UpDate

UpDate is a section that reports on recently enacted legislation, new reports and publications, relevant conferences, and new programs concerning health policy issues. In this issue, we summarize a conference on pharmaceuticals sponsored by Project HOPE, and provide a roundup of recent publications on a variety of topics. Health Affairs *welcomes announcements of new publications and reports to be considered for UpDate.*

I. CONFERENCE SUMMARY

Pharmaceuticals In Developing Countries

Four Seasons Hotel
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Pharmaceuticals, an important segment of health care systems in developing countries, can account for more than 25 percent of governments' health care budgets. Interaction with pharmacists or community health workers dispensing drugs is often individuals' first and only contact with the health care system in developing countries. Shortages in available drugs or an inability to transport the drugs to the places they are needed can lead to a loss of confidence in the government health system, adversely affecting other public initiatives such as maternal and child health programs.

Despite the importance of a well-functioning pharmaceutical system, many developing countries have been plagued by a host of management and other supply problems. The World Health Organization (WHO) and other multilateral organizations have provided assistance on these issues; however, many problems persist.

In response to this perceived need, Project HOPE hosted a conference entitled, "Pharmaceutical Management in Developing Countries: Allocating Resources to Ensure Better Health Care." The U.S. Food and Drug Administration (FDA) Commissioner and representatives from seventeen countries, the U.S. Agency for International Development (U.S. AID), the World Bank, the Pan American Health Organization (PAHO), and Africare spent the two days sharing experiences, discussing their problems, and planning future strategy.[1]

In the conference's keynote address, FDA Commissioner Frank Young gave his perspectives on pharmaceutical issues, detailing the history of U.S. pharmaceutical regulation and focusing on quality issues. He voiced a need for international cooperation and sharing of information in the coming period of extensive pharmaceutical advances. He also expressed a need for "a cooperative spirit involving all sectors of our nations: the consumer, the physician, the academic communities, government, and industry." Such a partnership, he felt, could make critical strides toward improving pharmaceutical quality and access.

Representatives of the developing nations

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described significant problems with their countries' pharmaceutical systems. Out of a variety of experiences, two recurrent problems emerged: financing (especially cost-recovery strategies and foreign exchange shortages) and personnel training (especially in management, dispensing, and retention). Presentations covered all aspects of the systems, from the processes that must precede drug acquisition, such as choice of drugs and selection of suppliers, to distributional and dispensing issues that must be faced after receipt of the pharmaceutical supply.

Concerns Of Procurement

"In a situation where the allocation for drugs within our national health budgets is probably on the order of a quarter, at best perhaps half, of estimated need, . . . looking at where one puts these resources becomes a critical element," A.B. Hatib-Njie, Director of Medical Services, Medical and Health Department, The Gambia, said.

Selection processes. All representatives of developing nations agreed that a well-defined national drug policy is necessary for a rational pharmaceutical system. Integral to such a policy is a formulary (or list for the public sector) of basic or essential drugs that is nationally specific and takes into account such factors as efficacy, safety, benefit-risk ratios, local epidemiological profile, cost, minimization of side effects, avoidance of combination or duplication, the use of generic drug names, and prescriber competence. Many participants believed that the model formulary developed by WHO was a good starting point, although its adjustment to local needs is critical.

Problems associated with the donation of pharmaceuticals was another recurring issue. Organizations or countries with worthy intentions frequently donate drugs that ignore the country's formularies or that are packaged or organized contrary to the established national system. This sometimes results in cataloguing and sorting costs that exceed the benefits of the donation. Strategies for sensitizing philanthropic groups to these concerns are needed.

A number of participants mentioned the overly bureaucratic nature of the process of selecting suppliers, and cited the need for help in streamlining these processes. In addition, representatives from most countries indicated a need for better quality controls. Two basic strategies emerged: the development of quality control laboratories and testing centers to be located in the developing countries, and an increase in quality-certification schemes for exporting countries. Most agreed that national (or at least regional) testing was preferable, but it was clear that the two options need not be mutually exclusive.

Both Ulrec Mondesir of Saint Lucia and Daniel Williams of Grenada commented on the Eastern Caribbean Drug Service (ECDS), which, in its early stages, is seen as a procurement success story. The program currently encompasses six of the eight Organization of Eastern Caribbean States (OECS) members. It provides a centralized tendering service in addition to technical assistance, training, a limited amount of construction and equipment for warehousing improvements, and one vehicle and one computer for each participating country. The service, which is funded by U.S. AID, also is exploring the potential for private-sector involvement and cost recovery.

