



The Evolving Role of Pharmaceutical Assessments: A USAID Perspective

A. Boni

Office of Health, Infectious Diseases and Nutrition, USAID, USA

The U.S. Agency for International Development (USAID) has been a pioneer in the family planning area, providing both contraceptives to programs worldwide and technical assistance to develop more effective distribution systems. However, the Agency has never been a donor of pharmaceuticals and only over the last 10 years has it become increasingly involved in the pharmaceutical sector.

USAID's initial efforts were focused on developing indicator-based assessment tools and approaches. The objective was to diagnose pharmaceutical systems, identify problem areas, and improve public sector sustainability by reducing financial waste, enhancing managerial efficiency, and improving the allocation and use of resources.

The collapse of the former Soviet Union, with its centralized procurement and distribution system, provided an opportunity for constructive USAID support to regions with new pharmaceutical management responsibilities but little experience and negligible budgets. A period of drug shortages was quickly followed by a virtual inundation of the market with drugs of unknown quality, safety, and efficacy.

Experience conducting pharmaceutical assessments with local counterparts in Russian *oblasts* quickly demonstrated the value of assessments as a didactic and empowering tool. Joint analysis of findings with Russian partners led to the development of technical assistance workplans and the introduction of formulary systems to improve drug selection, contain costs, and promote the rational use of drugs.

In response to USAID health priorities and international initiatives focusing on particular health problems (e.g., the Integrated Management of Childhood Illness), specialized tools were then developed to identify the factors contributing to lack of drugs and the interventions needed to strengthen health systems. Similarly, access to drugs and drug use practices in the community had to be assessed, given the importance of the private sector in providing health services.

Meeting the challenge of using global initiative resources effectively calls for rethinking the role of pharmaceutical assessments. The potential flood of drugs into weak health systems, known deficits in human resource capacity, and the need to improve deficient laboratory support services are just a few of the current realities facing developing countries. To help address these issues, a new paradigm is needed. Pharmaceutical assessments must be rapid and targeted, and must offer guidance about the feasibility of interventions, including their scale-up and expansion potential, as well as corresponding human resources requirements.

This presentation will highlight USAID's experience with pharmaceutical assessments and argue for a more strategic and viable approach for strengthening pharmaceutical management systems in the new international health environment.

The Evolving Role of Pharmaceutical Assessments: A USAID Perspective

Anthony Boni, U.S. Agency for International Development, USA

Slide 1: Targeting Improved Access

Slide 2: The Evolving Role of Pharmaceutical Assessments: A USAID Perspective

Slide 3: Themes of the Presentation

Good morning. First of all, I would like to thank the organizers for the opportunity to speak with you today. From the presentations I heard yesterday, I find that many of us are on the same page—and that is critical in the important times facing us.

The purpose of this presentation is to tell a story about USAID's involvement in the health commodity management arena. In the process, it provides lessons learned about the value and role of pharmaceutical management assessments. The story begins with the agency's important worldwide efforts in the population/family planning area and their initial impact. An experimental activity in pharmaceutical management systems strengthening, the Rational Pharmaceutical Management Program, followed many years later.

This program developed USAID's initial assessment approaches and capacity building strategies, which were used effectively in addressing the void left by the collapse of the Russian Federation's centralized procurement and distribution system. The RPM Program then played a major role in supporting reproductive and child health, malaria, TB, and HIV/AIDS programs by developing specialized tools to identify the causes of drug availability problems, as well as the corresponding health systems and human resource capacity issues.

Last, we will look briefly at the challenges confronting us today, many of which have been mentioned by previous speakers. It is argued here that assessments can help define a constructive path forward so that we can capitalize on the historic opportunities represented by the vastly increased resources available to expand important health programs worldwide, particularly those involving HIV/AIDS care and treatment.

Slide 4: The Contraceptive Paradigm

Back in the late seventies, I joined USAID's population program to help deal with the fallout of the agency's contraceptive inundation approach, which was under review by Congress. The world had been flooded with contraceptives, and, as was reported at the time, there was the smell of burning rubber as contraceptive products were expiring across the globe.

The assumption was that large numbers of men and women were waiting to use contraceptives if only they were available. Optimistic quantities of contraceptives were shipped yearly to country programs without due consideration of in-country inventory levels and consumption data. Indeed, such information was largely not available.

However, this was still a fairly simple world. There were few products to forecast and manage, and they were always available through the centralized procurement system that I ended up managing. We had another advantage as well: We purchased supplies of assured quality from domestic FDA-approved supply sources. Consequently, contraceptive availability problems were relatively easy to identify, and technical assistance was provided to improve forecasting, scheduling of shipments, customs clearance, warehousing, management information systems, and distribution. However, since assessments generally revealed deficient public sector distribution systems, the solution—and this is very reminiscent of what one is hearing today—was to set up costly vertical programs, many of which were in no way linked to the existing health system.

I should note again that the less-than-anticipated demand for contraceptives was a critical factor back then. The demand factor today is clearly one that we should monitor closely as multiple donors and programs begin to rapidly expand the availability of antiretroviral treatment to country programs. Global and country-level coordination of efforts and planning are imperative to avoid a deluge of drugs hitting the ground without adequate systems and human resource capacity to manage and use them effectively.

Slide 5: USAID Goal: Promote Sustainability in the Public Sector

When I joined USAID's Office of Health in the early nineties, I was surprised to learn there were no projects providing technical assistance to improve the availability and use of health commodities in the agency's health programs. In fact, unlike the situation with contraceptives, where USAID was the world's major donor to family planning programs worldwide, the agency did not provide pharmaceuticals. At the same time, the agency's primary objective in its health financing programs was to improve the sustainability of public sector health programs.

