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The Essential Drugs Monitor is produced and distributed by the WHO Department of Medicines Policy and Standards (PSM). It is published in Arabic, Chinese, English, French, Spanish and Russian, and has a global readership of some 300,000 to whom it is free of charge. The Monitor carries news of developments in national drug policies, therapeutic guidelines, current pharmaceutical issues, educational strategies and operational research.

WHO's Department of Medicines Policy and Standards seeks to ensure that all people – wherever they may be – are able to obtain the drugs they need at a price that they and their country can afford; that these drugs are safe, effective and of good quality; and that they are prescribed and used rationally.

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IN THIS ISSUE:

Key People in Essential Medicines 2–3
We meet 3 dynamic members of the essential medicines "family", Batool Jaffer Suleiman, Zafar Mirza and Jorge Bermudez

Rational Use 4–25, 36
Highlighting the International Conference on Improving Use of Medicines (ICIUM 2004)
Articles based on papers presented come from many countries. Topics include injection use, drug and therapeutics committees, ARV use in Botswana and Uganda, the selection process for medicines on Thailand's EML, and much more…

Access 26–28
This section features articles on efforts to overcome multidrug-resistant TB, and describes the use of the Rapid Assessment Protocol for Insulin Access, developed by the International Insulin Foundation

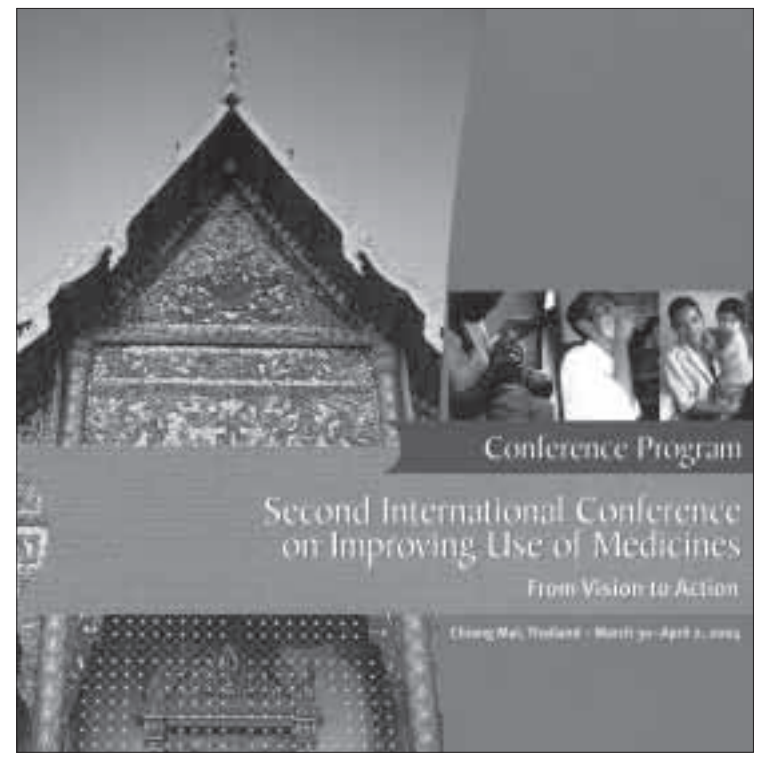
Newsdesk 28–29
WHO/UNICEF Technical Briefing Seminar for staff of pharmaceutical support programmes
Restructuring of WHO/HQ medicines department, introducing the new directors

Medicine Prices 30–31
An update on the WHO/HAI medicines project, with reports of progress in Africa and Malaysia

Published Lately 32–35
Includes guest reviewers

EDITORIAL

Improving the use and supply of medicines



In 2004, a major conference on Improving the Use of Medicines was held in Chiang Mai, Thailand. Several articles and an interview arising from the conference appear in this *Essential Drugs Monitor.* These include a description of how a rating system for the selection of essential medicines has been developed in Thailand, a report of research on adherence to AIDS medicines from Botswana, and an article highlighting the difficulties in making choices about AIDS treatments in Uganda. This issue also features a very popular poster competition promoting rational use messages in Indonesia, experience with insurance coverage in the Philippines and a review of interventions to tackle the long-standing problem of excessive use of injections. The interview with Batool Jaffer Suleiman highlights the innovative approach taken by Oman to promoting rational use in the small Gulf country, and provides many useful insights from which others can benefit. We report some of the findings and the overall recommendations made at the very successful Chiang Mai conference, part of the global effort to improve the use of medicines, and attended by almost 500 leading policy-makers and researchers.

Two articles about supply are featured. One highlights the efforts of the pharmaceutical company, Lilly, to share the technology for producing two medicines for treating multiple drug-resistant tuberculosis and the other is about a buyers club for ARVs in Thailand. Also related to ARVs is an article on South Africa, where in November 2004, a course on Promoting Rational Drug Use in the Community was held. One of the course outputs was an encouraging report, based on participants' field visits, on the initial roll-out of ARVs in pilot sites in the Pretoria area. Also from South Africa, we feature an article about producing a national formulary based on the *WHO Model Formulary.* This experience led to a modification in the way WHO disseminated its 2004 edition of the Formulary, with the majority of copies given free of charge and with different electronic formats and different language versions made available. WHO also developed a manual to adapt the Model Formulary to develop a national or local edition.

