

**Central Asian Republics:
Final Report of the
Rational Pharmaceutical Management Project**

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Rational Pharmaceutical Management Project
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Executive Summary

Background

The Rational Pharmaceutical Management (RPM) Project was developed by the U.S. Agency for International Development (USAID) and has been implemented in more than 20 countries worldwide. The project provides technical assistance and training to public health specialists in improving the pharmaceutical sector. In the Newly Independent States (NIS), RPM has implemented programs in Russia, Ukraine, Moldova, and Kazakhstan.

From November 1998 to June 2000, RPM worked with Kazakhstan public health officials, regional pharmacy professionals, and the donor community to highlight the role of drug procurement and management in strengthening disease management. On request from the USAID Mission in Almaty, RPM provided short-term technical assistance, training, and facilitated policy dialogue in various aspects of drug management.

This report summarizes the RPM objectives, activities, and accomplishments of the technical assistance, followed by recommendations for further efforts in the region and lessons learned.

Objectives

The objectives of the RPM Central Asian Republics (CAR) program included:

- Increase local capacity in pharmaceutical procurement in order to—
 - Develop understanding of the drug procurement cycle and procurement techniques
 - Help local counterparts improve tuberculosis (TB) tender documents and processes
 - Observe TB tender and provide comments and recommendations
- Capacitate *oblast*-level managers in formulary system implementation approaches
- Capacitate *oblast*-level managers in conducting indicator-based pharmaceutical sector assessment, and use of pharmaceutical indicators for monitoring performance and outcome
- Initiate pharmaceutical policy options dialogue between national and *oblast*-level decision makers

Implementation Strategies

To achieve the set goals and objectives RPM used a variety of implementation strategies. Those included training workshops in drug procurement and cost-effective drug selection, hands-on technical assistance in developing standard bidding documents for national TB tenders, observation of the national TB tender and provision of comments and analysis, an indicator-based pharmaceutical sector assessment, and a policy options workshop.

Cooperation with Other Projects

RPM was instrumental in bringing together experts from the CAR-based, USAID-funded projects and building upon local expertise developed by those projects. The RPM CAR activities were carried out in collaboration with the USAID ZdravReform Project implemented by Abt Associates, and some activities at various times were carried out in collaboration with Project HOPE, the Academy for Educational Development (AED), World Health Organization (WHO), and Centers for Disease Control and Prevention (CDC). Collaboration was approved and received firm support from the USAID/Almaty Mission.

Accomplishments

The following major accomplishments and results highlight RPM's impact in Kazakhstan:

- Forty-one pharmaceutical sector professionals from nine NIS countries were trained in competitive procurement practices.
- Standard bidding documents and drug specifications compliant with internationally accepted procurement standards were developed for the National TB Program.
- RPM and several counterparts made suggestions to improve the mix of TB drugs being procured. As a result 83 percent of the drugs procured through the 1999 TB tender were DOTS (Directly Observed Treatment, Short-course)-compliant, up from 26 percent in 1998.
- Despite higher drug quality standards, prices for first-line TB drugs were 1.5 percent lower than in 1998. RPM observed that the 1999 TB tender was transparent and followed standard norms and procedures.
- More than 100 health workers from throughout Karaganda Oblast representing major hospitals and family group practices were trained in cost-effective drug selection and formulary system implementation.
- A pharmaceutical sector assessment was conducted in Karaganda Oblast that identified gaps in the oblast's pharmaceutical system and suggested possible actions to correct those problems.
- The draft program for developing drug policy and reforming the Karaganda Oblast pharmaceutical sector was designed and approved by the Karaganda Oblast decision makers at a policy options workshop that followed the assessment.

Drug management in Kazakhstan has been strengthened at both the national and oblast levels by the capacity-building activities described above. To make the RPM efforts sustainable, the present report outlines recommendations for further reforms of the pharmaceutical sector, including development of national and oblast drug policies, further improvements in tender practices, establishment of drug information centers, and the implementation of drug procurement and use monitoring mechanisms.

Acronyms, Initialisms, and Glossary

AED	Academy for Educational Development
<i>Akimat</i>	Oblast Administration
CAR	Central Asian Republics
CDC	Centers for Disease Control and Prevention
CHP	Center for Health Purchasing [<i>Densaulyk</i>]
DMIS	Drug Management Information System
DMTB	Drug Management for Tuberculosis
DRG	diagnosis-related group
DOTS	Directly Observed Treatment, Short-course
DUR	drug utilization review
EDL	Essential Drug List
ENI	USAID Bureau for Europe and the Newly Independent States
FDC	fixed-dose combination
FGP	family group practice
FTC	Formulary and Therapeutics Committee
GMP	Good Manufacturing Practices
KNCV	[Royal Netherlands Tuberculosis Association]
IUATLD	International Union Against Tuberculosis and Lung Disease
MDRTB	multidrug-resistant tuberculosis
MIS	Management Information System
MoHES	Ministry of Health, Education, and Sport (from late 1999, the National Agency for Health)
MSH	Management Sciences for Health
NIS	Newly Independent States
NIT	National Institute of Tuberculosis
<i>oblast</i>	[comparable to a U.S. state]
<i>rayon</i>	[comparable to a U.S. county]
RPM	Rational Pharmaceutical Management [Project]
SBD	standard bidding document
TB	tuberculosis
USAID	United States Agency for International Development
USD	U.S. dollar
USP	United States Pharmacopeia
WHO	World Health Organization

Program Overview

Background

In August 1998 the USAID Europe and Newly Independent States (ENI) Bureau requested that the Rational Pharmaceutical Management (RPM) Project develop a country program on pharmaceutical management in the Central Asian Republics (CAR). Initial findings showed that there was interest in procurement training within the CAR public health sector. Furthermore, RPM determined that pharmaceutical procurement processes recently used in Kazakhstan did not conform to internationally accepted norms. This was evident in the flawed process and outcomes of the 1998 Kazakhstan national tuberculosis (TB) tender. As a result, RPM recommended that pharmaceutical procurement systems in Kazakhstan be strengthened to improve procurement techniques, competition, and transparency, and that special attention be given to bolster the TB drug procurement process.

In August 1999, on the request from the USAID/Almaty Mission, RPM developed a country program that included training in cost-effective drug selection and procurement methods for *oblast*-level health managers. (An *oblast* is comparable to a U.S. state.) The program was concluded with an in-depth, indicator-based pharmaceutical sector assessment in Karaganda Oblast followed by a Pharmaceutical Policy Options Workshop.

Objectives

The RPM objectives and tasks in the CAR included:

- Increase local capacity in pharmaceutical procurement in order to—
 - Develop understanding of the drug procurement cycle and procurement techniques
 - Help local counterparts improve TB tender documents and processes
 - Observe the TB tender and provide comments and recommendations
- Capacitate oblast-level managers in formulary system implementation approaches
- Capacitate oblast-level managers in conducting an indicator-based pharmaceutical sector assessment and using pharmaceutical indicators for monitoring performance and outcome
- Initiate pharmaceutical policy options dialogue between national and oblast-level decision makers

Implementation Strategy and Major Activities

To achieve the set goals and objectives RPM used a variety of implementation strategies, which included the following:

- Training workshops in drug procurement and cost-effective drug selection
- Hands-on technical assistance in developing standard bidding documents (SBDs) for national TB tenders

- Observation of the national TB tender and provision of comments and analysis
- Training and hands-on assistance in conducting an indicator-based pharmaceutical sector assessment
- Financial support for collecting and analyzing the indicator data
- Dissemination of the assessment results, and assistance to local counterparts in developing the agenda for the policy options workshop
- Coordination of the USAID-funded projects in addressing the issues of pharmaceutical sector management
- Policy dialogue between the oblast and national-level governments
- Capacitation of oblast-level decision makers in developing a drug policy
- Dissemination of RPM materials on formulary system implementation and drug information developed during the RPM/Russia and RPM/Ukraine projects

The RPM training courses on drug selection and procurement were built around well-tested training modules based on the MSH/World Health Organization (WHO) book *Managing Drug Supply*. Use of Russian language materials and manuals developed by RPM during the 1993 to 1999 activities in Russia, Ukraine, and Moldova helped build an understanding of the RPM methods and approaches. The list of publications and materials used in and developed for the CAR program is in Annex 1.

RPM was instrumental in bringing together experts from the CAR-based, USAID-funded projects and local counterparts. Because RPM did not have permanent representation in the CAR, from the very beginning it was the RPM strategy to collaborate with international projects and build upon local expertise developed by them. In the environment of short program time frames and the unpredictable political situation in the CAR, the strategy allowed RPM to be flexible and react in time to the ever-changing situation. Almost all the RPM CAR activities were carried out in collaboration with the USAID ZdravReform Project implemented by Abt Associates, and some activities at various times were carried out in collaboration with Project HOPE, the Academy for Educational Development (AED), WHO, and the Centers for Disease Control and Prevention (CDC). Collaboration was approved and received firm support from the USAID/Almaty Mission.