As I know I don't have to explain to this audience, substantial evidence was available to help make the case for USAID involvement in the pharmaceutical arena. Dr. Shongwe spoke yesterday about how drugs are essential to the success of health programs. Drugs have both symbolic and health outcome importance. The credibility of public health systems largely depends on the availability of drugs. Drug availability, or the lack thereof, dramatically affects utilization rates at health facilities and the receptiveness of clients to public health messages by care providers.

Also, in most developing countries, funds are not sufficient to meet needs, nor are funds used as efficiently as possible. Evidence exists that avoidable wastage throughout the entire supply chain significantly reduces the therapeutic benefit of resources expended, hence the negative impact on public sector sustainability. Such was the case that was made for USAID's first pharmaceutical management activity.

Slide 6: The Rational Pharmaceutical Management (RPM) Program

In 1992, USAID awarded two RPM cooperative agreements which were designed to work collaboratively—one to MSH for pharmaceutical management system strengthening and the other to the United States Pharmacopeia for the provision of unbiased, up-to-date, accurate, and

locally developed drug information. I want to acknowledge my intellectual debt to the directors of these two agreements, as they are here today: Jim Rankin and Keith Johnson, respectively.

The RPM programs were only intended to carry out experimental activities in several countries as the agency continued to hedge its bets about involvement in the international pharmaceutical arena. To move forward USAID's initial efforts to improve the efficiency, equity, and quality of pharmaceutical management systems, RPM/MSH developed an indicator-based tool. It included 46 indicators designed to obtain relevant data for systematic systems diagnosis. The approach was based on the pharmaceutical management cycle framework you have seen many times.

Slide 7: Pharmaceutical Management Cycle

Given the complexity and interrelated nature of the pharmaceutical management cycle, identifying the reasons why drugs are not available and possible intervention options requires an understanding of the entire system. Even today there is a tendency to think that distribution-related problems are solely responsible for the lack of drugs in country programs. Consequently, so it goes, expansion and scale-up of critical health programs will be established solely with a focus on distribution and the movement of supplies.

In short, multiple factors, including insufficient resources, widespread wastage, and inefficient pharmaceutical operations, may contribute to the lack of drugs. Faulty product selection and quantification, deficient procurement practices leading to high prices and poor-quality products, distribution system losses, and inappropriate use of medicines are just some of the common reasons.

Slide 8: Value of an Indicator-Based Assessment Tool

So, why are indicator-based assessment tools important? USAID as a donor has not been a provider of pharmaceuticals and supplies. Unlike the situation with contraceptives, the agency had little leverage in influencing country pharmaceutical management operations, based as they frequently are on long-established structures, procedures, practices, and strong vested interests.

However, information, particularly information about cost issues, can be very powerful. Indicator-based pharmaceutical assessments establish an evidenced-based platform for discussion of possible health system improvements. They clarify how scarce resources are being allocated and perhaps wasted, while identifying strengths, limitations, and major constraints of existing systems. They can facilitate policy dialogue concerning options resulting from findings and can serve a valuable didactic function in communicating the relationships among pharmaceutical system variables. They can also provide valuable baseline information against which the impact of interventions and change over time can be measured.

Slide 9: Russian Pharmaceutical Sector: 1993–1994

Let's turn to Russia. Although not included originally on the RPM agenda, the dissolution of the former Soviet Union provided a valuable opportunity for USAID to hone its assessment

approaches while addressing severe drug availability problems and deficits in pharmaceutical management capabilities.

When USAID/Moscow invited RPM to visit Russia to begin dealing with the problems identified on this slide, numerous missions had already been there to assess various aspects of the health care situation. The Russians were clearly exasperated with being “assessed and studied.” There was also an atmosphere of liberalization and freedom from centralized control as the breakdown of the centralized procurement and distribution system was viewed with relief at the oblast level, although capacity to manage drugs there was nonexistent.

But there was freedom, and that included the ability to make their own drug selections from the vast array of products that soon flooded the market without adequate regulatory oversight. “The more the better” attitude to drug use quickly began to prevail. There were other serious hurdles to RPM involvement in Russia, including concerns about the motivations behind U.S. pharmaceutical assistance.

Slide 10: RPM Implementation Strategy

Assessments were the foundation of the RPM Implementation Strategy, and they were key to overcoming existing obstacles. A paradigm was developed in Russia that continues to this day in all RPM Plus programs.

Extensive sessions were spent with Russian counterparts to discuss pharmaceutical management issues and the proposed assessment tool. It was tailored to meet individual oblast needs. Local counterparts conducted the assessments, were involved in analysis and report writing, reported the findings in options analysis workshops to other oblast staff, and helped formulate the RPM technical assistance plans. Assessment findings regarding how resources were used for drug purchases identified that many duplicate, unnecessary, and even dangerous products were being purchased, with wastage of valuable scarce resources.

As noted, drug choices soon increased exponentially in the national marketplace. The resulting confusion provided fertile ground for the introduction of the formulary concept and the establishment of Drug and Therapeutics Committees [DTCs]. No full-time RPM advisers were ever assigned to work on the RPM Program in Russia. Only technical guidance was provided and the Russians were the implementers, with technical support from a local RPM office with Russian staff. Further, Russian partners from the first RPM demonstration oblast became technical assistance providers to neighboring oblasts as well as effective advocates at the national level for pharmaceutical management reform. Joint workshops were also held to share experiences and lessons from the three RPM oblasts.

Slide 11: Selected RPM Outcomes

The formulary concept did not exist in Russia prior to RPM. By the end of the program, Drug and Therapeutics Committees were active in all the RPM oblasts, and hospital and oblast-level formularies had been established. In several oblasts, they formed the basis for pooled procurement activities. Unsafe, dangerous, duplicate, and ineffective drugs, as well as those that

did not meet medical needs, were eliminated as DTCs selected drugs based on cost, quality, safety, and efficacy. Cost savings as a result of formulary system implementation and modern procurement practices were documented in all oblasts.

