

**GLOBAL HEALTH COUNCIL AND
MANAGEMENT SCIENCES FOR HEALTH
1999/2000 TECHNICAL SEMINAR SERIES
PROCEEDINGS**

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Background

The Global Health Council/Management Sciences for Health Technical Seminar Series was launched in October 1998 with the goal of providing a regular forum for sharing important experiences and information about efforts to improve public health. In mid 1999, the Pan American Health Organization (PAHO) joined MSH and GHC as a sponsor of the series.

MSH has long been committed to bridging the gap between what is known about public health problems and what is done to solve them. MSH has extensive expertise in the areas of drug management, primary health care, population, health reform and financing, management information systems, and training, much of which has been obtained through opportunities from projects and cooperative agreements with USAID. Among the projects represented in the seminar series are the Rational Pharmaceutical Management (RPM) project, the Family Planning Management Development (FPMD) project, and the Lessons without Borders project.

Since 1992, RPM has been working to improve the efficiency, equity, and quality of drug management by promoting improvements in the allocation and use of resources in pharmaceutical systems. The technical areas given priority in RPM include:

- Rationalizing drug selection and procurement in the public sector,
- Improving information management and inventory control,
- Expanding drug information resources and promoting rational drug use.

The seminars RPM presented reflect the technical knowledge and lessons learned about improving pharmaceutical management in developing countries. In addition, the seminars offered a unique opportunity to share many of the tools that RPM has developed and the experience in using them. RPM hopes that its participation in the GHC/MSH Technical Seminar Series has contributed to meeting the goals and objectives of the series and the expectations of the attendees.

The current proceedings reports on two seminars organized by RPM during the fourth quarter of 1999 and the first quarter of 2000. Proceedings of seminars presented prior to this are available from RPM.

**THE STRATEGIC ROLE OF DRUG MANAGEMENT FOR
PUBLIC HEALTH LESSONS LEARNED
FROM DEVELOPING COUNTRIES**

November 16, 1999

Panelists

Anthony Savelli, RPM/MSH
Keith Johnson, US Pharmacopeia, USP
Dennis Ross-Degnan, Harvard University Drug Policy
Research Group/INRUD

Respondents

Al Bartlett, USAID
Rosario D'Alessio, Program for Essential
Drugs and Technology, PAHO

Moderator

Anthony Boni, USAID

Anyone who has been involved with international health during the past decade knows only too well of the magnitude and swiftness of changes in the health sectors in countries around the world. Despite these efforts to make positive change, some observers have begun to note that the problems and concerns that led up to decisions to make changes persist or have, in some cases, become aggravated, or that new problems have arisen. What is clear is that our understanding of how to design, implement and monitor reforms, whether at the national, regional or local level, is far from complete. This seminar explores some of the factors influencing the direction change and their implications for planning for adequate drug management to meet public health needs.

Tony Savelli, Director of the Rational Pharmaceutical Management (RPM) project, introduced the subject by noting the most salient issues affecting drug management in developing countries today:

- Devolution of responsibility for drug management to those without sufficient skills and preparation;
- Decentralization of drug financing to the less financially solvent and often unprepared district level;
- Active drug markets with growing numbers of private pharmacies, wholesalers and manufacturers operating in the absence of sufficient regulations to ensure the safety of drugs and their affordability;
- The emergence of drug resistant diseases such as TB and the continued spread of HIV, for which the drug treatment costs can rapidly consume the health budgets of many countries;
- A drug information explosion instigated by increased access to the Internet.

RPM has been active in countries undergoing some form of health sector reform that involves a change in the role of government in assuring the provision of public health services. One valuable lesson learned for efficient and effective drug management is that some drug supply functions are best left for the central government to manage while others may improve if left to the local levels. For example, there is some indication that quantification of drug needs may be most effectively conducted at the local level where local needs are better known. In another example, the economies of scale associated with bulk procurement, availability of trained personnel, and reduction in paperwork are strong arguments for maintaining centralized procurement functions. Unfortunately, such structural reforms are made without adequate understanding of their functional and financial implications, before new systems and skills are in place, and sometimes before consensus is achieved among key stakeholders.

In apparent contradiction to such structural reforms is the increasing concern for emergent diseases such as drug resistant tuberculosis (TB), malaria and HIV. Rather than focussing on system strengthening, these concerns can lead to programs that resemble the same vertical programs discouraged under typical structural reforms. However, the magnitude of the problems, and the resources required would seem to indicate a vertical intervention.