Challenges Facing RPM CAR Implementation

The RPM Project faced some significant challenges as it implemented the Kazakhstan program, including the following:

- No mechanism exists for drug supply and supplier performance monitoring at the national or oblast level. Lack of the data impedes implementation of rational procurement mechanisms.
- Responsibilities for the implementation of the National TB Program are dispersed among various departments of the Ministry of Health, Education, and Sport (MoHES), and there is at present no mechanism to coordinate activities. Similarly, there is little harmonization of TB treatment policies and related activities between the MoHES and the National Institute of Tuberculosis (NIT).

- Frequent changes in the staffing and structure of public health management at the national level result in lack of institutional memory and consistency in political commitment. Identifying key health officials responsible for various aspects of the pharmaceutical sector was difficult.
- There is no permanent Tender Board in Kazakhstan; rather, every year different officials are appointed to conduct national tenders. Technical assistance in tendering procedures could not be sustainable.
- Geographic factors prevented RPM from wider involvement of national-level experts in RPM activities. (For example, the capital of Kazakhstan moved from Almaty to Astana, 1,200 kilometers away.)

Chronological Activity Timeline

RPM activities in the CAR began in 1994 with a reconnaissance trip by the RPM Director, and ended in May 2000 with a policy options workshop in Karaganda Oblast, Kazakhstan.

Table 1. Activity Timeline

Date	Activity
Feb. 1994	Reconnaissance trip to Kazakhstan
Nov. 1998	Reconnaissance and planning trip of the RPM Director to Kazakhstan and Kyrgyzstan
Jan. 1999	Regional CAR General Procurement Workshop in Alatau, Kazakhstan
Apr. 1999	Hands-on technical assistance in standard bidding document (SBD) development for the Kazakhstan national TB tender
June 1999	Training for Kazakhstan Tender Commission members in tender procedures
June 1999	Kazakhstan national TB tender observed and commented on by the RPM CAR Country Program Manager
Nov. 1999	Reconnaissance and planning trip to Karaganda Oblast, Kazakhstan
Jan. 2000	Workshop on cost-effective drug selection and procurement in Karaganda Oblast, Kazakhstan
Feb. 2000	Data collectors training seminar
Feb. 2000	Indicator-based pharmaceutical sector assessment in Karaganda Oblast, Kazakhstan
May 2000	Pharmaceutical Policy Options Workshop in Karaganda Oblast, Kazakhstan
June 2000	Project closed

Program Accomplishments

Increase Local Capacity in Pharmaceutical Procurement

Pharmaceutical procurement capacity at the local level has increased in three important ways:

1. By developing an understanding of the drug procurement cycle and procurement techniques
2. By helping local counterparts improve TB tender documents
3. By observing the TB tender and providing comments and recommendations

Developing an Understanding of the Drug Procurement Cycle and Procurement Techniques

Between 1994 and 1999 the Central Asian Republics implemented significant health sector reforms to improve the efficiency and quality of health care services in the region. These reforms included the privatization of retail pharmacies and wholesalers involved in the procurement and distribution of drugs, and the devolution of public-sector drug supply responsibilities from the national to the oblast level. As a result, local health authorities face decision making and managerial responsibilities for which they have little training.

In November 1998, Management Sciences for Health (MSH)/RPM Project received funds from the USAID ENI Bureau to address these and other issues in the CAR. RPM kicked off its programming in January 1999 with a Regional General Procurement Workshop in Almaty. The workshop's target audience was specialists involved in drug procurement for public health, and an emphasis was placed on TB drugs. RPM invited more than 40 participants from the CAR, Georgia, Armenia, Azerbaijan, Russia, Ukraine, and Moldova. The workshop was conducted in collaboration with Abt Associates, AED, and Project HOPE. The WHO sponsored the participation of seven health managers from Tajikistan.

Workshop Objectives

To achieve the program objective of developing local capacity in drug procurement, RPM developed the following workshop objectives:

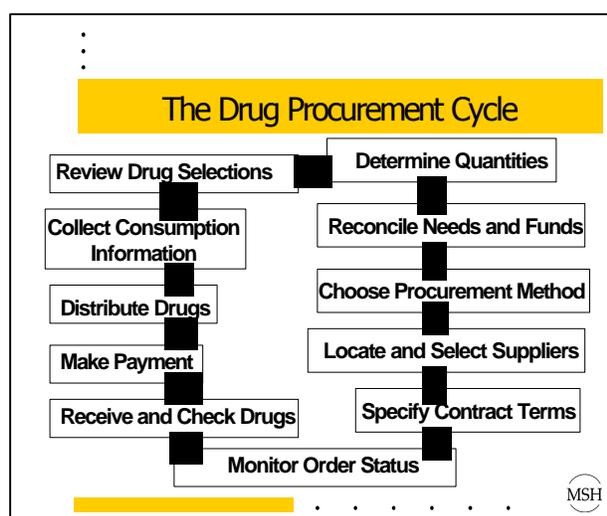
1. Explain the basic structure and components of the pharmaceutical management cycle and the components' relationships
2. Present the steps included in the drug procurement cycle and the four procurement alternatives (open tender, restricted tender, competitive negotiation, and direct purchase)
3. Highlight the components of a comprehensive quality assurance program and identify practical procedures for starting or improving programs
4. Illustrate the factors to consider in making drug selection for procurement decisions, using the example of antituberculosis drugs
5. Explain the need for, and essential components of, effective tender documents; identify ways to improve the documents
6. Present the criteria used to adjudicate drug tenders, and the importance of transparency in the tender process; identify ways to make the tender procedures more transparent and objective

7. Demonstrate the elements of an effective drug supply contract and identify ways to improve the contracts
8. Review consumption and morbidity-based drug quantification methods
9. Outline pharmaceutical procurement problems in the Newly Independent States (NIS) and identify the required assistance to work on those problems

Mode of Implementation

The workshop was conducted using lectures, interactive presentations, small group activities, discussions, and informational materials. RPM staff, speakers from the USAID-funded projects ZdravReform and Project HOPE, and representatives from Kazakhstan, Kyrgyzstan, and Russia delivered presentations on drug procurement issues.

Presentations and activities were followed by discussions in which participants had the opportunity to share experiences and questions.



Outcomes

Participation

RPM trained 41 procurement specialists from nine NIS countries in modern methods of drug supply management. In their professional capacities, 41 percent of participants are responsible for drug procurement at the national level, and 36.3 percent operate at the oblast and city level. Three participants represented the private sector, and three represented nongovernmental organizations.

Evaluation

Results of the workshop evaluation revealed that participants believed the training and information on procurement methods would be useful in their future activities (8.4 points on a 9-point evaluation scale). The evaluation also showed that confidence and knowledge in drug supply elements increased.

Interaction

Participants from nine NIS countries had the unique chance to share and compare approaches to solving pharmaceutical supply management problems.

Regional Impact

Following the workshop, two participants from the Public Procurement Institute in Moscow designed a course on competitive drug procurement for procurement agencies in the Russian public health sector. The course was based on the materials provided by RPM at the workshop.

Outputs

Workshop Materials

RPM developed a package of workshop materials for the participants, including a Russian translation of “Managing the Tender Process” from *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals*.

Proceedings

RPM published proceedings (Zagorski and Gabra 1999) shortly after the CAR General Procurement Workshop. The proceedings include a summary of problems with the CAR pharmaceutical sector identified by workshop participants, as well as an RPM proposal for further activities in the CAR.

Helping Local Counterparts Improve TB Tender Documents

Rates of TB, and particularly of drug-resistant TB, have reportedly reached epidemic levels in Kazakhstan. Public health officials and donors alike have expressed concern over the lack of TB drug availability and have dedicated significant time and resources to exploring methods of alleviating the spread of TB in the region. RPM proposed that more effective procurement practices and drug management could ameliorate the TB drug availability situation.

Recently, two important health sector policy initiatives were approved in Kazakhstan that pertain to TB drug management and availability—

1. In 1997 a National TB Program was adopted that declared WHO’s Directly Observed Treatment, Short-course (DOTS) standards mandatory for treating tuberculosis. DOTS treatment guidelines have proven to be cost-effective and successful, and many countries have adopted this intervention methodology.
2. In 1998 the Law of the Republic of Kazakhstan on Public Procurement was passed, which requires the use of competitive practices when purchasing commodities with public funds. TB drug procurement would fall within this rubric.

The first Kazkh national TB tender using DOTS guidelines was conducted in August 1998 and reportedly resulted in the procurement of a large number of low-quality TB drugs that were then poorly distributed. Since there was no official reporting or documentation of the drug quality or the distribution effort, this could not be confirmed. However, RPM reviewed the 1998 TB tender

documents and discovered several significant deficiencies that could have resulted in the purchase of inferior drugs and services. In addition, the results could be attributed to the MoHES's limited capacity to conduct competitive procurement.