Because of effective dissemination of lessons learned at the yearly Russia-wide Man and Drugs Congress, as well as the availability of manuals, formulary use extended throughout Russia without the need for technical assistance. The Russian Federation Ministry of Health [MOH] recognized the importance of these efforts by naming an RPM oblast the nation's demonstration site for pharmaceutical management reform.

Slide 12: Lessons from the Russian Experience

So what are the lessons? Flexibility and attention to counterpart concerns and the existing context dictated the technical path RPM followed in Russia. When RPM began its work there, drug shortages were the problem, and the intent was to help promote modern procurement practices and international tendering, but lack of budgets and local laws initially prevented this from occurring.

RPM success in Russia can be attributed to the Russians themselves, who bought in to the concepts and approaches presented because they provided practical and demonstrable solutions to their problems. The major tools—a formulary development and maintenance manual, and a drug utilization review manual—were developed with and endorsed by counterparts who considered them local products.

Once again, the ownership issue was the major success factor in Russia. To echo the sentiment expressed by Peter Mugenyi yesterday, the Russians owned the RPM Program. Investments to support training and dissemination of experiences brought about fundamental changes in the way of doing business not only in the RPM oblasts but at the national level as well.

Slide 13: Specialized Assessment Tools

This brings us to the specialized assessment tools developed by RPM and RPM Plus. They are listed on this slide. Why were these tools required? The truth be told, comprehensive, generic, national pharmaceutical assessments were a difficult sell. They were costly and time consuming, and it was hard to convince field missions of their value in terms of producing immediate results. However, many USAID-supported health programs were experiencing drug availability and implementation problems, so the demands for field assistance began to flow in as USAID Missions became aware of the RPM Program.

There was a recurring theme from the field: Health initiatives won't go far unless the drugs are there! In short, specialized assessment tools were generally less costly than full systemwide assessments—they can be rapid, and they addressed specific needs. They also involved local counterparts and established an evidence base for discussion of options for improvement.

Slide 14: CES for RH Commodity Management

The Cost Estimate Strategy [CES] tool includes a model and a corresponding survey. In the model, spreadsheets are used to calculate the total quantity and costs of drugs, supplies, and medical equipment necessary to carry out reproductive health [RH] treatments. A reference database (based on international standards) of commonly used medicines and supplies is contained in each spreadsheet. The survey includes a series of data collection forms to collect actual data on product availability and RH treatment practices.

In Zambia, the CES approach helped to define and quantify commodity requirements for the national integrated reproductive health care strategy, and also helped to highlight the need to further define and refine standard treatment guidelines for selected RH conditions. The Zambia assessment also provided information for interested donors, including JICA [Japan International Cooperation Agency], which contributed funding for the purchase of reproductive health commodities.

Slide 15: Problems and Actions in Senegal from DMCI

I thought this slide might be of interest because it lists some of the problems that were identified during the application of the Drug Management for Childhood Illness [DMCI] tool in Senegal. IMCI [Integrated Management of Childhood Illness] drugs not included on the essential medicines list [EML], poor procurement practices, drug availability problems, and poor prescribing—these are all concerns that can be addressed with available approaches. The suggested remedies were discussed in a workshop by local stakeholders, and the actions listed in the table were endorsed for implementation.

Slide 16: Use of Medicines in Home (Senegal C-DMCI 2002)

The tools discussed so far relate to specific health problems, but there was still an important black hole that had to be explored—drug use in the community. The Community Drug Management for Childhood Illness [C-DMCI] tool was designed to look more in-depth at patient use of medicines in the home. This slide highlights the importance of understanding what's going on in the home once the patient, or in this case the mother or caregiver, leaves the health facility.

Most of us would consider CQ [chloroquine] as a relatively simple regimen, but a very low percentage of caregivers in Senegal gave the drug correctly to their children. Based on this information, the Senegal MOH is planning a number of interventions focusing on improving the use of medicines at the community level. Although this is just data from two cities in one country, I think it shows that adherence should not be assumed and that such assessments are necessary.

Slide 17: Value of Specialized Tools

Specialized assessment tools have clearly served to engage and educate counterparts, providing the evidence base for the consideration of intervention options while assuring local ownership and commitment to implementation of workplans.

Often, assessment findings have led to reforms in other areas of the health system. When a DMCI survey revealed that prices being paid for drugs were several times more than what could be obtained on the international market, the resulting pressure brought about procurement reform and the introduction of more transparent and accountable practices.

Assessments that involve key stakeholders can also contribute strongly to enhanced communication at the country level (e.g., between essential medicines staff and personnel working on specific health programs) to assure that drugs appearing on EMLs and standard treatment guidelines are consistent.

Sharing of assessment information with donors has frequently resulted in leveraging investments, as many donors are always seeking rational ways to programs their funds as they pursue their interest in specific health programs.

And we have the case of the RPM Plus Drug Management for TB tool, which has now been endorsed by all major global players in the TB arena as the standard for assessments. This assures that a systems approach is used in assessing the drug components of TB programs.

Slide 18: Global Events Lead to Changing Paradigm and Evolving Approach

I think that all of us here can attest to how attitudes have changed over the past several years, as the international community responds to greatly increased information on the devastation prevalent in the developing world as a result of the major diseases, particularly HIV/AIDS.

Understandably, the focus of attention has been on access to medicines and all the issues considered relevant in that regard. But access means different things to different people. And, how do you measure access to know whether and when you have achieved it? The SEAM Program, along with other partners, has spent considerable time in answering these questions.

For many, the most important step in achieving access is to make the drugs more affordable. The fact that prices of both generic and the research-based industry ARVs [antiretrovirals] have dropped significantly can be seen as a success.