RPM envisions that governments will continue to need help working out the optimal configuration of structural and functional changes in their health systems to meet their growing public health needs. Decentralization of services, devolution of responsibilities, integration of

vertical programs, privatization and outsourcing of services will continue to dominate the dialog of reform and improvement where drug management is involved. Improvement efforts will necessarily include capacity building along with the creation of a supportive environment with proper incentives to promote optimal performance.

One element of a supportive environment in drug management is the ready availability of good information to make decisions about drug selection. Keith Johnson, from the US Pharmacopeia, addressed the role of information in the modern era of computers and the Internet. Mr. Johnson pointed out that although necessary, information alone is not sufficient for good decision making at any level. Informed selection decisions help to define prudent procurement, good prescribing and rational drug use in the community. Although there is an exponential increase in the volume of information available to the average person, this information is often biased, not based on evidence, becomes outdated after three or four years. Quality information is not uniformly available to all as it may very costly.

USP under RPM has been committed to providing tools to enhance access to and dissemination of unbiased and reliable information to health care professionals and consumers. Key components of the strategy USP included development of drug information center networks and local formulary development, obtaining good baseline data on existing drugs and drug use, getting stakeholder commitment, and building on existing infrastructure. Drug information networks are now being challenged with being able to identify the appropriate information to address issues raised by globalization of trade, of being able to access and interpret data from evidence-based medicine, empowerment of the consumers and self-care, and the effect of advertising direct to the consumer.

The structural and functional changes occurring in health systems around the world addressed by Mr. Savelli and Mr. Johnson have, ultimately, redefine the relationships between the payer, provider, and consumer of health services. One trend in particular is the increased emphasis on the role of the private sector in health care delivery, specifically that of managed care. Dr. Dennis Ross-Degnan argued that many lessons could be learned from experiences in the USA and other countries where reforms have been implemented with the intent to influence provider behavior away from of industry and financially motivated behaviors toward behaviors more in line with the goals of rational drug use.

Interventions to change drug use behaviors may be classified as educational, administrative, regulatory or economic. Only some interventions, however, have been shown to be effective in improving the rational use of drugs. For example, distributing educational printed material to prescribers has never been shown to be effective, but focused, problem-oriented and skill building training are effective. Administrative interventions fostering ongoing supervision or audit have also succeeded. Areas that require further investigation include the use of opinion leaders, the development of professional and consumer organizations, and the role of managed care organizations and third party payers. Dr. Ross-Degnan pointed out that more is known about the public sector setting where the context of care is more readily controlled and studied. He encourages further investigation to understand how to overcome barriers to more rational prescribing by private sector providers, community practices, and hospitals.

Rosario D'Alessio from PAHO responded to the presentations by stating that health sector reform, whether in the form of decentralization or privatization, and globalization are embraced by the development community as ways of improving access to pharmaceuticals by the poor. The evidence to this effect, however, does not exist. Therefore, according to Dr. D'Alessio, policy makers and managers are necessarily operating on faith most of the time. For this reason, it is particularly important to have as much evidence about what works, where, and why, and to build on these experiences. Having a good conceptual framework that explains the functioning of such complex systems as drug supply is a good place to start.

In support of Mr. Savelli's and Mr. Johnson's presentations, Dr. D'Alessio concurred with the observation that training will remain a key component in future efforts. She believes that although the call for more and more training from countries seems non-stop, this can be easily understood when one examines the context of change in the developing countries. According to Dr. D'Alessio, training has to be continuous effort not only because information becomes out of date, but more importantly because key personnel constantly change with changes of the governments.

Al Bartlett from the Office of Health and Nutrition, USAID was the second respondent. He discussed the three different but complementary foci of the three speakers, while emphasizing the importance of drug supply as a cross cutting issue as all health sector improvement programs are constrained by drug availability. He agreed with Dr. D'Alessio in the ultimate goal of health reform is to provide access to the poorest of the poor and that the success of health sector reforms are now being questioned.

To address this question, Dr. Bartlett suggests that the place to start is the development of good indicators of process of care that link to delivery outcomes. These indicators should be adaptable to a public, private, centralized or decentralized system depending on the situation. The approach should ask questions about the availability of drugs, help to address the constraints, and examine ways of strengthening the system as a whole. The best way to proceed in extremely poor countries is still uncertain, however RPM's *Drug Management for Childhood Illnesses* (DMCI) Manual illustrates a useful approach.