The procurement system within the ECDS employs a restricted tendering system. To receive a place on the approved supplier list, manufacturers must complete a vendor registration form that assesses financial status, technical competence, and managerial ability. The process preestablishes the quality of the manufacturer, which then allows price to determine the procurement. As Mondesir explained, "Now because {of} bulk purchases, competitors' prices for public tendering, and the assurance of prompt payment to suppliers, the ECDS is expected to reduce overall purchase costs of pharmaceuticals in the region of 25 percent. The agency is also expected to be financially self-sufficient in five years."

Indeed, the unit prices of pharmaceuticals in the participating eastern Caribbean states have been reduced significantly. Estimated savings have averaged 37.2 percent, ranging from a high in Saint Lucia of 66.1

percent to a low in Montserrat of 16.1 percent. Staffing and salary levels and related motivation issues were cited as constraints that might impede savings progress in specific areas.

Local manufacturing. The support and development of a national industry to produce essential drugs, where economically feasible, was a priority repeated by several developing nations. It was believed that local manufacturing would ensure independence and protection against lack of supply or delay of supply by the international companies. In addition, it was felt that local industry could help the government reduce the need for foreign exchange, which is always in short supply.

"With the appropriate incentives, a local industrial infrastructure could concentrate on the manufacture of the basic products needed for the majority of the population at affordable prices for the state and parastatal institutions," Ceferino Sanchez of the University of Panama explained. Both Edmund Harris of the United Kingdom and Tadao Shimao of Japan cautioned that local manufacturing is not a panacea and that such products could cost considerably more than imported items, especially when considering the often high costs of imported raw materials. However, Sanchez cited estimates that a country with a gross national product in the $2–$4 billion range and a population of two to three million people, which now is able to import $12–$14 in pharmaceuticals per capita, could sustain a viable local industry.

The conference participants almost uniformly stressed the need to create new program models that comply with the country's social, cultural, and economic environments. Too often, programs that look good on paper fail because of ignorance of local customs. Representatives also called for regional cooperation in the development of purchasing and other strategies. There was great interest in exploring the potential for the computerization of inventory, cost, and other information systems. Participants expressed interest in more training in computer use and management of systems.

Issues Of Access

Distribution. Transportation and distribution issues also have confounded pharmaceutical management in developing nations. An early barrier to efficient distribution is often at the port of entry. Bureaucratic delays and foreign exchange shortages can mean delays of several days to several weeks between consignment arrival and delivery to the central medical stores. Once shipments arrive from port, ground transport problems and improper cold storage can hamper the next distribution step. In addition, lack of security can lead to significant theft. One African participant estimated that 20 percent of his country's drugs are pilfered out of the system.

Designing improved storage facilities, developing distribution schedules, and using delivery route protocols were cited as crucial for improving distribution. Appropriate training was stressed at every level, including cost recovery, accounting, costing of merchandise, and banking transactions.

Dispensing. Dispensing practices and personnel training varied greatly by country, but these issues, particularly training, were among the most important of concerns. Some nations focused on the activities of physicians and pharmacists, whereas others stressed dispensing by village health workers, many of whom are illiterate.

Hani Oweis, Director of International Health in Jordan, cited many prescribing problems. He explained, "To overcome the inadequate techniques in prescribing, several efforts have been taken by the Ministry of Health with the help of WHO to train and supervise medical practitioners." In a statement echoed by other country representatives, he added, "Dispensing limits have been tried in my country, but practitioners seemed reluctant to follow {them}."

Participants agreed that compliance problems were greatest among specialists and older physicians. These problems seemed to stem largely from an inability to monitor such activities adequately. Dispensers working under the most stringent prescribing constraints, such as village health

workers, were perceived by some as much more compliant and consistent in their work. Several participants also mentioned conflict-of-interest difficulties with physicians who both prescribe and sell drugs.

The short supply of physicians and pharmacists also has a negative impact on efforts to encourage appropriate dispensing procedures. "For example, we have . . . {in} our clinic day about 200 patients to see, and we have two specialists and two house officers. With that load, we find it very hard to take a very extensive history, and you are fairly brisk with your prescription writing," noted Lennox Pierre, chairman of Trinidad and Tobago's Hospital Management Company Drug Committee.

The importance of prescribing simple treatment regimens was stressed repeatedly as a way to increase patient compliance. Most participants also noted that public education regarding appropriate drug use is lacking, including a need for understandable package inserts. At times, drugs are sold by the piece, placed in plastic bags (which often do not protect drugs from the sun and do not seal properly) or wrapped in paper with no written instruction. Pill boxes, although more expensive, are regarded as cost-effective in protecting the drugs and allowing room for instructions (using words or pictograms when necessary).

Prescribers need both initial and continuing education and training. Compliance with formularies should aid this process. Pharmacy inspection and quality control, and pharmacy administration and management, also were targeted for increased training and education. Participants expressed frustration from the loss of trained professionals, both to the private sector and to emigration. These losses were believed to result from a lack of governmental financial support and, as one participant suggested, from adverse conditions and poor treatment by government administrators.

