of STD management into reproductive health services/MCH and maternal care and treatment for HIV+ individuals, and the use of ARVs as related to maternal-child transmission. Strategies in the area of STD management must address the private and/or informal sector since many patients with STDs do not seek care in the formal sector.

Annex F. List of Key Professional Contacts

(arranged by location and date of initial contact)

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Annex G. References/Bibliography

DOCUMENTS OF GENERAL APPLICABILITY

MSH Materials

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Annex H: Evaluation Scope of Work

Rational Pharmaceutical Management Cooperative Agreements

Today, fully 20 years after the Essential Drugs Concept was formulated at the international level, 17 years after the "Health for All" declaration was made at Alma Ata, and 10 years after the Nairobi Conference on the Rational Use of Drugs was held, some 2.5 billion people, or one-half of the world's population, continue to be denied their right to health and lack secure access to essential medicines.

(Health and Drug Policies: Making Them the Top of the Agenda, Development Dialogue 1995:1, The Journal of the Dag Hammarskjold Foundation)

Introduction

The USAID Global Bureau's Center for Population, Health and Nutrition intends to evaluate the Rational Pharmaceutical Management (RPM) components of the Health Financing and Sustainability (HFS) Project (936-5974).

RPM activities began in September 1992, with five-year cooperative agreements (CAs) awarded (competitively) to Management Sciences for Health (MSH), a leader in pharmaceutical management technical assistance, and (on a sole source basis) to the United States Pharmacopeial Convention, Inc. (USP), the international leader in drug standards and developer of one of the leading compendia of drug information in the United States. (See Table 1)

The cooperative agreement mechanism was chosen because it was felt that there were many important unanswered questions regarding critical pharmaceutical management issues, that flexibility and innovation were required in developing approaches to deal with known problems, and that an assistance instrument was the most appropriate vehicle for improving country situations. The organizations involved were selected because of their knowledge and experience and the fact that their mandates coincided with the objectives being pursued by USAID: introduction of sustainable reforms in pharmaceutical systems and improvements in the quality of care in the health sector.

RPM was to develop state of the art tools, techniques, methodologies, software, information resources, and training materials, test and evaluate them in selected countries, and make them available to other USAID projects and to other agencies and organizations active in providing pharmaceutical management technical assistance. It was expected that many of the tools and methodologies developed and refined by RPM would become the standards used by future projects in this sector. The CAs were originally to carry out core-funded, experimental programs of assistance in up to three developing countries to improve selective elements of pharmaceutical management, promote rational use of drugs, and increase access to country-specific pharmaceutical information.

At about the same time that the original CAs were awarded, the dissolution of the Soviet Union and the consequent shift from command to market economies provided a unique set of problems and opportunities in pharmaceutical management. The Add-on awarded to the MSH cooperative agreement in September 1993 was the result of NIS Task Force concerns that health care workers lacked the management skills to ensure that even basic drug needs of the population were being met. The Add-on was designed to complement USAID/Moscow's strategy of ensuring "pharmaceutical security" by improving the availability of vital drugs. Subsequently, in December 1994 and January 1995, the ENI Bureau, on behalf of USAID/Moscow, awarded additional separate CAs to MSH and USP for related work to be carried out in the Russian Federation. All four CAs are managed by the Global Bureau under the HFS Project.

Table 1 provides basic project identification and financial information on the four RPM cooperative agreements.