The discussion following the seminar focused on the dangers of private monopolies, the difficulty of managing contracts (outsourcing), the appropriateness of drug kits and the problems and advantages of restrictive formularies.

IMPROVING DRUG USE IN AN ERA OF RESURGENCE OF INFECTIOUS DISEASES

April 5, 2000

Panelists

Dennis Kyle, Walter Reed Army Institute of Research
Andrei Zagorski, RPM/MSH
David Lee, INRUD/MSH

Respondents

Amy Bloom, USAID
Renato Gusmao, PAHO
Mary Ettling, USAID

In an era of the resurgence of infectious diseases bolstered by antibiotic resistance, viable solutions remain illusive. Hopes of keeping pace with these renewed diseases with new and improved antimicrobials are overshadowed by questions of their efficacy and cost. This seminar focused on how certain aspects of drug management can help to slow the spread of these infectious diseases.

The first presenter, Dennis Kyle, from the Walter Reed Army Institute of Research focused on with the development of new drugs to combat drug-resistant strains of malaria. He began his presentation by stressing the urgency of the situation, stating the grim realities that 2.1 billion people live in malaria invested areas, 270 million new infections are diagnosed per year, and 2 million people die each year, most of which are children under the age of five in Africa. In the past, chloroquine was the key drug for the treatment of malaria. However in 1957, on the border of Thailand and Cambodia, and independently in 1959 in Colombia, resistance to chloroquine was found and rapidly spread to the rest of the world. In response, mefloquine was discovered in the 1960s, but resistance to this drug has also rapidly spread. Although there is a whole selection of drugs for the treatment and prevention of malaria, resistance is spreading quickly for some, and all have side effects that are intensified as the dosage is increased to compensate for the emerging resistance.

On average it takes 16 years to develop new a new drug and, according to Dr. Kyle, they are not being developed fast enough to combat the new strains of malaria, leaving few options for patients. One possibility is to salvage current drugs. This could be done by creating combinations of drugs to minimize the effects of resistance or by conducting laboratory-based studies to develop rationales for clinical trials of differing dosage or formulations of existing drugs, factoring in pharmacokinetics. Another possibility is to instigate rational policies to control the use and availability of new drugs (e.g., malarone and artemisinin derivatives). Lastly, it was suggested that simplifying drug registration requirement would speed up the process of having drugs available in the market. An example of this is globally recognized registration.

Andrei Zagorski (RPM/MSH) presented the findings of a joint review team of CDC, RPM, USAID, and WHO representatives on the management of tuberculosis (TB) in the Ukraine, paying special attention to gaps in drug management that affect the availability and use of TB drugs. Zagorski began by reviewing the context of health care in Ukraine. Between 1990 and 1998, the Ukraine, like other countries in the region, saw a dramatic rise in TB prompting them to initiate a national program in 1999 with international assistance. The review team found both a lack of drug policies in general and a lack of enforcement of existing policies. The team also noted problems with the drug registration system, quality assurance and no enforcement of good manufacturing practices (GMP) of domestic drugs. Furthermore, the team noted inefficient procurement practices that meant that the Ukraine was probably not purchasing all that they could even with the limited resources available to them. For example, procurement occurred at the Oblast level where inadequately quantified drug needs were met by purchases of brand name products at extremely high prices.

The team concluded that Ukraine needed a strongly enforced national TB policy with better registration, selection and procurement, adherence to treatment guidelines, and the restriction on use and sales of TB drugs, together with corresponding capacity building at the Oblast level. As

an example, Mr. Zagorski mentioned RPM's success in implementing a similar program as outlined above in Kazakhstan, which faced similar TB drug management problems prior to 1998.

The following presentation by Dr. David Lee (INRUD/MSH) focussed more narrowly on efforts to improve the use of antimicrobials in developing countries. Dr. Lee presented the results of a literature review of studies that document the impact of interventions to change prescribing, dispensing or actual consumption of antimicrobials. Only 38 intervention studies were found that met minimal study inclusion criteria, of which 23 were in Asia, nine in Africa, six in Latin America and none in the Newly Independent States (NIS). And of these 38, 25 were in primary health care settings, seven in the community, three in hospitals, and three in private pharmacies. Most of the studies examined drug use in acute respiratory infections, diarrhea, malaria, and urinary tract infections. Findings of the review were consistent with those of other studies that had a broader drug focus, that a combined managerial and educational intervention had the greatest impact, managerial intervention alone worked well, and educational and economic intervention alone worked only moderately. However, many gaps still exist in our understanding of what works best and in which contexts. Specifically, further analysis is needed to break out details of successful interventions in hospitals, the community and in the private sector including drug sellers and dispensers.