The RPM Project was asked to provide technical assistance in TB drug procurement to the Kazakhstan MoHES, USAID, the National Institute of Tuberculosis (NIT), and other parties involved in the Kazakhstan TB tender scheduled for June 1999. This work began with direct technical assistance provided by RPM in April and June 1999. RPM also observed the TB tender in June 1999, although the latter activity falls under RPM Objective 3.

Mode of Implementation

To meet the objective of improving TB tender documents and processes, RPM Senior Program Associate Michael Gabra visited Kazakhstan in April 1999 to provide direct technical assistance and hands-on training to parties involved in the TB tender scheduled for June 1999. Specifically, Gabra identified omissions of standard tender components from the 1998 TB tender document, incorporated the missing components into the 1999 draft TB tender document, reviewed the TB drugs chosen for the 1999 tender by the NIT, and submitted a draft generic standard bidding document (SBD) for pharmaceuticals to the MoHES.

To begin the process of familiarizing the parties with proper procurement techniques and to discuss issues of specific relevance to the TB tender, RPM met with representatives from the MoHES, NIT, USAID, WHO, and the ZdravReform Project. During this meeting the group discussed several topics related to the TB tender and to the pharmaceutical procurement system in Kazakhstan. The overarching concern expressed was that the tender document for the June 1999 TB tender be improved and adjusted to meet internationally accepted standards for pharmaceutical procurement. Recommendations produced at the meeting include:

- Full and coordinated implementation of the WHO DOTS strategy by the MoHES and NIT
- Reconcile the TB drugs recommended by WHO DOTS and those listed for purchase by the NIT, ensuring proper quantification of TB drug needs
- Support adequate pharmaceutical sector legislation and registration policies
- Modify the language of the TB tender document to ensure the quality of the drugs procured
- Improve the management, distribution, and monitoring of TB drugs

RPM made a thorough analysis of national procurement legislation and the 1998 TB tender documents. After the gaps had been identified, RPM suggested a set of additions and changes to the 1999 tender document to improve the procurement process and bring it into compliance with accepted international standards. A total of 21 additions and changes were suggested that addressed such important aspects of tendering as—

- Bidder eligibility
- Definition of domestic manufacture and priority
- Qualifications of manufacturer
- Bid bonds and performance bonds

- Product samples
- Technical specifications for each product
- Packing requirements
- Shelf life of goods and expiry date
- Analysis and inspection by the national laboratory
- Labeling requirements
- Good Manufacturing Practices (GMP) and other quality considerations
- Corrupt or fraudulent practices
- Primary and secondary awards and contracts

The Kazakhstan Tender Commission accepted 15 of the 21 suggested improvements. Two omissions, however, require close attention as they may have significant impact on product quality and availability.

1. The TB Tender Commission did not require that potential suppliers submit product samples for laboratory testing, nor did it allow enough time for the National Laboratory to perform tests had the samples been submitted. In a part of the world where TB rates are growing dramatically, largely because of reported poor drug quality, laboratory analysis of TB drugs is crucial.
2. The TB Tender Commission does not plan to sign contracts with second-best suppliers to secure an uninterrupted drug supply in case the winner defaults. Contracts in which the secondary supplier agrees to fix the award price for the duration of the contract is standard international practice and has proven to be very useful. In some countries awards are split between the winner and second-best supplier.

Outputs

RPM assistance led to the development of tender documents free of most of the major omissions found in the 1998 TB tender documents. With the additions proposed by RPM and accepted by the TB Tender Commission, the 1999 Kazakhstan TB tender documents are in compliance with internationally accepted standards (e.g., The World Bank's *Standard Bidding Documents: Procurement of Pharmaceuticals and Vaccines*, trial edition September 1993; reissued 1996 and 1997).

The following documents and materials were developed with RPM assistance:

- Generic standard bidding document template
- Instruction for bidders
- Drug specifications recommendations
- Spreadsheets for supplier prequalification
- Spreadsheet for tender adjudication
- Templates for tender protocols

- Contract template
- Principles of good procurement practices
- Development of a job description for an in-house Kazakh procurement specialist

Observing the TB Tender and Providing Comments and Recommendations

Preparation for the Tender

Tender commissions in Kazakhstan are *ad hoc* bodies, and members sometimes have limited procurement experience. In the case of the 1999 TB Tender Commission, only two of the members had been involved in the 1998 TB tender and could rely on their previous experience.

Since many of the members of the MoHES Tender Commission were not familiar with tendering procedures and documents, RPM was asked to conduct a brief 1–2 day training to cover this gap. This training was conducted by RPM CAR Country Program Manager Andrei Zagorski in Almaty, Kazakhstan, in June 1999, one day prior to the actual national TB tender.

On the request of the Tender Commission, special attention was given to contracting suppliers for TB drugs. Correct contracting may ensure adequate supplier performance and drug quality. The following issues were covered during the training:

- Tender drug nomenclature and technical specifications
- Instruction for bidders and bidding documents
- Bid opening and evaluation procedure
- Tender adjudication process—
 - Preliminary examination
 - Evaluation and comparison of bids
 - Domestic preference
- Award of contract
- Signing of contract
- Drug supply quality assurance—
 - Supplier performance monitoring
 - Drug quality monitoring and reporting
 - Requirements for Drug Management Information System (DMIS)
 - Types of reports required for rational drug management

In addition, RPM worked with the head of the Drug Policy Department of the MoHES, who is also the head of the TB Tender Commission, and recommended that the following additions be made to the final contracts with winning bidders:

- Prices should be fixed for the duration of the contract period.
- Drug specifications should be listed in a separate attachment (not simply a reference to the Instructions for Bidders).
- Packaging standards should be part of the contract.
- Drug quality requirements—

- Laboratory tests are the responsibility of a supplier.
- Each batch and lot should have quality certificates.
- Labeling requirements should be specified.
- Drug information format should be specified (contents and language).
- A delivery schedule should be developed and be part of the contract.
- Fines for late delivery or substandard quality should be identified and agreed upon.
- A clause on corrupt or fraudulent practices should be added.

The RPM consultant reiterated the recommendation that contracts should be signed with the second-best bidders to fix the price and quantities in case the winner defaults.

Regional Impact

At the request of the USAID Mission, the head of the Procurement Department of Fergana Oblast in Uzbekistan attended RPM training in preparation for the Fergana Oblast pooled competitive procurement.

The 1999 TB Drug Tender

As previously mentioned, the 1998 national TB tender reportedly resulted in the procurement of low-quality drugs at high prices. At the time of the tender there was significant controversy about transparency in the tender process and contract awards. To mitigate such problems in the 1999 TB tender, the USAID Mission in Kazakhstan requested that RPM assistance in developing tender documents and training in the tender processes be followed by observation of the actual TB tender. USAID also requested that RPM provide recommendations to the TB Tender Commission during and after the tender process.

The Republic of Kazakhstan allocated 274 million tenge to procure TB drugs for the National TB Program. At the exchange rate of one U.S. dollar (USD) to 132 tenge, this equaled \$2,075,757. The TB tender took place in Almaty on June 22–23, 1999.

Mode of Implementation

RPM CAR Country Manager Andrei Zagorski observed the 1999 TB tender and provided comments and recommendations.

Tender Process

The 1999 TB tender was transparent and conducted in accordance with internationally accepted procedures. No complaints on the tender process were filed by any of the potential suppliers or observers.

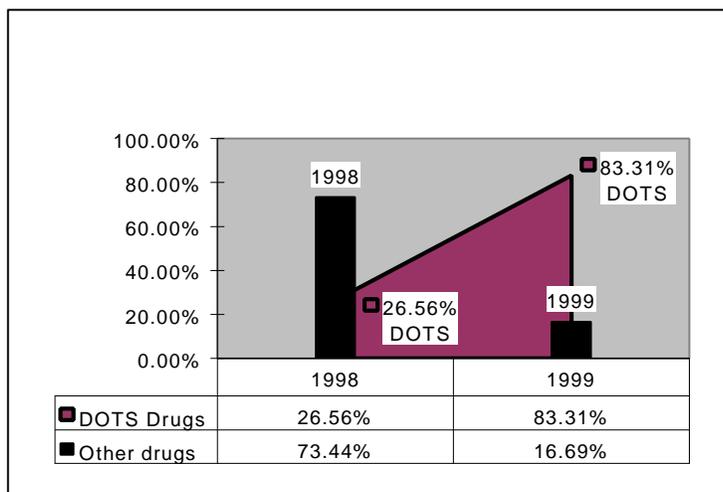
Tender Outcomes

Drug Products Compliant with WHO DOTS Guidelines

Through the 1999 TB tender, Kazakhstan procured ten TB drugs, 83.31 percent of which (by value) were first-line TB drugs, and 16.69 percent of which were second-line TB drugs used to treat drug-resistant TB. It should be noted that all the drugs procured through the 1999 tender are compliant with WHO DOTS standards.