Table 1

CA	Start/End Dates	CA Number	Total Est'd Project Cost	Total Est'd USAID Contribution	Total Est'd Cost Sharing	Obligations to March 1997
MSH World Wide	Sept. 25, 1992 Sept. 23, 1997	HRN-5974-A-00-2059-00	9,830,000	8,900,000	930,000	7,937,311
MSH Russia	Jan. 6, 1995 Dec. 31, 1997	HRN-0004-A-00-5002-00	2,374,264	2,374,264	NA	2,374,264
USP World Wide	Sept. 17, 1992 Sept. 15, 1997	HRN-5974-A-00-2052-00	2,078,156	1,286,076	792,080	1,285,000
USP Russia	Dec. 22, 1994 Dec. 31, 1997	HRN-0004-A-00-50001-00	1,124,000	1,124,000	N/A	1,124,000

This scope of work defines an evaluation program to be conducted by a five-person team, describes the background and questions to be asked, and summarizes the funding and logistics arrangements. Findings will serve to guide plans for an enhanced technical mandate under a proposed project extension.

2. Background

A. RPM's Scope of Work

As derived from the March 1992 Project Paper Supplement to the Health Financing and Sustainability Project, the following summarizes RPM's goal, purpose, and intended activities.

Goal: To improve the health status of target populations in LDCs through improvements in the 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, and (2) improving the allocation, use and management of health sector resources, both public and private, and (3) enhancing access to, dissemination and utilization of accurate, unbiased drug information.

Technical Areas and Activities: RPM's goal and purpose are to be achieved through work in three technical areas, which are described succinctly as follows:

- Establishment and automation of drug registration systems;
- Strengthening and rationalization of public sector pharmaceutical procurement and supply management; and
- Expansion of drug information resources and promotion of rational use of pharmaceuticals.

Within these technical areas, RPM was to provide such services as long term assistance at the country level and information dissemination. Examples of specific activities to be carried out included: *Diagnostic assessments of pharmaceutical sectors; Policy analysis and dialogue; Training; Studies and operations research; Improved information management; Communications strategies and social marketing; and collaboration with other other donors.*

B. Project History

As noted, USAID awarded the initial cooperative agreements to MSH and USP in September 1992. In December of the same year, the MSH Drug Management Program relocated from Boston to Washington DC. The first technical activity was development of an approach for the assessment of pharmaceutical sector operations. Country assessments began in June 1993, and over the ensuing year, RPM carried out assessments in Ghana, Ecuador, Nepal, El Salvador, the Eastern Caribbean, and Ukraine with core funding, and in Mozambique with mission funding. Subsequently, the project selected Ecuador, Nepal, the Eastern Caribbean and Mozambique as country arenas for long term assistance programs.

As noted, during the period, December 1994 - January 1995, Russia-specific cooperative agreements were awarded to MSH and USP. While the events summarized above were taking place, work went forward on development of tools for pharmaceutical management, including such products as the *Rapid Pharmaceutical Assessment Manual, International Drug Price Indicator Guide* and computer software products such as the *INVEC2* inventory control program and *PASS* for analysis of drug prescribing practices. In 1995, USAID adopted the field support funding strategy which caused dramatic cuts in planned core funding for the two Global CAs. The go ahead was given to market the project more broadly with field missions. In consequence, RPM has since added new country

programs in Peru, Zambia and Bangladesh, and has joined a regional public health logistics initiative managed by REDSO/ESA.

3. Evaluation Scope of Work

The evaluation is planned for the period June - August, 1997. The purpose of the evaluation will be to:

A. Assess the degree to which MSH and USP were able to complete the program descriptions contained in their respective cooperative agreements, and identify any factors that may have constrained their achievement of proposed activities. More specifically, assess RPM's impact on: 1) allocation, use and management of health sector resources; 2) institutional capabilities of relevant host country participating organizations; 3) drug management policies, practices, and procedures; and 4) access to, dissemination and utilization of unbiased drug information.

B. Provide guidance for modifications to be made in the configuration and content of the USAID cooperative agreements under RPM to address the PHN Center's needs for pharmaceutical-related expertise, and provide recommendations delineating how RPM resources can be used to support the center's strategic objectives (attached).

C. Assess the impact of USAID's funding via CAs on MSH and USP - i.e., MSH's capability to develop state of the art approaches to improve pharmaceutical management, and USP's involvement in the international arena as a provider of accurate, up to date drug information for enhanced health outcomes.