Dr. Lee reported that, based in part on these findings, in 1998, the Applied Research in Child Health (ARCH) project, the International Network for Rational Use of Drugs (INRUD), RPM, and WHO/EDM formed a joint research initiative for intervention research. Phase I will focus on interventions targeting health care providers in Asia, Africa, and Latin America, and phase II, now in preparation, will target households, the community, hospitals and assessing the impact of policy. The hospital interventions are concentrating on the activities of pharmacy and therapeutics committees.

In response to Dennis Kyle's presentation, Mary Ettling further emphasized that as chloroquine resistance has spread over the last twenty years, mortality in Africa has doubled, claiming 5% of the lives of African children, and has raised the cost of treatment at least tenfold. Most treatment is not only poor in drug selection and dosage, but also occurs outside the formal sector. In many parts of Africa, a child can be infected 1,000 times per year. The only strategies available are to work at the home and community levels with an integrated management of childhood illnesses approach to improve access and coverage. The development community needs to work in partnership with the private sector and we need to develop new diagnostic and treatment strategies. The main issues that still need to be addressed are the absolute lack of finance and the poor quality of health care. Another outstanding issue worth mentioning is the competing demands of easy access to life saving treatment with the implied over use of such drugs and the research and strategies to improve rational use to contain the development of resistance.

Renato Gusmao, from PAHO, addressed the basic problem that health service delivery is poor and health sector reform has reduced the power of the state to enforce regulations. Dr. Gusmao stated that the treatment of illness through private providers is thought of as a private good, not a public good, absolving the state of any responsibility. However the massive extent of irrational use, including sub dosage, observed in the private sector contributes to increasing the transmission of vector born diseases and the development of resistance to antimicrobials. For this

reason, Dr. Gusmao asserts that the treatment of infectious diseases is a public good. And if we see these treatments as public goods, governments would have more authority to regulate and health services would gain more credibility. This in itself is necessary in order to be able to sell the idea of reform.

Amy Bloom (USAID), spoke of the global emergency of TB which infects one third of the world's population and kills two to three million people a year. The Directly Observed Short-Course (DOTS) treatment has been shown to be successful, but it includes more than just directly observed treatment. This strategy involves five essential components including government commitment, correct diagnoses by sputum smear microscopy, standardized regimens for treatment, regular supply of anti-TB drugs, and a monitoring system for program supervision and evaluation. Ms. Bloom stressed that even if the drugs were readily available, DOTS is necessary because poorly supervised or incomplete treatment fosters the development of multi drug resistant TB (MDRTB), a situation far worse than no treatment at all. MDRTB is surfacing all over the world, however, the rates are particularly worrisome in Latvia (22%) and India (13%). Treating MDRTB is both more expensive and more toxic magnifying problems all around. There is an international "green light" initiative to only allow second line drugs to countries that fulfill a certain quality of TB program.

In response to the previous presentations, Ms. Bloom noted that, from the perspective of successful TB programs, integration of vertical programs and decentralization of services that characterize health sector reform are very worrying for the maintenance of rational TB services. Most TB cases are treated in the private sector, where research shows treatment is often poor in the choice of drugs, dosage, and length of treatment. Regulation of non-official sites and access to official sites are vital for the treatment of TB. For TB, it is absolutely necessary to have access to the proper drugs, dosage, quality, and to get treatment from those qualified to treat TB. This is difficult to regulate, especially with health sector reform. No new drugs for TB have been developed in the last 20 years, but now, finally there is a sense of overwhelming urgency and interest in dealing with TB's resurgence.

Information Dissemination:

Electronic mail was the primary means of information dissemination. A message specific to each seminar was sent out approximately one to two weeks in advance. These messages included a brief description of the seminar topic, a short biography of the speakers, respondents, and moderator, along with the date, time, and, venue.