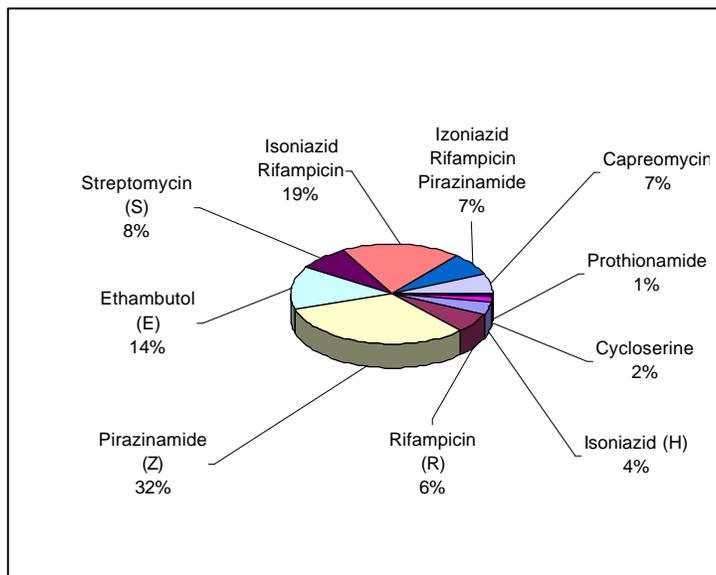
In contrast, in the 1998 TB tender, which was expected to effectively initiate implementation of the WHO DOTS program, this did not happen due to a lack of the drugs necessary to launch the program. For example, of all the drugs purchased in 1998, only 26 percent by value were in compliance with DOTS standards. The situation changed in 1999. Figure 1 illustrates changes in the proportion of DOTS-compliant versus non-DOTS-compliant drugs in 1998 and 1999.

Figure 1. TB DOTS Drugs in 1998 and 1999 Tenders



The mix of drugs in the 1999 TB drug procurement represents a considerable step toward rational TB drug use. Figure 2 illustrates the breakdown by value for each drug product of the 1999 TB drug tender. However, RPM was concerned that the MoHES would insist on direct, single-source procurement of fixed-dose combination (FDC) Myrin (HRE). In the 1998 TB tender, FDC Myrin accounted for 62.45 percent of funds allocated for the TB drugs, despite its noncompliance with DOTS standards. RPM suggested that the MoHES instead purchase vital first-line drugs with the remaining funds to be better equipped to effectively treat new TB cases.

Figure 2. Drugs Involved in the TB Tender 1999



Product Quality Standards Improved

The Drug Policy Department of MOHES informed RPM of significant problems with the quality of TB drugs procured through the 1998 tender. According to the department, TB facilities complained about late deliveries by suppliers, decomposition and malodor of tablets, and notably low efficacy of the products. These complaints, however, were not recorded officially, and it is not possible to identify the suppliers with poor performance.

RPM determined that the deficient tender documents and drug specifications discussed above may have contributed to the low quality of TB drugs procured in 1998. For 1999, with improved tender documents, strict supplier prequalification criteria, and clear drug specifications, TB drugs were procured from manufacturers of high international standing, such as Novartis, GlaxoWellcome, Eli Lilly, and Sanavita. However, if drug quality standards are not enforced in contracts with suppliers and through supplier performance monitoring, there is no guarantee of drug quality even from reputable international suppliers.

Product Prices Reduced

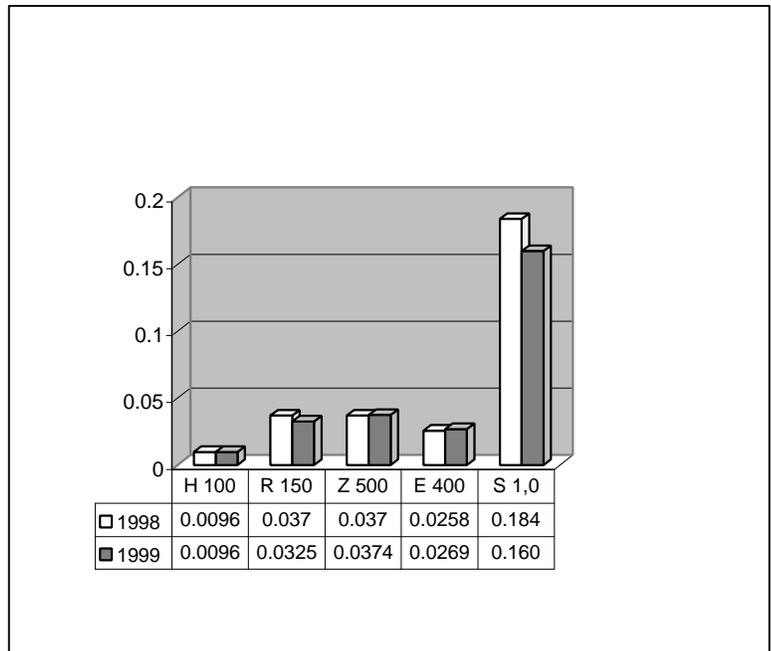
Of fifteen potential suppliers that purchased tender documents only eight actually submitted bids. This was because new 1999 tender requirements called for higher drug quality standards (WHO GMP certificate, registration in the country of manufacture, pharmacopeial standards, etc.), so fewer suppliers were likely to qualify. With the reduced number of potential suppliers, the TB Tender Commission expected significantly higher prices than in the 1998 tender. However, the price of first-line TB drugs was actually reduced.

RPM compared the prices paid (in USD) for TB drugs for 1998 and 1999. Figure 3 illustrates the changes in prices (in USD) between the 1998 and 1999 TB tenders for first-line TB drugs.

Using 1998 and 1999 TB tender prices and 1999 drug quantities, RPM calculated that 1999 USD prices for first-line TB drugs were reduced by 1.5 percent from 1998 levels. This 1.5 percent price reduction could be attributed to larger pack sizes specified in tender documents (1,000 tablet bottles instead of 20 or 100 tablet blisters in 1998) and to larger quantities of products put on tender in 1999.

This price reduction suggests high cost-effectiveness of the 1999 TB tender,

Figure 3: First-Line TB Drugs: Price Comparison



especially since the drugs will likely be of better quality and efficacy than those procured in 1998.

Capacitate Oblast-Level Managers in Formulary System Implementation Approaches

In November 1999, the MSH/RPM Project met with the USAID Mission in Kazakhstan to finalize the RPM CAR workplan. The USAID Mission provided RPM with funds for work at the oblast level. Karaganda was chosen as the work site to train hospital and family group practice (FGP) physicians in cost-effective drug selection, use, and procurement, and to conduct a pharmaceutical sector assessment and policy options workshop.

Workshop: “Cost-effective Drug Selection and Formulary System Implementation in Oblast Hospitals and Family Group Practice”

The workshop was conducted from January 26 to 28, 2000, in Karaganda by the RPM Project in collaboration with the USAID/CAR ZdravReform Project, Karaganda Oblast Health Administration, and the Karaganda Medical Academy. Sixty-six invited participants represented major oblast hospitals and FGPs. The estimated total number of health workers who attended the workshop was more than 100.

Objectives of the Workshop

The objectives of the workshop were to give participants an understanding of the basic structure and components of the pharmaceutical management cycle, aspects of stepwise formulary system implementation, cost-control strategies, formulary-based drug procurement, and the important factors influencing drug quality and safety.

The main emphasis was on the necessity of developing a working mechanism of cost-effective drug selection for use and procurement in various public health settings and medical insurance.

Topics:

- Drug Management Cycle
- Formulary Drug Selection based on:
 - Cost-effectiveness
 - Efficacy
 - Safety
- Formulary-Based Procurement
- Competitive Procurement
- Rational Drug Use

Mode of Implementation

The workshop objectives were achieved through lectures, discussion, and provision of materials, including the MSH/RPM-developed *Manual for the Development and Maintenance of Hospital Drug Formularies* and *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals*, a Russian language version of the United States Pharmacopeia’s *Drug*

Information for the Health Care Professional, and a reference on drug synonyms. Presentations were delivered by MSH RPM staff, a speaker from the USAID ZdravReform Project, representatives from the Karaganda Oblast Health Administration, and academicians from the Karaganda Medical Academy. Presentations were followed by discussions in which participants were given a chance to share their experiences and questions.

Outcomes

Karaganda Oblast has been a pilot site for a number of USAID projects, and it is anticipated that future projects will continue to address existing problems in the development of drug policies, rational drug selection, use, and procurement. The workshop exposed a large audience of oblast health workers to modern methods of addressing pharmaceutical sector problems, thus laying the foundation for the USAID-sponsored technical assistance to come.