4. Time Frame and Team Composition

The RPM evaluation will take place within a three month time frame - June 1997 through August 1997. A Team Planning Meeting will be held the week of June 16 during which the team will conduct planning activities and agency interviews in Washington DC. Field visit will be conducted June 21 - July 25. A preliminary draft report will be due by the end of August, with the final report and debriefing completed by the end of October 1997.

The Contractor will provide the services of three team members consisting of a project management specialist/team leader with experience in overall development of pharmaceutical sector programs, and two essential drugs/pharmaceutical

management and policy specialists. Additional team members (not to be provided by the Contractor) will consist of a health sector reform specialist, two drug information/child survival specialists, and a public health policy specialist.

The Team Leader will be responsible for preparation and submission of the Final RPM Evaluation Report to the Division for Health Policy and Sector Reform (AID/G/PHN/HN/HPSR). Specifically the Team Leader will be responsible for: the technical quality of the evaluation; assuring that the relevant expertise of the Team is incorporated into the report; assigning specific tasks and responsibilities for each team member with the scope of work for the evaluation; and coordination of evaluation activities with relevant USAID CA and contractor staff.

In addition to the aforementioned team members, the Contractor will provide the services of an experienced facilitator to design and implement a team planning meeting (see section 6 for specific level of effort for team members).

The Team will be allocated a total of approximately 5.09 person months to complete the assignment. The includes the team planning meeting, document review, domestic and international field visits, draft report writing and presentation and final report writing and debriefings. The Level of Effort and qualifications for each team member are outlined in Section 6.

5. Scope of Work Questions

A. Project Implementation and Technical Performance

1) Assessment Based Approach: RPM has emphasized indicator based assessments of pharmaceutical sector operations as the means for obtaining baseline information, identifying strengths and weaknesses within country settings, developing programs of interventions to improve pharmaceutical systems, and evaluating the effectiveness and impact of interventions. Questions to consider include:

What methodologies have been developed to better plan and manage pharmaceutical sector assessments? How were countries selected for RPM assessment? What has been learned applying these methodologies in terms of the usefulness of individual indicators? How have host country managers benefitted from the use of the indicator based approach? How was RPM assessment methodology modified to address individual country priorities and differences? Have there been unanticipated results from the application of the RPM assessment approach?

(Additional Russia specific)

- *How were oblasts selected for RPM assessment?*
- *How did RPM overcome the Russian perception that they had been over assessed, based on the repeated use of this approach during the humanitarian aid phase of donor assistance?*

2) **Country Programs:** Country programs were designed based on assessment findings, available points of entry, potential for sustainable improvement and reform, relationships established with collaborating organizations, and perceived host government and mission priorities. Assistance strategies have consisted of workshops, direct technical assistance, study tours, consultancies by internationally recognized experts, and high level technical meetings. Questions to consider include:

What were the most significant assessment findings used in designing country programs? What assistance strategies were utilized in country programs? Were the strategies appropriate for the country programs? What results were achieved from these strategies? How has RPM impacted the goal of improved allocation and use of financial, human and information resources within the health sector? What were major obstacles and constraints in achieving stated objectives? What were the views of USAID mission staff and local counterparts of RPM's technical contributions and responsiveness to local needs?

(Additional Russia specific)

- *How did RPM adjust its focus and content as mission objectives shifted from "pharmaceutical security" to improvements in: financing and resource management, governance structures, quality of care, and information management?*
- *Were there additional benefits in conducting policy options workshops to disseminate pharmaceutical assessment findings, beyond the production of individual RPM oblast work plans, and if so what were they?*
- *What unique problems and opportunities were encountered by RPM in Russia and how were they addressed? Specifically, how did RPM deal with: lack of experience with the Russian health care system? decentralization of decision making authority? oblast public health budget shortfalls? on-going privatization efforts?*
- *How did RPM communicate essential elements of Western pharmaceutical systems and achieve their acceptance in the Russian pharmaceutical sector? In light of the conceptual and operational differences, was it*

appropriate to apply Western pharmaceutical practices such as formulary development, drug utilization and review, and independent drug information centers etc. to the Russian context?