The Global Fund to Fight AIDS, TB and Malaria (GFATM), the TB Global Drug Facility, Stop TB, Roll Back Malaria, and the World Bank Multicountry AIDS Program are just a few examples of the international donor community's response. And now we have the USG [U.S. Government] HIV/AIDS Initiative and the WHO 3 by 5 program. The funding being committed through these programs is unprecedented. So, how do we spend all of this funding responsibly to achieve the expected results?

I have been reluctant to express any cautionary notes, but I will sneak a few in here. I am emboldened by the excellent presentation by Malcolm Clark yesterday, who ran the numbers regarding the commodity implications of the U.S. President's Emergency Plan for AIDS Relief. For those who were not there, I urge you to look at his slides. Malcolm spoke of national markets and health systems being potentially overwhelmed. And the USG initiative is just one of the many new sources of ARV drugs and health commodities for country programs.

My worst nightmare is that with multiple programs providing resources, and the need to expend them quickly to show results, we may be on the brink of a second inundation, not with contraceptives this time, but with ARVs and other products for comprehensive care and treatment programs. Suffice it to say that some well-funded and technically supported HIV/AIDS treatment programs have not achieved the uptake of demand that was expected, and the press has already been reporting about the expiry of ARVs in certain countries

Enough said. The point is that we have to make sure that appropriate investments are made and that we monitor carefully the overall flow of commodities to country programs. We have to get it right.

Slide 19: Pharmaceutical Management, Access, and Use of Medicines: A Systems Approach

As a reminder, we must not forget that the pharmaceutical system exists in support of, and operates within, the existing health care system. This slide is just meant to show graphically the relationship of systems within systems.

Ultimately, medicines have to get to the patient, so we have to consider issues of access. And access is more than the price of products; it also includes geographic accessibility, affordability, availability, and local acceptability. In addition, the system must ensure that the medicines are safe, efficacious, cost-effective, and of good quality.

After achieving access, we then need to address a myriad of issues to assure that medicines and other health products are prescribed, dispensed, and taken properly by patients in the community. And by community, I am referring to all the support systems that may be needed to help address issues of stigma, adherence, and other factors influencing treatment-seeking behavior and patient use of medicines.

Slide 20: The Mombasa Experience

I won't go into detail with this slide since the Mombasa experience and the RPM Plus approach were covered admirably yesterday by Michael Thuo. I will only say that the commodity management system assessment, including lab services, was conducted jointly with local stakeholders. Much of the success of the Mombasa experience to date was due to the up-front investment in the assessment process—building local ownership, identifying immediate priorities, planning training, and developing workplans.

As Michael Thuo described yesterday, the Mombasa ART [antiretroviral therapy] Program is a USAID-funded initiative to provide support to Kenya's MOH to introduce antiretroviral drugs into the existing health care system as part of a package of comprehensive care and treatment. Current ARV access and use in the public and private sectors was reviewed in order to understand the context into which this program is being introduced, particularly to identify factors which could potentially impact the effectiveness of the ART Program and to collect information on lessons learned by existing programs.

Slide 21: The USG PMTCT and PEPFAR Programs

I think this slide is self-explanatory. The USG will now become a major purchaser of antiretrovirals and other drugs and health commodities needed for the implementation of USG-supported programs.

The U.S. President's Emergency Plan for AIDS Relief [PEPFAR] will be targeting 14 countries. I am pleased to say that the RPM Plus Program being implemented by Management Sciences for Health will be working in at least 10 of these countries. This effort will involve all USG agencies. The USG Global AIDS Coordinator, Randal Tobias, who is located in the State Department, will be directing USG efforts. The scale-up and expansion for comprehensive care and treatment will include the entire spectrum of services required: VCT [voluntary counseling and testing], PMTCT [prevention of mother-to-child transmission], ART, treatment of opportunistic infections, palliative care, and other support services.

Slide 22: An Evolving Role and Approach

At this point, I will just make selected comments regarding the remaining slides. Much attention in recent years has been focused on intellectual property, patents, and pricing issues as they relate to access. Although important and deserving of attention, we should now turn to all of the access issues, including the need to assure that investments are being made to strengthen systems and capacitate needed human resources.

USAID's investments supporting ART programs in Kenya, Ghana, and Rwanda have led to a greater understanding of the challenges that must be addressed. We can anticipate that we must urgently address such issues as laboratory services and equipment needs, including pharmacy and lab SOPs [standard operating procedures], and human resource constraints, among others. In many countries, this is happening while we speak, so no one is suggesting there is any time to wait. I think we all agree that we need to move forward immediately, but we must do so systematically.

Therefore, it is even more critical to do political mapping of all players and programs. Only then will we have a clearer sense of the different sources of funding and the pharmaceuticals that will be arriving in a country—and when. Concrete plans have to be in place to respond to both demand and capacity issues.

Slide 23: The HIV/AIDS Pharmaceutical System

Which brings me to the following slide on the HIV/AIDS pharmaceutical system, which I won't discuss, except to say we should be mapping all country programs accordingly. Donors should have a shared understanding of the countries in which they are working.

Probably more for HIV/AIDS than most other health issues, it is important to have a good understanding of the context in which the pharmaceutical system functions in support of HIV/AIDS services. So, the assessments have to be able to show the flow of medicines as well as the key stakeholders and the level of their involvement within the pharmaceutical framework.

This generic diagram represents the stakeholders and their interaction. Each country is different, and a specific diagram should be created to reflect country-specific situations. This model may evolve to suit the particularities of a specific country. Once the mapping process is completed and weaknesses in the system are identified, options for strengthening the system must be identified and their feasibility explored. Donors should have a shared understanding of the countries in which they are working.

Key elements to consider when conducting PMTCT and PEPFAR assessments include structures such as the MOH Department of Pharmacy, Central Medical Stores Department, and health facilities. Another element is product flow, which includes diagnostic kits, ARVs and other HIV/AIDS-related pharmaceuticals, and laboratory supplies and equipment.