Pricing of medicines remains a hot topic and we include a short review of a meeting in Africa at which nine countries presented initial results of their pricing surveys. In addition, Zaheer Ud Din Baber describes the initial stages of preparing to do a survey in Malaysia. Readers are encouraged to visit the Health Action International web site at: http://www.haiweb.org/medicineprices/ to read survey reports from countries such as Chad, Kuwait, Malaysia and Mongolia.

Unusually, we include an article from a developed country. This describes the experience in the United Kingdom of involving patients in the process of developing standard treatment guidelines. This innovative approach could easily be duplicated in other countries or within groups developing guidelines.

Within the area of work related to medicines at WHO in Geneva, there has been a restructuring from one into two departments, resulting in the welcome appointment of a new Director, Malebona Matsoso, from South Africa. As usual, we highlight a number of new publications from WHO and others in our Published Lately section. We are grateful to our guest reviewers for their comments.

With this edition of the *Essential Drugs Monitor,* we are asking you, the reader, for assistance. We include a readership survey and we strongly urge you to complete the survey and send us your comments. The *Monitor* has been published for the past 20 years in a generally similar format. The world has changed with electronic distribution of information spreading across the globe. Does the *Monitor* still meet your needs? How could it be better? This is your chance to provide feedback that will make a difference to how or even whether the *Monitor* is produced in the future! We look forward to your responses.

Richard Laing, *Editor*

KEY PEOPLE IN ESSENTIAL MEDICINES

Working to improve rational use in Oman

An interview with Batool Jaffer Suleiman, Director of the Directorate of Rational Drug Use, Sultanate of Oman

RL: Thank you for meeting me today. I'm very interested in how Oman not only has a National Drug Policy but also a programme on rational use activities. But can we start by finding out about your background?

BJS: I was the first female pharmacist in Oman. I got my BSc in Pharmaceutical Science in 1977 and my Masters in Clinical Pharmacology in Canada in 1995.

RL: When did you become a Director?

BJS: That was in 1990 when I became Director of the Drug Control Department, and then in 2000 His Excellency the Minister of Health asked me to help set up a new Directorate because he was so worried about irrational use of drugs. On 15 April 2000, the Directorate of Rational Use of Drugs was officially established. This is one of three directorates in the pharmaceutical sector along with the Directorate of Pharmaceutical Affairs and Drug Control, and the Directorate General of Medical Supplies.

My Directorate is mainly responsible for conducting studies in all Ministry of Health institutions to highlight problems connected with irrational use of medicines. We are independent of the other two Directorates and report at a high level in the Ministry of Health

RL: What is the population of Oman?

BJS: It's 2.3 million in total with 1.5 million of these Omanis and the rest expatriates. The Ministry of Health has encouraged the training of more pharmacists to meet our needs and by the end of 2005 another 105 Omani pharmacists should join the workforce.

RL: I know that there are doctors from many countries working in Oman, making it harder to promote rational use, as they have trained in different places and have different attitudes and practices.

BJS: Yes, this was one of the main reasons for setting up the Directorate. I can give an example. In one hospital we observed that the use of metronidazole was very high, so we investigated and found that the Egyptian doctors in the hospital were prescribing it for diarrhoea. In Egypt most cases of diarrhoea are caused by giardiasis and the custom there is to prescribe metronidazole. These doctors were following the practice even though the diarrhoea had other causes.

Batod Jaffer Suleiman

We realised that we needed standard treatment guidelines and so we developed them. We had 36 manuals to cover common conditions at primary health care level, and not surprisingly we found that they were not used very much. I decided to concentrate on a pharmacotherapy chart, – a simplified chart for primary health care level, which was very well received. I even received congratulations from the Minister of Health himself.

RL: Have you done prescription surveys and measured the effects of rational use interventions?

BJS: Yes we first did a baseline survey using WHO indicators and at the same time we collected and analysed around 3,500 hospital prescriptions, finding that some 28% could be classed irrational. One very important principle and something that I really want to stress is that although we used real prescriptions in training courses we always removed the prescribing doctor's name. We would never criticise individual doctors responsible for irrational prescribing.

RL: Who finances your department – is it Ministry of Health funded or is it financed by drug sales, for example?

BJS: All our money comes from the Ministry of Health. There are charges for drug registration but all the revenue from that goes to the Ministry of Finance.

RL: What is your vision for medicines use in Oman in 5–10 years time?

BJS: Now we have very high standard medical stores and we have good drug management in Oman, so our focus is moving on to improving patient care.

RL: Do you have Drug and Therapeutics Committees?

BJS: Yes, in each of the 10 regional hospitals there is what we call a Pharmacy and Therapeutics Committee. They may not be operating to their full potential perhaps, but they are quietly doing a very good job. Also, at the Central level we have the Central Drug Committee, chaired by His Excellency the Under-Secretary for Health Affairs. I am a member as are the heads of the other two pharmaceutical sector Directorates, together with senior hospital consultants. Any drug to be approved for use by the Ministry of Health must be reviewed by the Committee, which looks at all aspects including at which level of the system it can be prescribed.

We have a National Formulary published in 2003 and all doctors, nurses and medical students receive a copy. We also have a primary health care Essential Drugs List, containing 170 medicines and there is another list for emergency items.