- *What key considerations should be kept in mind when implementing rational drug management in Russia?*
- *What approaches did RPM use to develop a demonstration site in the Ryazan oblast, and how successfully were activities rolled out to Novgorod and Pskov oblasts?*
- *How has RPM taken advantage of the availability of talented local experts as advocates and implementors of the program?*
- *To what extent has RPM succeeded in alleviating the managerial gaps in oblasts created by the devolution of decision making authority from the central to the oblast level in the areas of RPM technical involvement: drug selection/formulary development; DUR; pharmacy management; access to drug information; and education interventions?*

3) Tools Development: The RPM project design included development and application of practical tools designed to improve pharmaceutical management and the rational use of drugs by health care practitioners. Such tools are intended to be both applied within the context of the project's country programs and disseminated to other potential users. Questions to consider include:

What RPM tools were developed or improved as a result of the project? How do these products fill the needs of the project design? How have they been applied within the context of the country programs?

(Additional Russia specific)

- Were new monographs drafted for products unique to Russia? How were these products evaluated/selected?

4) Drug Information Development/Utilization: An objective of RPM was to establish mechanisms for the development, adaptation, and provision of independent drug information for the health care system. Questions to consider include:

- *How did RPM address the different information needs of various constituencies? Was drug information provided through RPM adapted successfully to meet local needs?*
- *What criteria were used for selecting drug information centers' sites? What other factors influenced site selection? Were drug information*

development capacities improved or created? Did the Drug Information Centers and collaborating organizations receive the equipment, medical literature, software and training necessary to: 1) successfully adapt and translate the USP database for local needs; and 2) receive, manage, and disseminate the information? Are all levels of the health care system fully aware that independent drug information is now available?

(Additional Russia specific)

- *How successfully was the USP model of information development transferred to PHARMEDINFO?*
- *How was PHARMEDINFO's capacity to perform the translation assessed?*
- *Were Russian health care professionals acquainted with publishing of the Russian Edition of USP DI?*
- *Was the demand for information adequately assessed in the oblasts?*
- *Are the drug information centers presently under-, over-, or appropriately utilized?*

5) Information Dissemination: It is intended that the results achieved by RPM be disseminated beyond the direct reach of the project to agencies, organizations and individuals that might make use of them. Questions to consider include:

What are RPM's approaches to information dissemination? What channels are being used and who are the recipients? For which products and information is demand greatest? Is there a feedback mechanism built in to see whether recipients are using the information and find it useful, or alternatively to tailor the information to meet audience needs?

(Additional Russia specific)

- *How has RPM communicated significant findings in the oblasts to the federal level?*
- *How successful has RPM been in disseminating Russian language materials within Russia and in the NIS?*
- *What NIS, national, and oblast channels did RPM utilize to disseminate project materials and information?*
- *How does the All-Russia Drug Information Network support information development and dissemination in the Russian Federation?*
- *What were the criteria for selecting the cities for All-Russia Drug Information network sites?*

6) Collaboration with Other Organizations: In order to maximize the impact of limited resources, it is important that individual projects and organizations collaborate effectively with other USAID projects, donors, and organizations, such as local NGOs. Questions to consider include:

To what extent is RPM collaborating with other international projects, agencies and organizations, including USAID-funded projects? What is the specific nature of these collaborations? At the country level? At the central project level? What is the nature and extent of collaboration between MSH and USP? To what extent is RPM leveraging the resources of collaborators to contribute to achievement of its own mandate? How has RPM assisted collaborating organizations in meeting their goals and objectives?