Information flow involves accounting requests and reports, test results, treatment failures, and ADR [adverse drug reaction] reports. Payment/finance flow includes source of funding, tracking from initiation of procurement order to receipt of product, and distribution down to the patient level. Human resources is one of the biggest problems facing many African countries today. The goal is to identify the different cadres of health personnel currently available and the role(s) they play.

Slide 24: The Implementing While Strengthening Paradigm

The U.S. President's Emergency Plan for AIDS Relief is demanding that its implementing agencies, field offices, and organizations implement immediately and "show results." We heard about WHO's 3 by 5 Initiative yesterday, and we know that the GFATM awards are finally starting to show disbursements, with products already procured and arriving in countries.

With regard to the "implementing while strengthening" paradigm, assessments can play a key role in helping to determine the "how" and "what to do," "when."

The question of urgency is challenging everyone to make medicines available to all who seek and need them. But basic essential drugs are still not available to large numbers of people in developing countries. So, without ignoring the long-standing challenges of ensuring access to medicines, we have to come up with an approach to address weaknesses in existing systems while we implement.

It is not reasonable to expect that countries will be able to address all of the human resource constraints in the short term, even with additional funding. There are no easy answers here, but we must come up with options, such as redefining the role of pharmacy assistants or nurses to be more involved, perhaps, in dispensing practices. And, as is the case with the Mombasa experience, the goal should be to develop an approach to strengthen the existing health system to ensure the sustainability of investments being made.

Slide 25: Take Home Message from Assessments

Well, they say that communication is repetition. I can't stress enough how important having local counterparts and stakeholders involved from the beginning of the assessment process has been to reaching consensus on how to move forward on implementation. Russia and Mombasa are just two examples that we have highlighted in this presentation to show how assessments contribute to local ownership, while building capacity and facilitating the development of realistic, step-wise workplans.

Again, overall pharmaceutical management includes all elements of the cycle, in addition to distribution. Let us not lose sight of this in the rush to get the drugs out. The temptation will perhaps be to try to verticalize HIV/AIDS programs to show short-term results.

Similarly, comprehensive care and treatment programs must be linked to the public health care system—multiple drugs other than ARVs are needed. Assessments have to carefully review the rationale for determining treatment protocols as well as the methodology used to quantify needs.

Slide 26: Take Home Message from Assessments

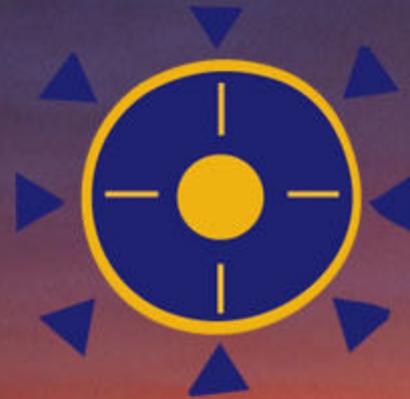
A recurring theme in many countries is the lack of human resources and weak infrastructure. This means we will need a process to prioritize carefully in order to address the most pressing problems first. Also, it will now not be enough to just offer options without determining their potential for success. They must be based in reality and achievable within the constraints of the existing environment. Therefore we must come up with alternatives that consider new roles for the private sector, NGOs, and other potential partners if we are going to effectively scale-up and expand treatment.

Okay, Rome wasn't built in a day! We have to commit for the long term and accept that we don't have all the answers. Assessments can provide a road map for how to move forward, and they can also be used to monitor progress and help to determine when changes are needed, leading therefore to sustainable improvements.

Last message: Make the most use possible of available assessments. They can serve multiple functions, such as political mapping, and be the basis for effective coordination among donors and other players. By sharing widely the information and findings that result from all assessments, and many organizations are conducting them, we can increase everyone's knowledge base of local situations. We can also help to avoid the dangers of unnecessary duplication and wastage, and better enable a division of labor and investments to address identified needs.

It is within our power to work together and not get caught up in a numbers game. The stakes are too high. Thank you for your attention.

SEAM CONFERENCE 2003



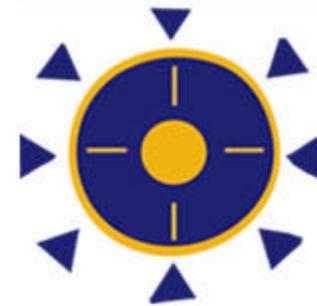
Targeting Improved Access

Dar es Salaam
United Republic of Tanzania
December 10–12, 2003

STRATEGIES FOR ENHANCING ACCESS TO MEDICINES

The Evolving Role of Pharmaceutical Assessments: A USAID Perspective

SEAM CONFERENCE 2003



Targeting
Improved
Access

Anthony Boni, USAID, U.S.A.

Dar es Salaam
United Republic of Tanzania
December 10–12, 2003

Themes of the Presentation

- USAID transition from contraceptive logistics to pharmaceutical management
- Russian experience provides a valuable model
- Specialized assessment tools target pharmaceutical management issues related to specific diseases or health initiatives
- New assessment approaches required to confront the challenges of scale-up and expansion
- Take home messages



The Contraceptive Paradigm

- Full Supply Model – continuing availability
- Few products to manage
- Central Procurement System
- Products of assured quality
- Straightforward requirement estimation
- USAID technical assistance (TA) in logistics management
- Vertical systems established



USAID Goal: Promote Sustainability in the Public Sector

- Making the case for the role and importance of pharmaceuticals
- Reducing financial waste in pharmaceutical operations
- Improving resource allocations
- Enhancing managerial efficiency