RL: What about staff development in terms of advanced therapeutics, such as renal dialysis and cancer care? Are these difficult areas in a small country?

BJS: At the tertiary care hospital we have pharmacists who specialise in such areas. I must say that one of the delights of working in Oman is that although we provide training, pharmacists also show a huge interest in self-education.

RL: Is Oman now a country where others come to learn from your success? You were the first of the Gulf Cooperation Council (GCC) countries to go beyond efficient procurement to look at efficient drug use.

BJS: Yes, we've had doctors from other GCC countries on our training courses, which is a great pleasure.

I have to say that my job is so interesting, highlighting issues related to irrational use of drugs – sometimes they are quite minor things and we can react quickly to improve them. For example, I found out that a hospital patient had received three bottles of eye drops at once, and soon after at a conference of eye specialists I was able to discuss this case of over prescribing.

RL: We've taken enough of your time, it's been fascinating, thank you.

BJS: It has been a pleasure, but please let me stress two critical points. You must have good relations with health personnel – don't criticise, just encourage to improve. In this way you will achieve more. Secondly I can't stress enough the importance of political commitment, the support of the Minister of Health has been so important. ❑

Interview by Richard Laing

KEY PEOPLE IN ESSENTIAL MEDICINES

Interview with Zafar Mirza

Patient advocate is new EMRO Regional Adviser

"The challenge we face now is how to make essential health services work in places where people are struggling not only with poverty but where they must overcome crisis – such as in Afghanistan, Djibouti and Yemen. The Eastern Mediterranean Region is very diverse. It includes some of Asia's poorest countries and some of its richest countries. So its health problems are wide ranging. But it's obvious to me that our priority must still be the poor popu-lations of the poorest countries. Where poverty is rampant, illiteracy is widespread, and with that comes the issue of access to medicines. We must ensure that people have access to safe and affordable essential medicines," said Dr Zafar Mirza.

After 13 years as founder and executive director of Pakistan's leading consumer watchdog organization, Dr Mirza has joined WHO as its regional adviser for essential medicines for the Eastern Mediterranean. The Network for Consumer Protection is now a national institution in Pakistan, fighting for the rights of consumers in the fields of pharmaceuticals and access to clean water, and also on tobacco-related issues. Dr Mirza – then a practicing psychiatrist – was inspired to establish a voice for consumers following a national drug injury tragedy.

"I never had a second thought about it. There was virtually no concern for access and safety issues in Pakistan at that time. Today, membership is country-wide and its leadership development has been such that I knew it was the right time to hand over", he continues.

Now based in Cairo, Dr Mirza is forthright about the challenges for his region. He pays tribute to WHO's achievements in essential medicines. But a strong NGO and advocacy background mean that he is not afraid to describe its shortfalls. People are his highest priority.

" I think that there is an area of access that has been ignored for too long by WHO – financial access. WHO has not fully confronted the role of private heath care providers, who are the predominant health-care providers in some Asian countries. Poor people are sometimes obliged to spend 70–80% of their precious income on medicines. We must ensure that they get value for money. Of course we must enhance financing of public heath care and easy access to safe, high quality essential medicines – but we should not ignore the private sector. National policies mean dealing effectively with both the private and public sectors."

Dr Mirza is also concerned about corruption and unethical practices by doctors. These practices are now recognized as one of the major determinants of irrational drug use. It is a controversial issue but one that WHO should confront. "It is scandalous and it is a problem that is becoming more and more widespread. Some drug companies use highly unethical practices to promote their product to doctors. They offer them financial incentives and it is poor people who ultimately pay for corruption with higher prices. Studies have shown that doctors are aware of this irrational medicine use, but there is a gap between what they know and what they do. What is needed is a comprehensive national medicines policy framework that prevents the pharmaceutical industry from exploiting this area. It's a big challenge but logical and efficient advocacy and capacity building will eventually achieve this," he continued.

Zafar Mirza

Zafar Mirza feels strongly that WHO's medicines role in the regions can never be simply about medicines. It is also about strengthening human resources for dealing with medicines issues in low- and middle-income countries. "The problems are of both quality and quantity. There are too few heath professionals and they are not properly trained. We must build that capacity and put a good structure in place. It is our responsibility to help governments to develop health strategies and systems based on the tenet that access to medicines is a basic human right. In my opinion not enough importance is given to citizens' rights. It is every citizen's right to have access to safe, effective medicines and every state's responsibility to ensure this. It is a paradigm that WHO should harness."

Dr Mirza, who is married with three children, qualified in Pakistan as a medical doctor in 1988. He then studied public health in developing countries at the London School for Hygiene & Tropical Medicine. He has worked in psychiatry and in rural heath services. ❑

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Interview with Jorge Bermudez

Addressing the unfinished agenda

"We have low-cost drugs but they are not necessarily accessible. We have the means to eradicate certain diseases, such as leprosy, and yet we haven't done so. This is an unfinished agenda. We must address it by protecting our achievements and finding sustainable solutions to remaining problems," said Dr Jorge Bermudez, who takes over as regional adviser for the WHO Regional Office for the Americas, in Essential Medicines, Vaccines and Heath Technologies.