Participants also believed that cost concerns should be significant factors in determining dispensing practices. However, lack of cost accountability by both patients and prescribers complicates efforts to emphasize cost containment. As Pierre noted, "It is very difficult for people to be cost-conscious in an environment and a system which is free at the point of usage."

Financing. Even in the absence of major management problems, financial constraints would substantially impede the ability of developing countries to maintain effective pharmaceutical systems. Widespread poverty in many nations often is aggravated by complex bureaucracy. For example, although budget constraints have left government-funded pharmaceutical programs unable to meet the country's demands through public financing, some politicians fear instituting user fees because the public has grown to expect "free" drugs. However, instead of receiving drugs at no cost, these same populations generally confront drug shortages and other inadequacies.

Ministries of health in most developing countries have found few "easy" sources of revenue, either for drugs or for other health expenditures. Government budgets are usually under great financial pressure. Income taxes and other direct taxes are difficult to collect in most developing countries because of the small formal labor market and a general lack of compliance by the population. Sales taxes and "sin" taxes, such as surcharges on cigarettes and alcohol, are often major sources of government revenues, and treasuries are usually unwilling to earmark such money for health needs. Given their limited alternatives, a number of countries have started to adopt user fees, either as a way of buying drugs directly or establishing revolving drug funds. Cost recovery from user fees varies from country to country.

Participants agreed that cost-recovery systems held promise for improving pharmaceutical availability even in very poor regions. As Mead Over, an economist with the World Bank, noted, "In many countries, 50 percent, sometimes more than 50 percent, of all the health care costs are currently being financed out of people's pockets, and many of those expenditures by individual poor people are for ineffective health care services (in the private sector)." When viewed this way, he explained, poor populations could benefit by diverting personal expenditures away from inappropriate providers and into

government health services that would then be able to deliver more effective care.

However, such user-fee projects are not without risks for the ministries. There is no guarantee that revenues raised will be available for recurrent health expenditures. Governments can force these revenues back into the central treasury, leaving pharmaceutical systems in the same financial straits as before.

In addition, the need for some government funding will continue since full cost recovery is not a realistic expectation. This is especially true for countries with the lowest per capita income, where it is unreasonable to expect most individuals to be able to contribute full economic costs (cost of the drugs themselves, transportation, storage, personnel, and so on).

Other financing alternatives, such as insurance, are frequently not feasible because of the absence of a substantial formal labor market. However, middle-income countries, such as in many parts of Central and South America, have reported favorable experiences with such strategies.

Promoting public/private partnerships in which governments take more advantage of private-sector resources represents another financing strategy raised initially by Jay Morris, Deputy Administrator of U.S. AID, and reiterated by Over. Examples of this strategy range from paying local mechanics to repair pharmaceutical delivery trucks rather than keeping mechanics on the full-time government payroll, to encouraging government to concentrate its funding on public health priorities and allowing the private sector to respond to the populations' curative care needs, for which individuals are more apt to pay on their own.

Concern also was expressed about the tendency to favor urban areas and high-cost hospital care over rural regions and village health systems. Seventy percent of government health spending in most developing countries goes to urban hospital-based care.[2]

Conclusion

In summarizing the conference discussions, Young, Alf Grech (special adviser to the Ministry of Health and Chief Government Medical Officer in Malta), and William B. Walsh (president of Project HOPE), with input from the group, developed a list of key concerns that could affect the ability to bring high-quality, cost-effective drugs to citizens in developing countries: (1) Knowledge of local issues and development of an appropriate plan taking into account local concerns; (2) quality assurance at all levels, particularly in the establishment of local or regional laboratories; (3) the need to develop models and policy options for the financing of pharmaceutical systems, and to develop internal political will for change; and (4) strengthening the infrastructure of pharmaceutical programs, including training, administration, proper procurement, and distribution. Developing countries can be encouraged by significant advances being made in these areas.

Additional concerns included the need for increased communication (between and within countries), the importance of regional cooperation, and the significance of cost-effective prescribing, particularly in developing drug lists and public-sector health programs, customized to individual countries' needs. In this vein, Young reiterated the FDA's willingness to organize an international fellowship program emphasizing training in quality assurance, testing, efficacy, and infrastructure development.

In general, conference participants saw significant potential for the creation of partnerships in the pharmaceutical systems area. Interactions between developing nations (both public and private sectors), developed nations, industry, nongovernmental organizations, WHO, health professionals, and patients seem to hold promise for continuing advancement in managing pharmaceutical systems.

NOTES

1. Africare is a private nonprofit firm headquartered in Washington, D.C., which provides technical assistance to African governments on developmental issues.
2. "Financing Health Services in Developing Countries: An Agenda for Reform," World Bank Policy Study (Washington, D.C.: World Bank, 1987).

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