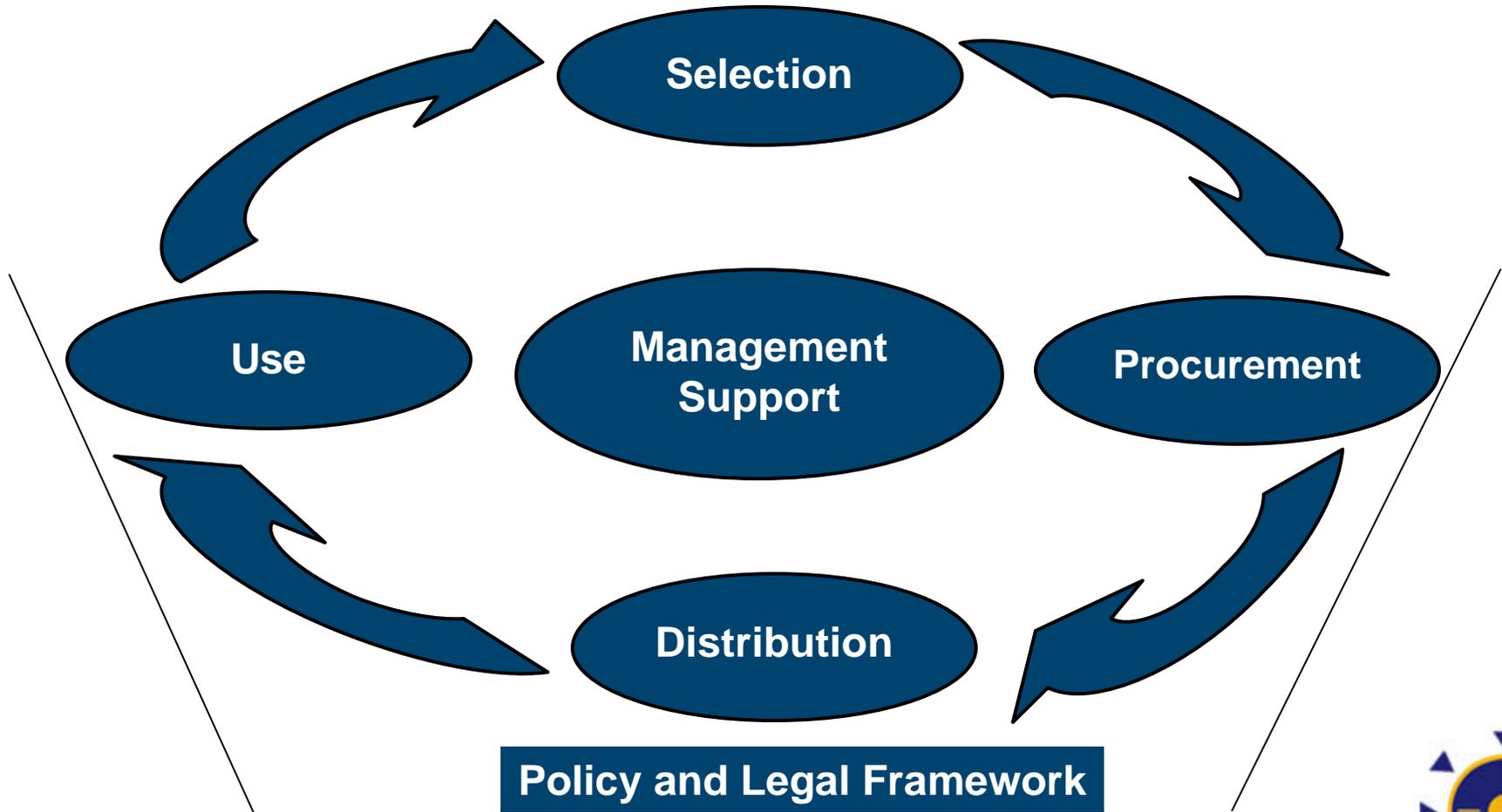


The Rational Pharmaceutical Management (RPM) Program

- In 1992, USAID funds RPM awards to Management Sciences for Health (MSH) and the United States Pharmacopeia (USP)
- RPM/MSH develops the “Rapid Pharmaceutical Assessment: An Indicator-Based Approach” tool
- Approach based on the Pharmaceutical Management Cycle framework



Pharmaceutical Management Cycle



Value of an Indicator-Based Assessment Tool

- Examines resource allocations to determine how funds are being used
- Identifies strengths/weaknesses/problem areas
- Provides evidence for policy dialogue
- Leads to identification of possible options for corrective action
- Provides baseline information for monitoring and evaluation of interventions



Russian Pharmaceutical Sector in 1993–1994

- Disruption of centralized drug supply
- Devolution of management responsibilities
- Drug shortages followed by market inundation
- Diminishing drug budgets for public programs
- Lack of local pharmaceutical management expertise
- Lack of accurate, unbiased drug information



RPM Implementation Strategy

- Involve local counterparts in entire assessment process
- Options Analysis Workshops to reach consensus, promote local ownership and develop realistic workplans
- Focus on costs, cost containment, and elimination of financial waste
- Introduction of formularies and Drug and Therapeutics Committees (DTCs)
- Russians involved in providing TA, developing tools and manuals, and monitoring progress



Selected RPM Outcomes

- Formulary concept institutionalized in the Russian health care setting
- Number of drugs in use in 61 major hospitals reduced by an average of 34.5% (range from 3.9-73.2%)
- Significant savings obtained through modern procurement practices in pilot oblasts
- RPM oblast site selected by the Russian Federation as a national demonstration site



Lessons from the Russian Experience

- Need to adapt to the changing situation
- Implementation strategy has to be built around stakeholding at all levels
- Tools and training must address specific local needs for local buy-in to occur
- Human capacity development key to successful pharmaceutical management system strengthening



Specialized Assessment Tools

- Cost Estimate Strategy (CES) for Reproductive Health (RH) Commodity Management
- Drug Management for Childhood Illness (DMCI) tool and Data Collector's Guide
- Drug Management for Malaria (DMM)
- Drug Management for Tuberculosis (DMTB)
- Community-DMCI