(Additional Russia specific)

- *How did parallel USP activities e.g. memorandum of agreement with the State Pharmacopeial Committee of Russia and Russian participants in USP's Visiting Scientist Program complement RPM objectives and activities?*
- *How do the Ryazan Central Oblast Hospital Drug Information Center and the Ryazan State University Drug Information Center support each others activities?*
- *What is the nature and extent of collaboration between RPM oblasts?*

7) Sustainability: The long term sustainability of RPM activities depends on the effectiveness of the interventions in creating and strengthening host country capability. RPM has used a combination of strategies including curricular reform, formation of permanent committees and departments, establishment of drug information centers, policy and legal reform, and extensive involvement of stakeholders. Questions to consider include:

Are host country counterparts and institutions better able to carry out their work as a result of RPM interventions? How have collaborating institutions been strengthened technically or structurally? Have RPM country programs stimulated the adaptation & implementation of related pharmaceutical management initiatives on the part of host country nationals and institutions, donors and other contract organizations? To what extent are collaborating institutions functioning autonomously?

(Additional Russia specific)

- *Is it feasible to "roll out" the RPM-related curricular changes made at the Ryazan Medical University to other universities? Would curricular changes have been possible if the project had not established the information-education center at the university?*
- *What factors contributed to the passage of the Novgorod Oblast State Public Health Law and formation of formulary and tender committees and departments? Was there resistance to the formation of these official bodies and, if so, how was it overcome? What effect did institutional changes have on project implementation?*
- *Is institutional change necessary as an adjunct to capacity building to sustain RPM activities?*
- *Is it feasible to transfer RPM accomplishments in participating oblasts to the federal level?*
- *How did USP's commercial contract with the PHARMEDINFO support RPM's goal of sustainability in the area of drug information?*
- *Are the Russian advisory groups established by RPM providing ongoing review of the adapted database?*

B. Project Organization and Management

1) Management Structure: The way in which staff are organized to carry out their work contributes to the project's overall effectiveness. Questions to consider include:

What is the organizational structure of the project? How does this structure serve the requirements of the project design? How have MSH and USP worked together to implement the project? How can communication and coordination between MSH and USP be strengthened in the future? How does RPM, as organized, respond to the needs of USAID missions and country programs? Of USAID Washington? Of other USAID projects? Is communication and responsiveness generally satisfactory? How has the MSH Rosslyn office enhanced RPM's ability to accomplish its objectives? What levels of staffing have been devoted to RPM activities by MSH and USP? What changes in staffing might be needed in the future?

(Additional Russia specific)

- *Has the MSH Russia office made RPM better able to establish and strengthen linkages with other projects or Russian organizations? Is maintaining the office cost effective compared to other ways the project might have been organized?*
- *Was staffing for RPM/USP adequate to initiate, support and monitor activities in all three oblasts?*
- *Was staffing for RPM/USP adequate to implement central events in Moscow?*
- *What changes in staffing might be needed in the future?*

2) Financial Management: The capacity of staff to direct financial resources toward their intended purposes, and account for their use, is another determinant of project effectiveness. Questions to consider include:

How does RPM manage budgets and track financial resources? How do current methods comply with USAID's monitoring and reporting requirements? Does RPM have appropriate and sound cost controls in place? As the project was designed, are there any terms of the cooperative agreements that cause problems with financial resource management?

3) Role of USAID: The two preceding topics tend to focus on the management capacities of the collaborating agencies. An assumption in RPM's design has been the "substantive involvement" of USAID in project management. Questions to consider include:

What has been the nature of USAID's involvement in project management? How has USAID contributed to fulfillment of RPM's objectives? What changes might be called for on the USAID side to strengthen project management? Would the institutionalization of a joint RPM annual work plan and report strengthen USAID's ability to better focus project activities?