A Brazilian who speaks Portuguese, English and Spanish, the 57-year old public health expert is frank about the challenges ahead. His background gives him a broad basis for these opinions. Before becoming Director of the National School of Public Health in Brazil, Dr Bermudez was a medical doctor specializing in tropical medicine (infectious and parasitic diseases).

"The Americas is a very interesting region, with very different countries. It's important to work with each of them, but of course we have chosen priority countries, based on social and economic indicators. These are Bolivia, Haiti and Guyana, Honduras and Nicaragua. In other words, we're focusing on Central America, the Caribbean and South America," he continued. "I think my key strength lies is my knowledge of how ministries of health and governments work."

Dr Bermudez has recently relocated to AMRO headquarters which are situated in Washington, USA. He is the author of several key texts on international pharmaceutical policy, and has an extensive background in academia and public health.

"New diseases and new issues are coming up all the time and it's vital that we react to these rapidly and effectively. Anthrax and SARS are just two examples. We must also address the constraints imposed by free trade agreements. We have to put access to medicines at the top of the agenda for countries, and ask how global and bilateral trade agreements are influencing or restricting access. For example, we are seeing a very negative impact for Central America. Where trade agreements are restrictive in terms of intellectual property and patents, the cost of medicines remains high. For example, the new HIV/AIDS treatment K20, which is included as part of public health care in Brazil, is very expensive in other Central American countries."

Jorge Bermudez

Dr Bermudez views the large Pan-America region as an opportunity to exchange knowledge and know-how – and for countries to work together. "We have to achieve the balance between new medicines and affordability. In a world of fewer frontiers we must adopt a more communal approach to heath. At the moment we see medicines tourism – where people go to another country to seek treatment – but this is not a real solution."

"Another great challenge is to learn from other regions. There is a real opportunity to do this. All the regions have different experiences, and sometimes different expertise, but ultimately we have a common goal." ❑

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Interviews by June White

RATIONAL USE

The International Conference on Improving Use of Medicines 2004


R. Laing

➢ Richard Laing

As part of a global effort to improve the use of medicines, 472 leading policy-makers, researchers, and other stakeholders representing 70 countries gathered in Chiang Mai, Thailand, in April 2004 for the Second International Conference on Improving Use of Medicines (ICIUM 2004). The conference considered experiences in theme areas of Access, Adult Health, Antimicrobial Resistance, Child Health, Malaria, HIV and Tuberculosis. (Presentations available at: http://mednet3.who.int/icium/icium2004/proceedings.asp).


Photo: WHO

Attentive ICIUM participants

Evidence presented made it clear that misuse of medicines continues to be widespread and has serious health and economic implications, especially in resource-poor settings. However, effective solutions for some serious medicines problems already exist. Participants called upon governments to implement policies and programmes in the priority areas listed below. (Detailed recommendations are available at http://mednet3.who.int/icium/icium2004/recommendations.asp).

The conference highlighted the need to move from small scale research projects to implementing large scale programmes that achieve public health impacts. Many promising and successful interventions were presented at ICIUM, yet global progress is confined primarily to demonstration projects. There are few reports of effective national efforts to improve the use of medicines on a large scale and in a sustainable manner. Thus a major research gap is to answer the question "How do we achieve large scale and sustained improvements within health systems?"

Countries should implement national medicines programmes to improve medicines use

- Data from Lao People's Democratic Republic, Kyrgyzstan, and the Sultanate of Oman show that systematic implementation of a comprehensive national medicines policy improves medicines use. Implementation should be based on local evidence; should cover both the private and public sector; should include interventions on multiple levels of the health care system; and should be long-term since implementation takes time, continued stakeholder commitment, and adequate human resources.
- Broad-based insurance systems covering essential medicines for the poor can be developed in low income settings. Countries should strengthen efforts to develop and extend insurance systems, and they can use these insurance systems to leverage better prescribing, more cost-effective use by consumers, and lower prices from industry.
- Generic prescribing and dispensing policies can dramatically decrease the cost of medicines to consumers and health programmes. They must be accompanied by programmes to assure medicines quality.
- Although challenging, policies to separate prescribing and dispensing are feasible to implement and can result in lower costs to consumers and programmes and improved use of medicines.
- In settings where patients share in the cost of care, policies can be structured to promote more appropriate use. Charging fees per full course of medicines results in higher quality than charging per unit or per visit.
- Prices are a major determinant of access to medicines. A new standardised methodology allows countries to measure prices and affordability of essential medicines. All countries should measure essential medicines prices, rationalise policies that determine price, and monitor comparative price information over time.

Successful interventions should be scaled up to national level in a sustainable way

- One exciting finding presented at ICIUM 2004 is the efficacy of 3-day antibiotic therapy for childhood pneumonia, the major killer of children in developing countries. Short-course antibiotic therapy is effective for non-severe pneumonia, costs less, increases adherence, causes fewer side effects, and decreases the emergence of resistant bacteria.
- Multifaceted coordinated interventions, rather than single interventions, are more effective in changing prescribing by both public and private sector providers. Interventions should be based on detailed analyses of existing problems and must take into account financial incentives. Evidence from Sweden demonstrates that a nationwide, multifaceted intervention can improve antibiotic use and contain antimicrobial resistance. Intervention strategies should be tailored to local needs and may include media campaigns, treatment guidelines, and individual and group feedback on practice.
- Misuse of medicines in hospitals remains problematic. However, data from Indonesia, Cambodia, and Lao PDR show that a structured quality improvement process improves use of medicines in hospitals and can be transferred across countries.
- Countries should monitor impacts when scaling up interventions to improve use of medicines. In particular, they should use valid indicators to monitor the long-term impacts on equity of access to medicines, quality of care, affordability, and cost. This will allow countries to evaluate programme success and refine approaches based on evidence.