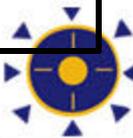
CES for RH Commodity Management

- Designed to assist RH program managers, governments, and the donor community to better estimate costs of RH commodities
- CES helps guide decision-making for improving the availability, rational use, and management of RH commodities
- Provides a framework for incorporating cost information into policy and program decisions



Problems and Actions in Senegal from DMCI

<i>Problems</i>	<i>Actions</i>
Drugs needed for IMCI not on essential medicines list (EML)	<ul style="list-style-type: none"> • Coordination between drug and child health divisions of Ministry of Health • Revision of EML (including drugs by level)
Procurement prices of some much-used drugs were high	<ul style="list-style-type: none"> • Revision of tender process and supplier choice
Poor drug availability (in particular, no ORS in private pharmacies)	<ul style="list-style-type: none"> • Module of store management integrated into IMCI training and training of storekeepers • Supervision • Make ORS available in private sector
Poor prescribing in public sector and poor selling in private sector	<ul style="list-style-type: none"> • Expand IMCI in public sector and supervision • OR of co-trimoxazole in huts for ARI • Sensitization of IMCI in private sector and training of drug sellers



Use of Medicines in Home (Senegal C-DMCI 2002)

The child took CQ:	Thiès (n=156)	Kaolack (n=160)
correctly (once daily x 3 days)	7%	8%
Duration:		
- for 3 days (correct)	53%	63%
- more than 3 days	26%	14%
Frequency:		
- once a day (correct)	19%	19%
- twice a day	68%	72%



Value of Specialized Tools

- Raised awareness of pharmaceutical issues while educating counterparts
- Provided entry points for sustainable health system improvements
- Cost implication data greatly influenced policy decision making
- Fostered local stakeholder communication, as well as donor coordination
- Can be accepted as a standardized assessment approach

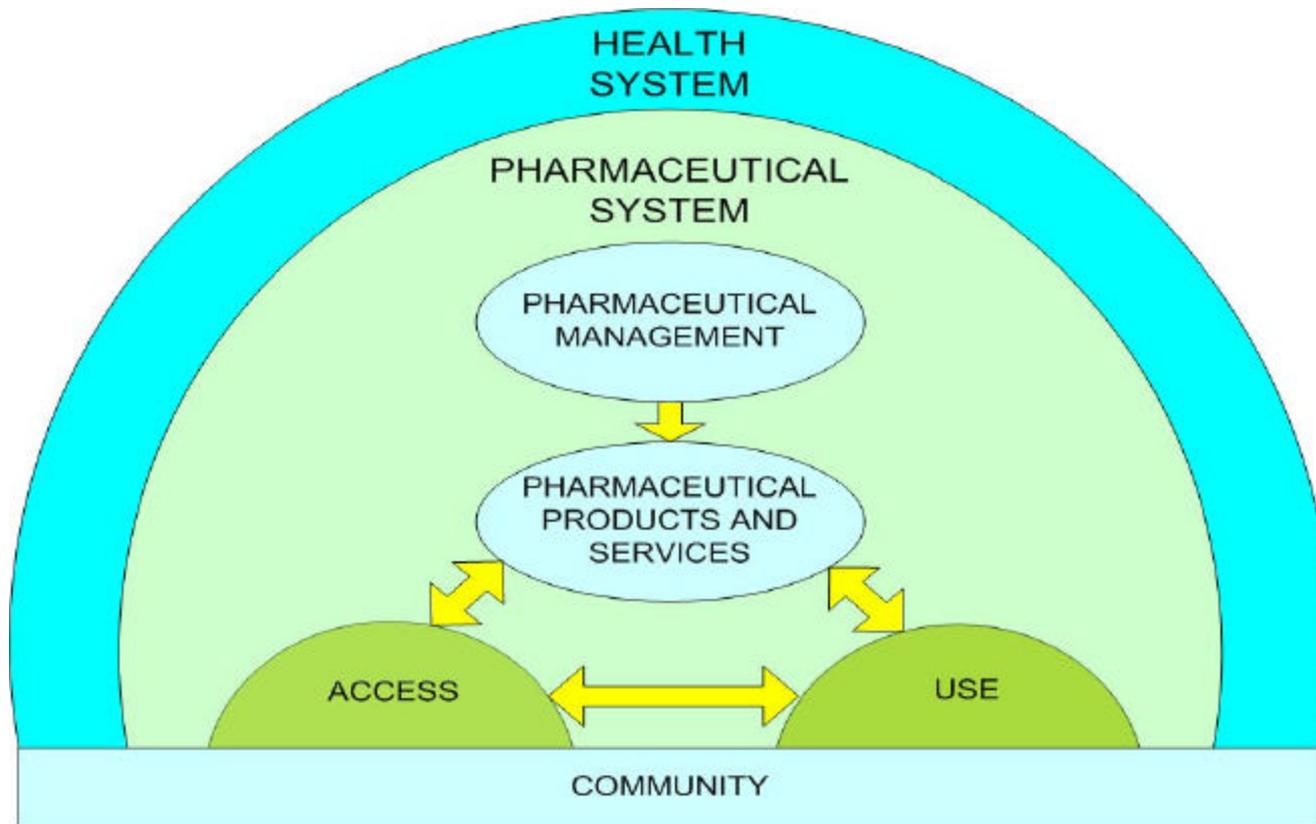


Global Events Lead to Changing Paradigm and Evolving Approach

- International acknowledgement of the global impact of AIDS, tuberculosis, and malaria
- Focus on “access” to medicines
- Falling prices for antiretrovirals
- Unprecedented funding from international donor community
- Historic opportunities accompanied by potential risks