C. Adjustment to Changes within the USAID Environment

1) Shift in Funding Mechanisms: An important assumption of the project design was that RPM would have substantial core funds to allocate to both country and central level activities, in accordance with its technical mandate. In 1994, however, USAID implemented a major reform, two consequences of which were: RPM's core funding to the CAs was dramatically reduced, and the CAs were instructed to seek the funding required for country level work from individual USAID missions through "field support" allocations. RPM's responses to these developments is a determinant of its ability to function effectively in a changed environment. Questions to consider include:

Overall, how has RPM adjusted to the change in USAID funding strategies? Now that RPM's financing comes substantially from USAID missions, based on their perceptions of need, has the project been able to preserve a program of activities that is appropriate in terms of the original scope and purpose? Is there evidence that RPM has been able to influence priorities at the mission level, and create demand for work in the pharmaceutical sector? Are there trends in demand from USAID missions that suggest important new areas of activity for RPM? Are there important features of the original design for which demand is less than expected? How were the CA tools development and dissemination activities affected by the reduction in core funding?

(Additional Russia specific)

- *Given the economic, social and political changes that occurred in Russia during the life of the project, would RPM have been successful if funds had been provided through a contract mechanism?*

2) Resource Allocation by Strategic Objective: In 1996, USAID defined four "strategic objectives" for the PHN Center. This development led to specific consequences for project design and implementation. The most important is that allocation of resources at both central and country levels to individual projects is now contingent upon the degree to which those projects contribute to achievement of strategic objectives. A related development is the use of "intermediate results packages," or focused programs of activities designed to lead to achievement of the objectives, as the building blocks of project design. The extent to which RPM's work contributes to strategic objectives, and the ability of the project to articulate its project plan into results packages is a determinant of its capacity to function effectively in the current environment. Questions to consider include:

To what extent does RPM support the PHN Center's strategic objectives? Has the project been responsive in formulating its plan to support the strategic objectives specified by individual missions?

3) Appropriateness of Mandated Project Activities: This issue overlaps with many of the topics listed above. The project design, as articulated in the *various Program Descriptions*, assumes the appropriateness and viability of a range of specific activities. Almost five years have passed since RPM began its work. Looking to the future, it will be important to understand which activities retain greatest relevance to needs at both central and country levels and what new interventions are necessary. Questions to consider include:

What lessons have been learned about demand for and the appropriateness of the different activities undertaken by RPM? Which activities have proven most successful? What are the reasons for these outcomes? How has the shift in USAID funding strategies described above affected the implementation of the program as designed? Has funding been sufficient to carry out the program of activities originally proposed?

D. Impact of RPM on MSH and USP

An objective of the RPM Project has been to strengthen the capacities of the two collaborating agencies to carry out their work in pharmaceutical management. It is important therefore to consider if and how MSH and USP have been strengthened. Questions to consider include:

How has RPM affected the capacity and technical capabilities of the two cooperating agencies? What specific technical activities outside RPM have been strengthened or enriched through RPM? To what extent have the tools developed by RPM been disseminated and applied beyond the RPM country programs by USP, MSH and other organizations?

E. Recommendations for the Future

1) Technical Priorities: USAID expects to extend the RPM project for a period of two years. Following that, the agency may launch new initiatives in pharmaceutical management in support of strategic objectives. Taking into account all of the topics and questions listed above, it is important to identify the most productive paths to follow in the future. Questions to consider include:

Based on lessons learned and field needs, what should RPM's technical priorities be for the future? What are the activities for which RPM, and by extension USAID, have the greatest comparative advantage, and for which the project should assume primary roles in implementation? Are there activities in which RPM should be involved, but for which other organizations might take a lead role? Which, if any, of the activities in the original program description should be deleted or de-emphasized in future work? What activities should be added? What technical activities are likely to warrant core funding support? What levels of funding are recommended for the future, in terms of these core activities?