Photo: Hardcopy photo provided to scan

Photo: WHO

Unpacking the Monitor at ICIUM - cheerful Thai pharmacy students

Interventions should address medicines use in the community

- In many countries, most medicines are purchased in pharmacies and other retail drug shops, often without input from a trained medical provider. Several interventions involving outreach, peer process, regulatory enforcement, and incentives have shown short-term success in improving practice in this setting. Working with professional and trade associations, countries should develop sustainable programmes to measure and improve quality of retail pharmacy practice.
- Poor adherence to therapy contributes to the emergence and rapid spread of resistance. Resistance to conventional drugs has been observed in patients with respiratory infections, malaria, diarrhoeal diseases, tuberculosis, sexually transmitted infections, and HIV/AIDS. As global programmes expand access to therapies for HIV, malaria, and tuberculosis, countries must implement systems to ensure adherence as an integral part of treatment programmes and monitor the emergence of resistance to treatments.
- Another exciting finding at ICIUM 2004 was that children can be effective change agents to improve community medicines use. Countries should consider school-based education programmes that involve children as a way for key messages to reach parents.
- Pharmaceutical promotion has negative effects on prescribing and consumer choice. Voluntary methods to regulate promotion have been shown to be ineffective. Countries should regulate and monitor the quality of drug advertising and of industry promotional practices, and enforce sanctions for violations.
- Complementary and alternative medicines (CAM) often play a significant role in meeting individuals' needs for affordable essential medicines. However, countries should review all of their policies concerning the quality, safety, and efficacy of CAM.
- Evidence is still lacking about how to improve use of medicines for chronic conditions, including mental health problems, in resource-poor settings. Given increasing prevalence worldwide, there is an urgent need to evaluate how medicines are currently used to treat chronic conditions and how to promote more cost-effective long-term use. ❑

RATIONAL USE

Indonesia: poster competition spreads the rational use message


H. Thamrin-Akib

➢ HUSNIAH R. THAMRIN-AKIB

INDONESIA has long acknowledged the importance of promoting the rational use of medicines and the need to find innovative ways to engage the public in this issue. One of its most recent initiatives – a poster competition has proved extremely successful.

In February 2002, Indonesia inaugurated its Directorate for Rational Drug Use (RDU) to develop specific norms, standards, procedures, guidelines, technical assistance and advocacy to improve the way medicines are used. However, for more than 30 years different interventions have been tried in the country both through regulation and education but not always with encouraging results. It is well known that rational drug use depends not only on prescribers and dispensers, but also on patients – the ultimate decision-makers. Patients needs objective, understandable information to make their decisions rationally, but they rarely receive it. Information to patients and communities can be given on an individual basis in a clinical setting, or through a mass communication campaign in a public setting. Providing information to the community as a whole is not a big problem, but to ensure that people absorb that information, follow though the ideas transmitted and act upon them is another matter. The easiest way to reach large numbers of people is through printed materials, but experience has shown that much of the printed material sent to the public ended up unopened in wastebaskets.

Actively engaging the public

Indonesia decided to experiment with a poster competition to increase awareness and to help people understand the main issues relating to RDU. This initiative was chosen because so many Indonesians enjoy art and painting, to such an extent that in some provinces painting is a daily activity. As part of the competition written information about RDU was handed out and people were instructed to make a poster based on the messages in that information. The idea was that people had to understand the written messages to be able to transform them into a poster and also that the competition would actively engage people in an RDU programme.

The messages were developed after assessments in five province showed widespread misunderstanding of drug use – such as antibiotics being appropriate for every disease, antibiotics increasing resistance to illnesses and the misconception that generic drugs are lower quality, less powerful drugs. Generic drugs were also perceived by some as cheap drugs for poor people that cannot cure diseases as effectively as brand name drugs. After the provincial assessments, a group of experts created a set of short, simple and easily understood messages.

The poster competition began as a pilot study involving a pre- and post-intervention trial with high school children and women as the target population. These groups were selected because children have the potential to make change in the future and women because they are the carers in the family who take decisions on health issues.

Ten women's associations and 10 high schools were selected, and five study groups and five control groups were chosen at each. A set of questionnaires to ascertain level of knowledge of rational use of antibiotics was handed to approximately 30 people from each of the groups, (both the study and control groups). Soon after, a set of five different messages on rational use of antibiotics was handed to the study groups, and information about generic medicines was handed to control groups. Contestants could choose which of the five messages they wanted to convey in their a poster, or they could choose a combination of the messages. When the posters were collected, the same questionnaires about rational use of antibiotic were again given to the study and control groups. Prizes were offered for the three main winners and to 30 other entrants in order to attract more participants. The District Health Officer was the coordinator of this WHO-sponsored competition.