Along with several students and consultants, representatives from the following organizations also received electronic invitations to each seminar:

Abt Associates	Women
Academy for Educational Development (AED)	International Eye Foundation
Adventist Development & Relief Agency International	International Life Sciences Institute
Africare, Inc.	Program for International Training (INTRAH)
Aga Khan Foundation, USA	Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO)
Alliance to End Childhood Lead Poisoning	Johns Hopkins University/Health and Child Survival Fellows
American College of Nurse Midwives	John Snow, Inc
American Public Health Association	Johns Hopkins School of Public Health
AMIDEAST	Macro International
AVSC International	Maximus
Catholic Relief Services	Medical Care Development Inc
Centre for Development and Population Activities	NAS/Committee on Population
Center for Health -Gender Equality	Pan American Health Organization
Christian Children's Fund, Inc.	Partners for Development (PAHO)
Clapp & Mayne	Partners for International Education and Training
Columbia University	Program for Appropriate Technology in Health (PATH)
Contraceptive Research Development Program	Pathfinder
Counterpart International, Inc	Peace Corps OTAPS/Health
Department of Health and Human Services	PLAN International USA
Development Associates, Inc	POLICY/The Futures Group
Eastern Virginia Medical School	POPTECH
Family Health International	Population Action International
Food for the Hungry International	Population Communication Services/Johns Hopkins University Center for Communication Programs (JHUCCP)
George Washington University	Population Reference Bureau
Global Health Council	Population Services International
Georgetown University Medical Center,	Project HOPE
Institute for Reproductive Health	Row Associates
Howard University	
IMPACT/Family Health International	
Inter-American Development Bank	
International Center for Research on	

SHV
Salvation Army World Service Office
SUSTAIN
The Child Survival CORE Group
The Futures Group International
University Research Corp

United States Bureau of the Census
United States Pharmacopeia
United States Agency for International
Development
World Bank
World Vision Relief and Development

MSH staff distributed flyers listing the dates and topics of seminars to organizations and colleagues with whom they work. This informal information dissemination took place throughout the duration of the series.

Participant Profile

On average, the 2 RPM-sponsored seminars attracted 50 participants from the organizations listed below. Most participants are professionals in the field of international public health who work for an established nonprofit, academic, or governmental organization, or are independent consultants. Students enrolled in international public health programs also regularly attend the seminars.

Academy for Educational Development (AED)	John Snow, Inc. (JSI)
Abt Associates	Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO)
AIHA	Johns Hopkins University
Basic Support for Institutionalizing Child Survival (BASICS)	Johns Hopkins University School of Public Health
Center for Health and Gender Equality CHANGE	JSI/Family Planning and Logistics Management (FPLM)
Clapp & Mayne, Inc.	JSI/MEASURE
Development Association	JSI/Mother Care
Family Planning Service Expansion and Technical Support Project (SEATS)	Maternal and Neonatal Health
FOCUS	PLAN
George Washington University	POPTECH
Georgetown University Medical Center	Population Council
Institute for Reproductive Health	Save the Children
Global Group 21	United States Agency for International Development
Global Health Council (GHC)	University Research Corporation/QAP
Independent Consultant	World Bank
International Eye Foundation (IEF)	World Vision

Evaluation Results

Evaluation forms were included in the seminar informational folders distributed to participants as they arrived at the National Press Club. Participants are encouraged to take a couple of minutes at the end of the seminar to fill out the evaluation form. The response rate was 15 percent and 34 percent for the November and April seminars, respectively.

The majority of respondents were informed about the seminars through e-mail announcements. Many of the respondents had also attended other Technical Seminars in this series and provided insightful comments given their prior experience. Most respondents had some experience with the topic presented that day and said that the seminars met their expectations. All respondents indicated that the information presented was insightful and thought provoking. Some characteristics of the seminars that the respondents found particularly “useful” were:

- Organization
- Presentation of differing perspectives
- Useful handouts
- Discussion among respondents and audience
- Specific country examples and experience

Respondents were also encouraged to suggested improvements for future seminars. They specifically cited the need to include more specific examples, showing how the principles presented can be applied in the real world, allow more time for discussion, have publications available for purchase, invite health services administrators, and spend more time on lessons learned. Respondents also suggested that presenters should have a time limit in order to preserve time to complete the scheduled 20-30 minute (if not longer) question and answer session at the end. (This was in response to the lack of time for the discussion at the end of the Improving Drug Use seminar due to the presentations that were longer than anticipated.)

Each evaluation form was written to reflect the topic in question that day. An example of one of the forms follows this section.

USAID has expressed interest in supporting RPM’s participation in future technical seminars.