The workshop was very well received, and was covered by local radio and TV stations. Interviews were given by the head of the Oblast Health Administration Dr. Ermekbaev, RPM CAR Country Manager Andrei Zagorski, ZdravReform Project consultant Dr. Nurgozhin, and Dr. Khe, head of the Oblast Center for Health Purchasing Densaulyk. The speakers outlined objectives of the workshop, the forthcoming pharmaceutical sector assessment, and the role of USAID-funded projects in health reform in the Republic of Kazakhstan.

Capacitate Oblast-Level Managers in Conducting Indicator-Based Pharmaceutical Sector Assessment and in Using Pharmaceutical Indicators for Monitoring Performance and Outcome

Pharmaceutical supply systems in many countries have inefficient or ineffective drug management procedures that negatively affect the availability of drugs and cause irrational use of those drugs that are available. As a result, oftentimes negligence in the pharmaceutical sector results in the failure of health sector reforms. No matter how well trained a medical staff may be, if drugs are not available or not affordable to patients, the health system suffers.

In Kazakhstan, a country that is transitioning to a market economy, there are many gaps in supplying drugs for public health, and the government needs possible options for ameliorating these problems. This pharmaceutical sector assessment measures the extent of the supply gaps, provides information for identifying possible solutions, and serves as a baseline against which to measure any subsequent interventions.

Assessment Objectives

The Karaganda assessment had the following objectives:

- Identify areas of irrational drug management in the pharmaceutical supply system with respect to selection, procurement, distribution, and use of drugs, including aspects of finance, policy, and law, as they affect drug management.

- Provide data that will give the USAID Mission an understanding of the pharmaceutical sector problems encountered in Karaganda Oblast.
- Provide Karaganda Oblast officials with a report on the status of the local pharmaceutical sector and identify options to address problems identified in the assessment.
- Describe the public/private-sector relationship and identify opportunities for increasing the role of the private sector.

The study team comprised Andrei Zagorski, RPM CAR Country Manager, and Marina Semenchenko, Senior Program Associate, both of MSH.

Data collectors consisted of physicians, pharmacists, and interns provided by the Center for Health Purchasing (CHP) Densauyk and by the Karaganda Medical Academy. Their role was to collect data at selected oblast and *rayon* (county) health facilities and pharmacies.

The assessment report was written by RPM staff and reviewed internally by RPM and externally by the Oblast Health Administration and CHP Densauyk.

Methodology

Assessment objectives were achieved through collection of background information, document review, structured interviews with key informants, structured collection of indicator data, and ABC/VEN analysis of procurement drug lists.

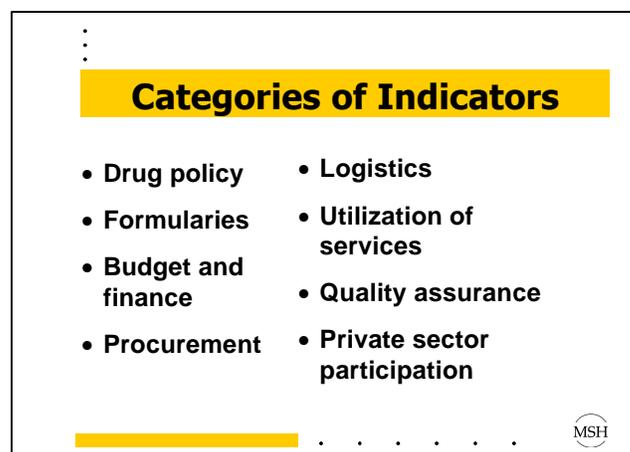
Tools

The assessment tools used in Karaganda Oblast were developed by modifying the structured questionnaires used in earlier RPM assessments in Russia. The indicators and sample forms contained in MSH's *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* were used for the collection of indicator data. The tracer drug lists were established in collaboration with Karaganda Oblast pharmaceutical experts during the Data Collectors Training Workshop, conducted in Karaganda in January 2000, prior to the assessment. The assessment tool contained the following components:

- Questionnaires used to interview key informants at the Oblast Administration, Oblast Health Administration, and health facilities
- Data collection forms, including—
 - Drug Use Data Form
 - Inventory Data Form
 - Stock-out Data Form
 - Price Comparison Data Form
 - Tracer drug lists

Pharmaceutical Indicators

The indicators used in the assessment are standardized measurements of a local pharmaceutical system. RPM has field-tested these indicators in several countries and regions, and used them to conduct three oblast assessments in Russia. Indicators can be used to compare the effectiveness and performance of health systems between countries or oblasts, or alternatively they can serve as baseline data against which the results and impacts of reforms and interventions can be measured within one health system. The latter was the purpose of the present assessment.



The assessment was the first systematic indicator-based survey conducted in Kazakhstan. It is expected that the indicator data will be used as a reference to measure future performance of the national pharmaceutical sector and of the health sector reforms implemented by Kazakhstan within the framework of USAID-funded projects.

Tracer Drugs

A number of indicators used in the study were measured using tracer drug lists. The indicators related to procurement, stock management, drug availability, and drug prices. Although ideally, data would have been collected on all drugs flowing through the system, such a thorough investigation would have required greater time and effort than was available. Therefore, prior to the assessment, two standard tracer drug lists were developed—one for the hospital survey and the other for the survey of primary health care (PHC) facilities and private pharmacies.

The lists were developed by local and RPM experts. The selected drugs represented major therapeutic categories. The drugs were not necessarily the most safe and efficacious from the point of view of international evidence-based practice, but rather those commonly used in the oblast. Drugs were identified by generic names. All selected drugs were also on the Kazakhstan Essential Drug List (EDL). To facilitate data collection based on the tracer drug lists, RPM provided data collectors with the latest edition of the reference *Synonyms of Pharmaceuticals*.¹

Selection of Assessment Sites

Sites for the survey were selected in collaboration with the Oblast Health Administration, which suggested focusing on those facilities that were its top priority of interest. These facilities comprised the seven largest public hospitals at the oblast and rayon levels, and five PHC facilities (including state and private FGPs, and an independent private polyclinic). All those facilities served an urban population (83 percent of the total oblast population). Some data were collected at a small private hospital and are used for illustrative purposes in the report. Note, however, that these figures are not included in the indicator data. In addition, the assessment

¹ *Synonyms of Pharmaceuticals* by G. Shashkova, V. Lepakhin, G. Kolesnikova. Russian Center “Pharmedinfo,” Moscow, 1999.

results do not reflect the situation in the pharmaceutical sector in rural areas.

Data on drug prices and availability were also collected at 25 randomly selected retail pharmacies in Karaganda and Jezkazgan cities and at the private drug wholesaler Pharmacia.

Data Collection and Processing

The assessment data collection was performed February 1–15, 2000, by 20 data collectors trained by RPM. Data collectors gathered quantitative data and interviewed key informants at the facility level. Computer specialists from CHP Densaulyk then entered the data into Excel spreadsheets, calculated the indicators, and generated summary tables and graphs. Interviews with key informants at the oblast administrative level and collection of background information were performed by the RPM staff.

Key Assessment Findings

A summary of key assessment findings is as follows:

- Karaganda Oblast does not have a clearly defined oblast-specific drug policy that would address all aspects of the drug supply system including selection, procurement, distribution, and use of pharmaceuticals.
- Existing oblast financial mechanisms do not ensure availability and affordability of essential drugs for patients in the public health sector.
- Lack of specific drug formularies for exempt patients is an impediment in ensuring the availability of vital drugs in the face of diminishing health budgets.
- Reimbursement to hospitals based on diagnosis-related groups (DRGs) is seriously undermined by the lack of accepted and approved standard treatment guidelines.
- Oblast competitive drug procurement procedures are not transparent and lack mechanisms to ensure drug quality and supplier compliance with contract prices.
- The latest version of the national EDL and accompanying manual developed by the USAID ZdravReform Project are not available at oblast facilities, and they are not followed by physicians in their prescribing practices.
- The national EDL and FGP formulary do not perform their function of ensuring that cost-effective, efficacious, and safe drugs are procured and used for treatment.
- Drug prices and treatment costs are not controlled and are very high at all levels of the oblast health system. A decrease in the number of patient visits to PHCs and in hospitalization rates, along with an increase in overall morbidity in 1999 as compared to 1998, may be attributed to the high costs of drug therapy.

- The lack of drug price control policies make pharmaceuticals very expensive in the private retail sector.
- Serious gaps were identified in stock management and pharmaceutical services in hospitals.
- There are no mechanisms in the oblast to control drug use at all levels of care. As a result, polypharmacy is a general trend that results in irrational treatment, expensive for both patients and the oblast health system.
- The oblast health management information system (MIS), currently being developed by local experts, may serve as a basis for the development of a drug management information system (DMIS) that would assist the oblast in the development of its drug policy and control.
- Evidence-based, unbiased drug information is not available to prescribers or patients.