Effective and pleasurable

Posters were analysed for artistic and aesthetic value, their effectiveness in communicating and the extent to which the content remained faithful to the rational use message. The judges were experts on rational use from the Faculty of Medicine at the University of Indonesia, a journalist, an expert from the Centre for Health Promotion in the Ministry of Health, and an artist from the Institute of Art in Jakarta. To analyse the effectiveness of the intervention, baseline scores on knowledge of rational use of medicines were compared to post-intervention scores.

The pilot project resulted in a total of 86 posters from high school children and 48 from women's associations. In the women's group there was 100% correlation between the posters' content and the rational use message they were intended to convey, while in the high school group the percentage was 98% (84 of 86 posters). Mean scores of knowledge on the rational use of antibiotics in the women's study group pre- and post-intervention were 5.8 and 8.6 respectively, while in the control group these were 5.9 and 8.4. In the high school study group scores before and after intervention were 6.7 and 8.0, while in the control group they were 6.2 and 6.9 respectively.

The competition was an effective method of bringing the rational use message to the community, and there were spin-off effects, including an exhibition of the posters and further distribution of some of the poster images in the form of T shirts and mugs. ❑

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RATIONAL USE

Recent progress towards the safe and appropriate use of injections worldwide


Y. Hutin

➢ YVAN HUTIN

REPORT FROM THE SECOND INTERNATIONAL CONFERENCE ON IMPROVING USE OF MEDICINES

In developing and transitional countries, 16 thousand million injections are administered each year – a ratio of 3.4 injections per person per year. These indicators suggest a gross overuse of injections.[1] In addition, approximately one third of all injections are administered with injection equipment reused in the absence of sterilization.[1] In 2000, the combination of injection overuse and unsafe practices may have accounted for one-third of new Hepatitis B infections, 40% of new Hepatitis C infections and 5% of new HIV infections.[2] To prevent injection-associated infections, injection use needs to decrease and injection safety must be achieved.

Poor injection practices are an illustration of inappropriate and unsafe use of medicines. The ICIUM Conference provided an opportunity to review the impact of various interventions conducted worldwide to decrease injection overuse or to achieve safer practices. This reports summarises the results of these interventions and suggest next steps in operational research and policy changes.

RECENT DATA ON INJECTION PRACTICES AND EFFECTIVE INTERVENTIONS

Studies presented at ICIUM that reported data regarding injection practices included:

- a review of surveys describing the use of essential drugs – including injections – in health care facilities;
- a rapid assessment of injection practices in Mongolia;
- an intervention to improve the safety of injections in Burkina Faso;
- a managerial intervention to decrease the use of injectable diclofenac in the Islamic Republic of Iran;
- interactional group discussions (see Box 1) to reduce injection overuse in three countries (Cambodia, Pakistan and the United Republic of Tanzania).

AN ASSESSMENT OF INJECTION PRACTICES IN MONGOLIA, 2001

Anecdotal reports suggested that injections were overused to administer medications in Mongolia. In 2001, an assessment of injection practices used standard WHO tools[3] to collect information on injection practices, their determinants and their consequences. The survey used standardised interviews and observations of a small convenience sample of 21 prescribers, 28 injection providers and 65 members of the public.[4] The latter reported receiving an average of 13 injections per year. Prescribers reported a total of 1905 prescriptions per week on average, 265 (14%) of which would include at least one injection. Among the members of the public, 18 (28%) reported that they would prefer an injection for the treatment of sickness with fever. Observed injection providers consistently used freshly opened, new single-use syringes and needles for all injections. However, there were breaks in infection control practices while administering injections and eight of the 28 providers (28%) reported occasional reuse of disposable syringes with new needles for antibiotic administration to the same patient in hospital. Injection providers reported 2.6 needle-stick injuries per year. While injection practices improved in Mongolia in recent years, additional efforts are needed to reduce the use of injections and to address persisting breaks in infection control practices.

Box 1

Interactional group discussions: an effective intervention to reduce injection overuse

Most prescribers attribute the overuse of injections in health care settings to a widespread preference for injections among patients. However, qualitative and quantitative studies indicate that in contrast to common perceptions, most patients do not prefer injections to administer medications. In fact, patients are open to alternatives to injectable treatments and they trust their doctors for the choice of the best type of treatment. In the 1990s, researchers in Indonesia conducted a randomized control trial to determine whether prescribers' practices could be modified through an intervention that would allow them to understand that most patients do not prefer injections. This intervention – interactional group discussion – consists in a moderated discussion between prescribers and patients. Such a setting allows confronting prescribers with the absence of preference for injections among most patients, including mothers of small children. Following the discussion, prescribers give fewer injections, and the effect is particularly sustained over time. Until recently, interventions based upon interactional group discussion had not been conducted outside Indonesia. However, ICIUM 2004 provided an opportunity to compare the experience of three teams in three different regions with this type of intervention.