Pharmaceutical Management, Access, and Use of Medicines: A Systems Approach



The Mombasa Experience

- One of three USAID learning sites for introduction of ART and procurement of pharmaceuticals for comprehensive care and treatment, including laboratory services
- Based on scaling up access to ART services through building capacity of existing health system
- Systems diagnosis and human capacity assessments conducted in both the public and private sectors
- Collaborative and inclusive approaches to build ownership and local capacity, including work planning



The USG PMTCT and PEPAR Initiative

- President's Emergency Plan for AIDS Relief (PEPAR) targets 14 countries: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Uganda, Tanzania, and Zambia
- Scale-up and expansion of comprehensive care and treatment services
- Procurement of antiretrovirals and other HIV/AIDS-related pharmaceuticals and supplies

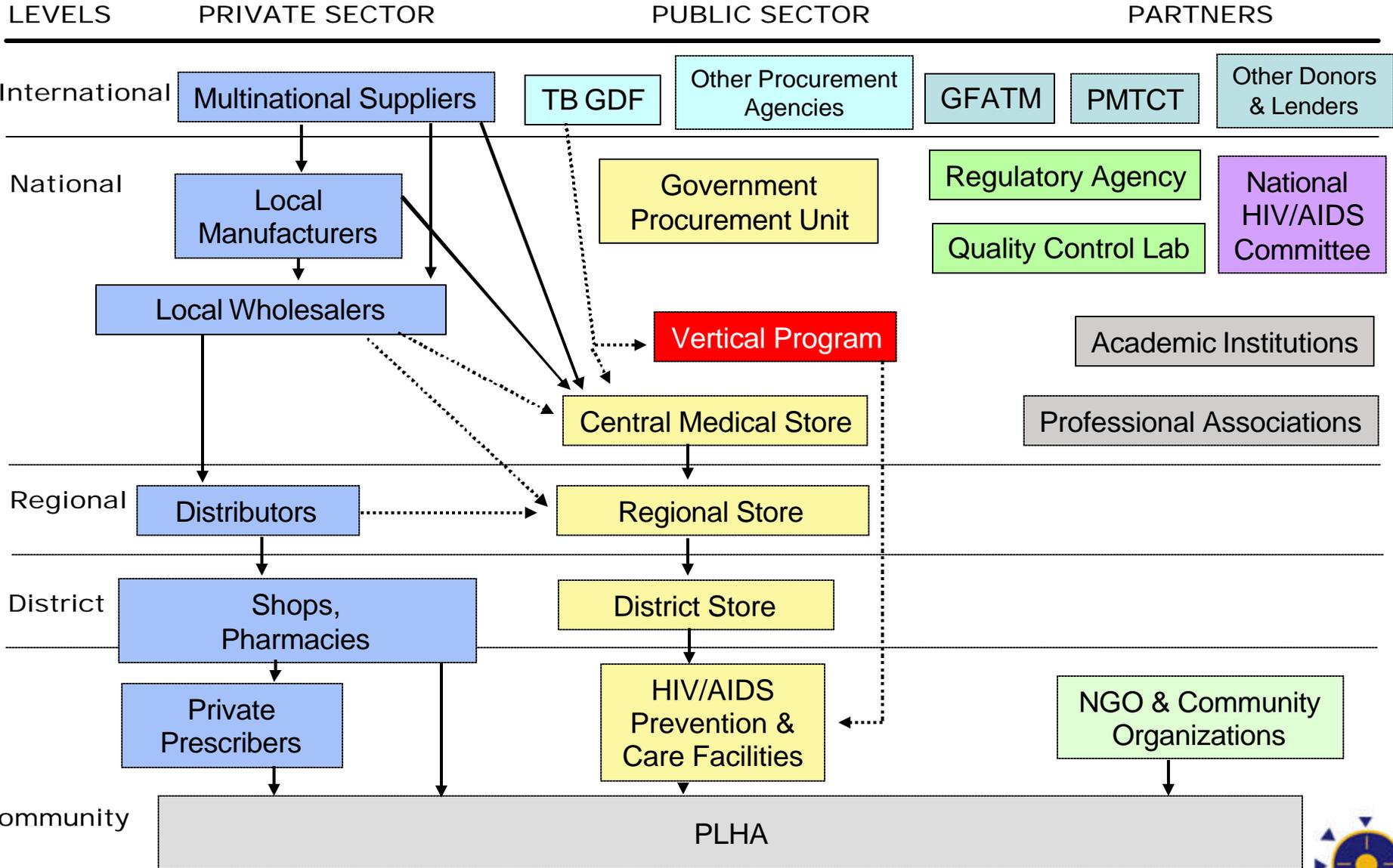


An Evolving Role and Approach

- Urgent need to respond to the multiple issues of access
- Building on the USAID experience of introducing antiretrovirals (ARVs) in Kenya, Ghana, and Rwanda
- Dealing with demand factor and absorptive capacity, while anticipating the “flood” of pharmaceuticals
- Pressure to identify immediate options and longer term plans to build capacity and develop systems



The HIV/AIDS Pharmaceutical System



The “Implementing While Strengthening” Paradigm

- Assessment approach has to:
 - Respond to demands for rapid scale-up and expansion
 - Identify immediate human resource needs and develop novel approaches and new roles
 - Address growing importance of laboratory services
 - Consider options for an integrated, systems approach for pharmaceutical management
 - Seek ways to increase access and promote rational use in the private sector (NGOs, FBOs, etc.)



Take Home Messages from Assessments

- Process is just as important as the assessment itself -- and local counterpart involvement at all stages is critical
- Overall pharmaceutical management and appropriate use should be the focus, not just product availability and distribution
- Comprehensive care and treatment programs require more than just antiretroviral drugs



Take Home Messages from Assessments

- Must identify systems and human resource issues requiring immediate attention
- Should include determining the feasibility of interventions for immediate scale-up and expansion, including use of the private sector
- Investments in time and funding are required for sustainable improvements
- Can and should play a pivotal role in facilitating effective donor and country-level coordination