Policy Options and Possible Interventions

Based on the assessment findings RPM suggested a number of interventions and activities to address the identified gaps. The proposed suggestions were grouped as short, medium, and long term.

Short-term activities are those that the Oblast Health Administration could conduct without external technical assistance, relying only on local capacity. Such interventions could be developed and implemented in one to six months.

Medium-term activities and interventions may require some technical assistance from international experts, but, if properly managed by the oblast, may also build upon existing local expertise. It will take more time to implement these interventions, up to approximately two years.

Long-term interventions include systemic changes to the pharmaceutical sector, and these will require changes in oblast legislation, as well as extensive technical assistance and international expertise.

It should be noted that the suggested activities were intended to serve as a point of departure for discussion at the policy options workshop, rather than as concrete recommendations.

Short-Term Activities

- At the Oblast Administration level, revise tender documents and include pharmaceutical specialists as permanent members of the Oblast Tender Board.
- Establish a Formulary and Therapeutics Committee (FTC) at the Oblast Health and facility levels (hospitals and FGP associations), and develop the FTC policies and procedures as outlined in the MSH/RPM *Manual for the Development and Maintenance of Hospital Drug Formularies*. The Russian language edition of the manual is available in the oblast.

- Initiate pilot formulary drug selection at health facilities that have Karaganda Medical Academy departments (for example, Oblast Clinical Hospital, Oblast Children’s Hospital), and two FGP associations (one in Karaganda based upon Medical Academy departments, the other a private practice in Jezkazgan).
- Using the technical expertise of the oblast CHP Densaulyk staff and RPM assessment tools, develop a set of pharmaceutical outcome and performance indicators. Incorporate the pharmaceutical indicator data collection process into the existing CHP MIS network.
- Use pharmaceutical indicators to initiate outcome and performance monitoring of drug procurement and prescribing, and to ensure compliance with the Essential Drug List and eventually with pilot formulary lists.
- At the PHC level, working with two existing FGP associations, initiate prescribing by international nonproprietary name.
- Disseminate the latest versions of the national EDL and accompanying manual developed by the USAID ZdravReform Project, and drug information and management materials provided by RPM.
- Develop a formulary list of drugs for exempt patients.

Possible Outcomes

- It is expected that controlled selection, procurement, prescribing, and use will increase technical and operational efficiency and health outcomes of health facilities in pilot sites.
- Pharmaceutical indicator data will allow the Oblast Health Administration to analyze performance, trends, and changes in the sector and have a basis for deciding on corrective measures. Data collected from pilot sites may help to gain support of other facilities in the oblast.

Medium-Term Activities

- Disseminate results of short-term interventions in pilot sites

Elements of a Formulary System

Drug policy and legislation	Drug Utilization Review programs
Active Formulary Committee	Adverse drug reaction reporting and monitoring
Updated formulary list	Drug quality assurance program
Drug information services	Ongoing training

- Develop a schedule and initiate implementation of a formulary system² at the oblast and facility levels
- Establish an oblast Drug Information Center
- Implement drug utilization review (DUR) in pilot sites
- Develop and implement standard treatment guidelines that include specific drug treatment based on the oblast drug formulary for use in DRG-based reimbursement mechanisms
- Establish mechanisms of reporting adverse drug reactions and drug product quality problems
- Establish a drug management information system (DMIS)

Possible Outcomes

The activities described above are expected to improve the performance of the health system within its existing legal boundaries. With implementation of the proposed interventions, pharmaceuticals should become more affordable to patients and will be safer and more efficacious. Implementation of the proposed interventions does not require systemic changes in drug legislation and finance. However, other necessary reforms of the pharmaceutical sector may require systemic changes in legislation, finance, and organization.

Long-Term Interventions

- An oblast drug policy that addresses all aspects of drug selection, procurement, distribution, and use should take the shape of an enforceable law.
- The formulary system should become the core of pharmaceutical sector management.
- New mechanisms for health financing should be developed to guarantee access to health services, including pharmaceuticals, to the majority of population. Financing mechanisms should be performance-based, create incentives to providers to perform adequately, and develop competition between health facilities.

² *Formulary system* is a process whereby the medical staff of an institution, working through a Formulary and Therapeutics Committee, evaluates and selects from the numerous available drug products those that are considered most efficacious, safe, and cost-effective. A formulary system is a mechanism to streamline procurement activities, minimize institutional costs, and optimize patient care. Essential elements of a formulary system include a functional formulary committee, drug policies and legislation, a constantly revised and updated formulary drug list, drug information services, ongoing drug utilization review programs, reporting mechanisms for adverse drug reactions and drug quality problems, feedback mechanisms, and ongoing training and education of prescribers and medical staff.

Assessment Output

RPM produced the Karaganda Oblast Pharmaceutical Sector Assessment Report, which served as the basis for discussions at the Pharmaceutical Policy Options Workshop conducted in May 2000.

Initiate Pharmaceutical Policy Options Dialogue

In February 2000, the MSH/RPM Project conducted an indicator-based pharmaceutical sector assessment in Karaganda Oblast. The assessment data were analyzed and a report was developed during March–April 2000. The report presented assessment findings, identified gaps in the Karaganda Oblast pharmaceutical system, and suggested possible courses of action to correct problems in each area. The suggested activities were intended to serve as a point of departure for discussion at a policy options workshop that was conducted by RPM in Karaganda Oblast on May 25–26, 2000.

Policy Options Workshop

The workshop was conducted on May 25–26, 2000, in Karaganda, by the Rational Pharmaceutical Management Project in collaboration with the USAID/CAR ZdravReform project, Karaganda Oblast Health Administration, CHP Densauylyk, and the Karaganda Medical Academy. The workshop was the last RPM CAR activity.

The workshop discussions and activities were built around the findings of an indicator-based pharmaceutical sector assessment conducted by RPM in Karaganda Oblast in February 2000. The assessment report was translated into Russian, and 100 copies were disseminated among participants prior to the workshop.

Participants

Ninety-two invited participants represented the USAID/Almaty Mission, National Agency for Health, the Government and Parliament of Kazakhstan, Ministry of Economy, Oblast Administration (*Akimat*), Oblast Health Administration, the Karaganda Medical Academy, Center for Health Purchasing Densauylyk, directors of major oblast hospitals, and FGPs. The estimated total number of health workers who attended the workshop was more than 100.

Objectives

The workshop sought to accomplish the following:

- Discuss the results of the indicator-based pharmaceutical sector assessment and use the data and information to guide decision making
- Familiarize the national-level decision makers with pharmaceutical sector problems and oblast and sector needs to address these problems
- Discuss the basic structure and components of the pharmaceutical management cycle, and the components' relationships

- Identify drug policy components and discuss existing gaps and requirements
- Define the components and role of the formulary system in drug sector management and steps for its implementation
- Discuss the role of the MIS in decision making and discuss existing gaps
- Identify possible alternatives for pharmaceutical sector financing
- Draft a plan and steps for oblast drug policy development
- Draft a plan and steps for formulary system implementation
- Assess existing resources and identify pilot sites for formulary system implementation at the hospital and PHC levels

Mode of Implementation

The workshop objectives were achieved through wide plenary discussion of the assessment results and the development of implementation approaches in four work groups (Drug Policy Options, Pharmaceutical Sector Finance Options, Management Information System, and Formulary System Implementation).

Presentations on the assessment results were delivered by MSH/RPM staff, speakers from the USAID ZdravReform Project, representatives from the Karaganda Oblast Health Administration, and faculty from the Karaganda Medical Academy.

Work group activities were facilitated by RPM staff, the ZdravReform Project, Oblast Health Administration, and CHP Densaulyk.

Outcomes

The following is the workshop resolution drafted by the Drug Policy Work Group.

The workshop work groups drafted proposals for the Oblast Administration (Akimat) and the Oblast Health Administration on a number of activities at improving pharmaceutical sector efficiency. Those proposed activities included development of an oblast drug policy, implementation of a formulary system, and establishment of a drug management information system (DMIS) and drug information center.

Oblast Health Administration and Akimat also discussed the necessity of a special study to evaluate the feasibility and economic viability of establishing insurance-based financial mechanisms for the pharmaceutical sector.

DRAFT
Resolution of Policy Options Workshop
Karaganda Oblast Health Administration

May 25–26, 2000

The Karaganda Policy Options Workshop members discussed the results of a pharmaceutical sector assessment. The assessment was conducted jointly by the USAID Rational Pharmaceutical Management Project, the Karaganda Oblast Health Administration, CHP Densaulyk, the Karaganda Medical Academy, and the USAID ZdravReform Project. The assessment identified existing problems in the oblast pharmaceutical sector and outlined possible options for sector reforms.

In accordance with the laws of the Republic of Kazakhstan, Karaganda Oblast has the right to develop its own drug policy provided that it does not contradict national legislation.