SAFER INJECTIONS FOLLOWING A CHANGE IN THE ESSENTIAL DRUGS POLICY, BURKINA FASO, 1995–2000

In 1995, the Ministry of Health of Burkina Faso reformed the national essential medicines policy to improve access to medicines and basic supplies, including single-use injection devices. While two studies indicated that injection safety improved dramatically between 1995 and 2000, the impact on the use of injectable medicines was unknown. Pharmaciens Sans Frontières conducted a retrospective study in 2001 to determine to what extent the improvement in injection safety observed between 1995 and 2000 was related to an increased access to injection devices; and to determine whether the increased access to injection devices and essential drugs could have led to irrational use of injections.[5] A total of 52 public primary health care facilities and 50 adjacent public pharmaceutical depots were visited. Of the 52 facilities visited, the number of them equipped with a pharmaceutical depot selling injection devices rose from 13 (26%) to 50 (96%) between 1995 and 2000. Of 50 depots, 96% had disposable 5ml syringes available in 2001. At all facilities, patients were buying injection devices at the depot for their injections. While injection devices were available in more facilities, the proportion of prescriptions including at least one injection remained stable at 26% to 24% between 1995 and 2000. Overall, the data suggest that establishing pharmaceutical depots next to health care facilities increased access to single-use injection devices and led to safer injection practices. No increase in the prescription of injectables was observed as a consequence of the improved availability of these devices.

REDUCING THE USE OF INJECTABLE DICLOFENAC IN IRAN

A high prescription rate of injectable medicines is the most pronounced indication of irrational drug use in the Islamic Republic of Iran. The Iranian Adverse Drug Reaction Monitoring Centre received six reports of sciatic nerve damage following intramuscular injection of diclofenac sodium in June 1998. All six occurred in children under 10 years old. Shortly after these events, the Centre issued an "alert letter" to health professionals to remind them of the contraindication of the product in children under 15. However, by the end of 1998, the number of reports increased to reach more than 100. Since this adverse event had been recently identified, the intervention of the Iranian Pharmacovigilance Centre was necessary to prevent a further increase in incidence.[6] This intervention included (1) communicating with health professionals, (2) changing drug use protocol and (3) implementing restrictions on local production and on availability. Following the intervention, the total quantity of diclofenac sodium used in the country decreased from 85 million to 60 million ampoules per year. The number of adverse drug reaction reports received followed the trend of product use and showed a reduction following the intervention. A multifactorial intervention was necessary to reduce use of diclofenac injection and enforce a more rational use of drugs in the country.

INTERACTIONAL GROUP DISCUSSION TO REDUCE INJECTION OVERUSE IN CAMBODIA

In 2002, rapid assessment data indicated that injections were overused to administer medications in Cambodia, and the Cambodian Ministry of Health conducted a randomized controlled trial aimed at (1) reducing overuse of injections in public health sectors through interactive group discussions, (2) determining whether interactional group discussions were effective in Cambodia and (3) addressing options to scale up this intervention.[7] Two strata were examined: Kompong Cham and Phnom Penh. The baseline data from the pre-intervention survey indicated that the proportion of encounters leading to the prescription of injections ranged from 77% to 97%. Six interactional group discussions were conducted among the intervention groups in Kompong Cham and in Phnom Penh. These discussions provided an opportunity for prescribers to be confronted with the actual absence of a preference for injections in the public, as was reported in Indonesia. A facilitator clarified misunderstandings regarding injection use. To evaluate the impact of the interactional group discussions, an assessment of the frequency of injection prescription was conducted three months after the intervention. Preliminary results of this evaluation (made available by the authors after the ICIUM Conference) suggest that the intervention was effective in reducing injection overuse. A collaboration has now been initiated between the United States Agency for International Development (USAID) and WHO to scale up the intervention in Cambodia.

INTERACTIONAL GROUP DISCUSSION TO REDUCE INJECTION OVERUSE IN TANZANIA

Irrational prescribing is commonly reported in various health care facilities in the United Republic of Tanzania. A

RATIONAL USE

study conducted in 1999 and 2001 in public and church-owned primary health care facilities identified common forms of irrational use of drugs, including polypharmacy, overuse of antibiotics and overuse of injections. It was observed that more than 70% of patients received at least one injection. To assess the impact of an interactive group discussion, a randomized controlled trial was conducted in 10 public and 10 private dispensaries in peri-urban Dar es Salaam, using 30 patient records (prescriptions) from each facility, randomly selected from June to August 2003.[8] The baseline study carried out from September to November 2003 revealed that injections accounted for 29% of prescribed medicines at public facilities and 37% at private facilities. The baseline study indicated an overuse of injections in both public and private primary health care facilities. Interactional group discussions to reduce injections were ongoing in 2004 and the post intervention survey will require 6–12 months to complete.

Interactional group discussion to improve injection practices in the informal private sector of Karachi, Pakistan

Health care providers in Pakistan practicing as general practitioners commonly over prescribe injections and reuse syringes. A pilot intervention was conducted among general practitioners in the informal private sector in a densely populated part of Karachi with the objective of reducing injection overuse and improving injection practices.[9] For this 12-month intervention, 20 general practitioners were assigned to an intervention and 20 others were used as a control group. The intervention consisted of (1) interactional group discussions between patients and prescribers on the topic of the use of injections to treat common ailments and (2) health education, using pamphlets and posters. Exit interviews monitored injection use and injection safety before and after the intervention in both groups. Pre-intervention information indicated that the proportion of visits followed by an injection was 88.3% among patients in the control group and 84.4% among patients in the intervention group. Following intervention, this proportion remained stable (87.3%) in the control group but decreased to 51% in the intervention group ($p<.05$). At baseline, 91.9% patients in the intervention and 85% in the control group were given an injection using a new single use syringe. Following the intervention, a newly packed syringe was used for 64.7% patients in the control group as opposed to 92% in the intervention group. Nearly 89% patients in the intervention group mentioned that the packed syringe was opened in front of them as compared to 55.6% in the control group ($p<.05$).