2) Project Management: Given an optimum portfolio of technical activities, it is important that project management be configured to implement them as efficiently as possible. Questions to consider include:

How can the RPM cooperating agencies best structure themselves for project management in the next two years? Is the information now generated by the monitoring system sufficient and appropriate for effectively managing the project? What changes in approaches to information management would be beneficial? What role should USAID play in ongoing project management?

6. Methods

A. Evaluation Team

Given the complex nature of pharmaceutical systems, the critical differences encountered in specific country settings, and the diverse manners in which RPM has worked to improve drug management, the evaluation will be conducted by an interdisciplinary team consisting of six - seven public health professionals with international experience. They will bring together diverse points of view on project management and content.

B. Information Sources

- **Document Review:** The evaluation team will review project documents including: Cooperative Agreements, annual and country work plans, monthly/quarterly reports, annual progress reports, financial reports, trip reports, training materials, manuals, and workshop proceedings.

- **Interviews:** The team will conduct interviews with Global/PHN, MSH and USP RPM staff, and collaborating organizations such as BASICS, FPLM, AIHA, World Bank, and WHO/DAP.

- **Country Visits:** Team members will travel to Nepal, Russia, Mozambique, Zambia, and Geneva. It is unlikely that all team members will visit each of these countries. Specific travel assignments will be made by USAID/Washington. For country programs not visited, the evaluation team should communicate with USAID missions to solicit their perceptions of RPM's contributions (see Attachment 1).

For the country visits, team members will visit with the organizations specified below:

Russia:

1. USAID/Moscow
2. RPM Moscow Office
3. Russian counterparts in Moscow, and RPM's three project Oblasts, as follows:

   A. Moscow: The Russian Center for Medical Technical Information (PHARMEDINFO), Ministry of Health, and the Russian State Medical University, Moscow Medical Academy;

   B. Ryazan Oblast (RPM Russia Project demonstration site): Public Health Department, Pharmaceutical Department, Ryazan Medical University, Oblast Clinical Hospital, Hospital #11, Oblast Children's Hospital, Skopin Rayon Hospital, Pharmacy #11, and Pharmacy #175, Clinical Hospital Drug Information Center, Drug Information Center of Ryazan Medical University;

   C. Novgorod Oblast: Public Health Department, Pharmaceutical Department, ASCO Insurance Company, Novgorod Pharmacia, Oblast Hospital Oblast, Children's Hospital, and the Oblast Veterans' Hospital, Oblast Hospital Drug Information Center;

   D. Pskov Oblast: Public Health Department, Pharmaceutical Department, Pskov Pharmacia, Oblast Hospital, Oblast Veterans' Hospital, City Hospital #1, and Pskov City Pharmacy #3, Drug Information Center of Oblast Hospital;

   E. Velikie Liuki Central City Hospital Drug Information Center;

4. Other relevant USAID funded projects:
   American International Health Alliance (AIHA)
   Partnership Project.

Mozambique:

1. USAID/Maputo;
2. Ministry of Health counterparts in the following departments: Pharmacy, Training (Formacao), MEDIMOC, Inspection (Inspeccao), and the National Quality Control Lab (LNCQM);
3. Other relevant USAID funded projects: the University Research Corporation (URC) Primary Health Care Program, and the UNICEF Essential Drugs Programme;
4. Other donors: Swiss Cooperation.

Nepal:

1. USAID/Kathmandu;
2. Ministry of Health counterparts in the Department of Drug Administration;
3. Other relevant USAID funded projects including the Child Survival and Family Planning Services Project and the AIDSCAP Project;
4. Other donors including WHO and GTZ;
5. Local NGO partners in the Drug Information Network of Nepal (DINoN).

Zambia:

1. USAID/Lusaka;
2. Ministry of Health Counterparts in the Department of Pharmaceutical Services, the Central Board of Health and Lusaka Urban District;
3. Other relevant USAID Projects including BASICS and the Family Planning Services Project;
4. Other donors including SIDA, DANIDA, Irish Aide and ODA.

Geneva: WHO Technical Staff