Oblast Drug Policy

The oblast drug policy identifies the pharmaceutical sector objectives, sets priorities and outlines strategic approaches, defines principles of relationships between the public and private sector, and allows collaboration with nongovernmental organizations and international donors.

The Aim of Oblast Drug Policy

The main aim of the oblast drug policy is to ensure the availability of vital and essential drugs to the population.

Elements of Oblast Drug Policy

- Legislation and regulation
- Economic strategies for the drug supply system
- Drug Management Information System
- Human resources development mechanisms
- Formulary system

Objectives of Oblast Health Administration in Drug Policy Development

In order to achieve the aim of the oblast drug policy, the Oblast Health Administration needs to develop objectives for each element of the policy, as well as strategies and mechanisms for its implementation. To accomplish this, the following objectives are to be met in order to improve management efficiency and optimize pharmaceutical sector activities.

Legislation and Regulation

- Develop oblast regulatory acts in support of drug policy and the formulary system
- Develop a proposal on changes in national drug policies for the government
- Develop implementation strategies and establish enforcement mechanisms

Economic Strategies for the Drug Supply System

- Develop measures to increase competition in the oblast drug market
- Guarantee the rational use of funds for the procurement of vital drugs, including for exempt patients, through the development and implementation of restrictive drug lists (formularies)
- Explore opportunities for alternative funding sources for the drug supply (for example, through pharmaceutical insurance mechanisms, copay programs, and the private sector)
- Improve tender documents and procedures
- Develop a proposal at the national level to establish mechanisms for reinvesting monies saved in the oblast public health sector back into the sector

Drug Management Information System

- Establish a center for unbiased evidence-based drug information for prescribers and patients
- Develop and maintain a database on postmarketing drug monitoring, adverse drug reactions, and drug quality problems
- Develop and implement ongoing monitoring of the pharmaceutical sector based on performance and outcome indicators

Human Resources Development Mechanisms

- Identify the scope of work and responsibilities for a clinical pharmacologist position in health facilities whose job would pertain to drug selection and use processes
- Evaluate existing resources and develop training programs for oblast prescribers in rational prescribing and use in conjunction with the Karaganda Medical Academy, and with assistance from international projects
- Develop a network for exchanging experiences in pharmaceutical sector reforms with other oblasts and countries

Formulary System

- Optimize drug selection, procurement, and use on the basis of the oblast drug formulary and specific drug formularies of health facilities

Implementation Strategies

Step 1

- Establish a drug policy development work group
- Assign responsibilities for the development of drug policy elements
- Develop a plan and timeline for the development of the drug policy
- Analyze existing oblast and national legislation and regulation pertaining to the pharmaceutical sector and identify needs in legislation development
- Approve principles of a formulary system as the main strategy of the oblast drug policy
- Establish an Oblast Formulary and Therapeutics Committee (FTC)
- Establish an Oblast Drug Information Center
- Select pilot sites (hospitals and FGPs) and establish facility FTCs

Step 2

- Develop and approve the FTC policies and procedures
- Develop and approve principles, criteria, and mechanisms for formulary drug selection
- Develop and approve mechanisms of drug formulary use in pilot facilities for prescription and procurement
- Improve existing competitive procurement methods, including the following:
 - Review and improve standard bidding documents (SBDs)
 - Develop drug specifications to guarantee drug quality and safety
 - Develop mechanisms for domestic production support
- Explore opportunities for legislative support of nongovernmental, nonprofit drug purchasing groups (one such group could be established at the Karaganda Hospital Association, another at the Jezkazgan Association of Family Group Practices)
- Develop a proposal at the national level to establish a body for state control and monitoring of the pharmaceutical sector to ensure the quality and legality of drugs
- Develop a proposal at the national level to improve drug registration and licensing mechanisms in order to increase competition on the drug market
- Discuss the results of pilot formulary implementation oblastwide

Step 3

- Approve and implement a formulary system as the basis for drug policy and pharmaceutical sector management oblastwide. The key elements of a formulary system are as follows:
 - Functional FTCs at the oblast and facility levels
 - Existence of written policies and procedures that define the principles of drug selection, procurement, and use

- Existence of a regularly updated restrictive oblast drug list (formulary)
- Competitive drug procurement based on the formulary
- Formulary-based drug prescription in health facilities of all levels
- Reimbursement of health services (pharmacotherapy component) based on the use of formulary drugs
- Existence and availability of sources of unbiased evidence-based drug information
- Ongoing drug utilization review (DUR) programs
- Existence of reporting and monitoring mechanisms for adverse drug reactions and drug quality problems
- Existence of feedback mechanisms
- Ongoing training programs for prescribers and patients
- Finalize and pass the oblast Law on Drug Supply

Likely Needs at End of Project

General

All activities planned for RPM in the CAR were completed. This section of the report discusses the likely needs of the CAR after the end of the project that pertain to general issues of the pharmaceutical sector, and, separately, to TB drug management. The USAID and donor support may be required to assist Kazakhstan in achieving the goals and objectives of the pharmaceutical sector reform.

Oblast Level

- Oblasts may require assistance in developing their drug policies. In Karaganda, the Oblast Health Administration seems to have a good understanding of the elements of a drug policy and the required implementation efforts. However, oblast decision makers do not have previous experience in such an activity. Oblast policy makers would certainly benefit from international experience. One option would be to organize a study tour to a country with similar public/private-sector relationships.
- Karaganda Oblast has all necessary prerequisites for the implementation of a formulary system (the RPM guidelines, political will, and experts in clinical pharmacology). However, because drug formulary development is a lengthy and technically complicated activity, some technical assistance may be required.
- Standard treatment guidelines are key to ensuring the correct use of drugs in a health system. Karaganda Oblast has the political will to develop standards, but it lacks experience. The oblast will benefit from hands-on assistance from internationally acknowledged experts.
- In order to ensure transparency in drug procurement, major technical assistance may be required to help the oblast develop drug-specific SBDs, drug specifications, and drug supply contracts. In 1999 RPM assisted Kazakhstan in developing tender documents for a national TB tender. However, not all recommendations were taken into account by the Tender Board, and the documents are not available at the oblast level. The tender process is another area that requires assistance. As the RPM experience showed, hands-on assistance in conducting a tender is effective, but for consistent results such assistance requires the presence of an observer or consultant at a series of tenders.
- Karaganda Oblast and national-level experts expressed a desire to establish state-controlled drug supply mechanisms as an alternative to private mechanisms. This, however, is not likely to solve the problem of affordability of pharmaceuticals at the facility level, but may instead be a step back to a command economy. International assistance may be required to help the oblast establish relationships with the private sector or establish nongovernmental independent drug procurement groups, (e.g., through existing hospital and FGP associations).
- There is a strong belief at the oblast and national levels that the establishment of a medical insurance system may solve the problem. There are, however, certain prerequisites for

establishing an insurance system, including the existence of enforceable drug formularies and treatment standards, the readiness and ability of the population to pay insurance premiums, and so forth. Both oblast and national-level decision makers may benefit from an in-depth survey of the economic viability of establishing insurance mechanisms and follow-up training.

- The existence of sources of unbiased evidence-based drug information is a prerequisite for activities aimed at improving prescribing and drug use practices. Currently neither the oblasts nor the national government has the means or experience to establish drug information centers. To establish drug information services, assistance will be required in obtaining sources of unbiased drug information (reference manuals, access to the Internet, etc.), training in drug information development and use, and equipment. The RPM experience in developing drug information centers and information materials in Russia may be used.

National Level

- The current drug registration system does not create a favorable environment for competition in the drug market. Drug registration is a source of hard currency for the country, and as such it does not serve the social goals. It is lengthy and expensive, making it impossible for many manufacturers, especially those producing good quality generic products, to enter the market. This leads to the development of monopolies for certain drugs, an increase in the number of illegal (nonregistered, smuggled) drugs on the market, and a rise in prices. International assistance may be necessary to prove to the national government that inexpensive, effective drug registration will, in the long run, bring more revenues to the state and make quality drugs more affordable to the population.
- Discussions with the oblast decision makers and physicians showed that there are few incentives for health workers to reform the health sector. A reduction in the number of hospital beds or a decrease in the length of hospitalization washes funds out of the health system. Whatever funds oblasts save due to health reforms are not reinvested in health, but are taken out and used by the government for other purposes. Such a situation undermines international efforts to implement health reforms in Kazakhstan and may be responsible for increasing resistance (proved by the RPM assessment) to reforms in primary health care. Assistance in the form of international projects may be required to develop an understanding of the problem at the national level.

TB Drug Management

Further Needs in Operations Research

Kazakhstan and other Central Asian Republics have been implementing DOTS for a number of years. However, according to statistics, the morbidity rate has not changed favorably.

Often, necessary TB drugs are not available. Furthermore, when drugs are available, they are often used irrationally. These two issues, drug availability and use, undoubtedly contribute to the TB morbidity and mortality seen in the CAR.

An indicator-based assessment of TB drug management is useful to (1) help identify the causes

of poor availability and use, (2) design drug management interventions, (3) convince decision makers to take action, and (4) measure progress.

RPM has developed a tool for such an assessment, the *Drug Management for Tuberculosis Manual* (DMTB).

Selection

RPM experience in Kazakhstan has shown the value of technical assistance to ensure that TB drugs selected for tenders are those that are needed for DOTS implementation. In general, the selection process has been fairly opaque (i.e., done behind closed doors). This has resulted in the procurement of a large number of non-DOTS drugs and TB drugs for multidrug-resistant TB (MDR-TB). One way to address the problem could be an open discussion of drug selection at the national level with participation of top international TB experts (KNCV, IUATLD, CDC, WHO).

Another issue related to the selection of TB drugs, but not confined solely to TB drugs, is drug registration. Currently the drug registration procedures are expensive and lengthy, and do not allow easy access to inexpensive, high-quality generic TB drugs. This limits the selection and keeps prices high. Training and technical assistance are required in drug registration.

Because TB treatment is under government control and is centralized, it creates a good opportunity to work on a TB facility drug formulary. At this point, as RPM assessment data suggest, patients have to pay out-of-pocket for a large number of irrationally prescribed drugs, medical supplies, and food.

Procurement

As the RPM experience has shown, technical assistance in TB procurement should be ongoing for at least several years to become truly sustainable. Tender documents should be reviewed and improved, and tender procedures should be observed (in order to provide hands-on assistance and develop local capacity in tendering). More attention should be given to drug supply contracts.

Two important components of good procurement practices are monitoring of supplier performance and reporting of drug quality problems. A database on suppliers and drug products should be developed and maintained to provide information for supplier prequalification. Ideally, to meet the national TB program drug requirements it may be advisable in the future to move from open to restricted tenders.

During the Karaganda assessment RPM learned that oblasts conduct their own TB drug procurements, separate and apart from national TB drug procurements. The feasibility of eliminating duplicate procurements should be explored.

Distribution

Anecdotally, there occurs a significant waste of TB drugs down the distribution pipeline. Improper storage and handling can also be damaging to drug quality. A special study of the distribution system down to the rayon TB facility level should be conducted.

Use

The DMTB assessment tool includes several indicators to study the degree of compliance of prescribers and patients with accepted treatment standards. An assessment may show if problems exist. There are, however, many drug use issues and potential problems that may be overlooked by prescribers and medical staff, and may not be detected during a short, one-time assessment. It is not safe to assume that a TB facility complies to standards unless there is an ongoing mechanism to check this, and take corrective action when needed. One such essential mechanism to ensure the proper use of drugs is an ongoing drug utilization review program.

TB Drug Management Information System (TB DMIS)

There is a great need in Kazakhstan for drug management information systems at all levels of health care. The National TB Program, however, may require a separate DMIS, since it is a separate vertical program. Establishing a DMIS is not easy, though, and will require much technical assistance, training, and the provision of equipment.

Lessons Learned

Project-Related Lessons

- The implementation methods selected for RPM activities were effective for achieving the immediate goals set by USAID. Specifically, targeted, short-term technical assistance is a cost-effective programmatic method when the expected output or outcome is a document (tender documents), participation in a one-time process (drug tender), or training in general issues (drug procurement). However, sustainability of RPM efforts will largely depend on the willingness of local decision makers to accept RPM recommendations to establish drug management mechanisms for national and oblast health programs.
- A pharmaceutical sector indicator-based assessment is a powerful tool that helps to identify drug management deficiencies, identify possible solutions, and initiate a policy options dialogue. When local experts are involved at every stage of the assessment, beginning with planning, it also helps create stakeholders. RPM, however, had a chance to conduct such an assessment and the resulting policy options workshop only at the very end of project, and thus was unable to build on its results and outcomes. An assessment and a policy options workshop should precede any activities aimed at reforming the pharmaceutical sector.
- Collaboration with several USAID-funded organizations and WHO proved to be very successful. RPM did not have significant previous experience working in the CAR, and benefited from the experience and technical expertise of Abt ZdravReform and Project HOPE. In preparation for the regional workshop in 1999, communication and leveraging with WHO allowed for a better understanding of procurement problems in the CAR.
- Subcontracting the Academy for Educational Development (AED) to organize the January 1999 Regional General Procurement Workshop helped avoid many problems that otherwise could have occurred if the workshop had been organized from the United States. AED's excellent skills in providing logistical support and bringing together participants from ten countries are commendable.
- The idea of a regional workshop proved to be fruitful. Participants were very interested in sharing their experiences with each other and learning about approaches used in other NIS countries to solve procurement problems. It is advisable that such workshops be conducted regularly.

Pharmaceutical Sector-Related Lessons

- In the CAR, even the presence of good and reasonable health policies and strategies that affect the drug supply does not guarantee the easy implementation of reforms due to lack of enforcement mechanisms.
- Deficiencies in drug registration mechanisms and the lack of unbiased drug information in the CAR may impede future activities and interventions in improving drug selection, procurement, and drug quality assurance.

- Despite the efforts to shift the focus of the health systems in the CAR to primary health care, hospitals remain important venues for improving drug management.
- The increasing role of nongovernmental professional associations and the private sector in delivering pharmaceutical sector services to public health systems presents many opportunities and challenges.
- Kazakhstan may benefit from the specialized training of oblast procurement specialists in aspects of pooled procurement.

National TB Program-Related Lessons

- Short-term technical assistance was sufficient to empower the TB Tender Commission. As a result, the 1999 national TB tender was conducted according to international competitive procurement standards.
- It is difficult to plan and implement any changes in the National TB Program without the data from an in-depth survey of the TB drug management system.
- The National TB Program may face significant difficulties without oversight from the National Agency for Health on drug selection for TB treatment, procurement, distribution, and use.
- Improvements in the drug component of the National TB Program may stall in the future without reliable survey data on the prevalence of MDRTB and data on the quality of TB drugs on the Kazakhstan market.

Annex 1. Reference Documents Produced and Tools and Manuals Used

Reference Documents Produced during the Project

Adams, I.C., Gabra, M.S., Savelli, A.V., Zagorski, A. *RPM Central Asian Republics Final Report*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, August 1999.

Gabra, M. *RPM Kazakhstan Trip Report, Visit to Almaty, Technical Assistance in Development of Tender Documents*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, April 1999.

Savelli, T. *RPM Trip Report, Kazakhstan and Kyrgyzstan, October 1998*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, October 1998.

Savelli, T. *Trip Report, Reconnaissance Trip to Kazakhstan, February 1994*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, February 1994.

Zagorski, A. *Central Asian Republics: Final Report of the Rational Pharmaceutical Management Project*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 2000.

Zagorski, A. *RPM Trip Report to Kazakhstan, November 1999*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, November 1999.

Zagorski, A., Gabra, M. *Workshop Proceedings: CAR General Procurement Workshop. Kazakhstan, Almaty, Alatau, January 1999*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, January 1999.

Zagorski, A., Semenchenko, M. *Karaganda Oblast, Kazakhstan, Pharmaceutical Sector Assessment, February–March 2000*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, March 2000.

Zagorski, A., Semenchenko, M. *Proceedings: Pharmaceutical Policy Options Workshop, May 2000*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, September 2000.

Zagorski, A., Semenchenko, M. *Workshop Proceedings: Cost-Effective Drug Selection and Formulary System Implementation in Oblast Hospitals and Family Group Practice, Kazakhstan, Karaganda, January 2000*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, [Draft] February 2000.

Tools and Manuals Used during the Project

Management Sciences for Health (MSH). *International Drug Price Indicator Guide*. Arlington, VA: MSH, 1999.

Management Sciences for Health in collaboration with the World Health Organization. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals*. 2d ed., Revised and Expanded. West Hartford, CT: Kumarian Press, 1997.

Management Sciences for Health/Rational Pharmaceutical Management (RPM) Project. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*. Arlington, VA: MSH/RPM, July 1995 (also available in Russian).

Moore, T., B. Bykov, T. Savelli, and A. Zagorski. *Guidelines for Implementing Drug Utilization Review Programs in Russian Hospitals*. Arlington, VA: Russia Rational Pharmaceutical Management Project/Management Sciences for Health, January 1997 (also available in Russian).

Savelli, A.V., H.O. Schwarz, A. Zagorski, and A. Bykov. *Manual for the Development and Maintenance of Hospital Drug Formularies*. Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health, 1996 (also available in Russian).

U.S. Pharmacopeial Convention, Inc. *USP Dispensing Information—Volume I: Drug Information for the Health Care Professional*. Englewood, CO: Micromedex, 1999 (also available in Russian).