Discussion

Evidence from the studies presented at ICIUM (Table 1) suggests that better communication between patients and providers[7–9] and managerial approaches (i.e., restricting access to selected unnecessary and dangerous injectable drugs)[6,10] can reduce injection overuse. In addition, improved access to single use injection devices improved injection practices without leading to an increased irrational use of injectable medications in Burkina Faso. While injection practices are still problematic in a number of countries including Mongolia,[4] there seems to be a general trend for a decrease in injection use in developing and transitional countries worldwide.[11] However, this global tendency cannot be attributed to the effect of a specific intervention or initiative.

The effectiveness of interactional group discussions between patients and prescribers to decrease the use of unnecessary injections (Box 1) has been reported in the 1990s.[12] However, since the original publication, this type of intervention had not been tested outside of Indonesia where the original studies had been conducted. Today, experience from Tanzania,[8] Pakistan[9] and Cambodia[7] suggests that the hypothesis behind the concept of interactional group discussion is valid in other countries. In the three countries where this intervention was conducted, it has been possible to confirm that prescribers overestimate patients' preference for injections and that when confronted with the actual statements of clients, they understand that they could prescribe fewer injections. In Cambodia and Tanzania the results of the post-intervention prescription surveys were not available at the time of the ICIUM Conference to evaluate the impact of interactional group discussions on injection use. In Pakistan, the post-intervention evaluation indicated that the interactional group discussions were in effective in reducing injection overuse. Furthermore, in Pakistan, the information, education and communication that were included as part of the intervention were also effective at improving injection safety.

The intervention conducted in Burkina Faso[5] differed from the others presented at ICIUM as it mainly focused on improving injection safety. Since 1995, the national drug policy aimed at opening public sector community pharmacies that were located next to primary health care facilities. These primary health care facilities offered essential medicines and single-use injection devices at low cost on the basis of a cost recovery scheme. This increased the geographical access to injection devices addressed the problem of chronic shortages of single-use injection devices[13] and led to an improvement of the safety of injections in the country between 1995 and 2000.

On the basis of the data presented at the ICIUM Conference, three recommendations can be proposed for immediate implementation. First, the effectiveness of interventions of a different nature suggests that various methods could be combined to improve impact on injection frequency and safety. Second, the use of standardised indicators of injection use (the proportion of patients who were prescribed an injection) allowed comparisons across these studies, illustrating the importance of using such indicators. Third, further work is needed to test the interactional group discussion approach in various other settings (e.g., Iran) and to scale it up in countries where it has been demonstrated to be effective. In addition, three recommendations can be proposed for long-term implementation. First, injection device security (i.e., availability of sufficient quantities of single use injection devices in each health care facility) should be ensured in each health care facility to eliminate the reuse of injection devices.[14] Second, all methods using interactive communication techniques (e.g., monitoring, training and planning – MTP) should be explored to reduce injection overuse. Third, bottom-up (communication) and top to bottom (managerial) approaches should be combined to improve injection practices. Further operational research should (1) explore the mechanisms that could be used to address the financial incentive to prescribing injections, (2) attempt to understand "positive deviants" among health care providers who prescribe fewer injections and (3) determine if the reduction of injection use in the formal, public sector would drive patients to use the informal, private sector. ❑

Table 1
Summary of the studies examining the effectiveness of interventions to improve injection practices

Country	Burkina Faso	Pakistan	Tanzania	Cambodia	Islamic Republic of Iran
Intervention	Ensuring injection device security through the national essential medicines policy	Interactional group discussions to reduce injection use and improve injection safety	Interactional group discussions to reduce injection use	Interactional group discussions to reduce injection use	Managerial intervention to decrease the use of injected diclofenac
Strength	Sustainable change in the national drug policy	Addressed injection safety and injection overuse	Focused and public and private sector	Empowered patients to encourage them to demand oral medications	Policy intervention conducted at the national level
Potential for scale up	Country-wide intervention	Yes	Potentially: Evaluation pending	Potentially: Evaluation pending	Country-wide intervention

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RATIONAL USE

Adaptation of WHO Model Formulary for use at primary health care level in South Africa


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In October 2002, WHO released its *Model Formulary*[1] in both print and electronic formats. The *Model Formulary* contains information on all 325 medicines contained in the WHO Model List of Essential Medicines and is intended to serve as a basis for medicines formularies produced by countries or organizations. One example is provided by the faith-based NGO "Mercy Ships", which has adapted the *WHO Model Formulary* to produce its own drug information resource for use on its hospital ships that serve developing nations. Its formulary emphasises dosages and indications, and is available free of charge on the Internet as an MS Word document[2] (for further information see page 20). In our case we have used the *WHO Model Formulary* as a basis to compile a formulary for primary health care in South Africa.

Background

South Africa has had public sector *Standard Treatment Guidelines (STGs) for Primary Health Care* since 1996.[3] In 1998, these guidelines were revised, guidelines for hospital level (adult and paediatric) were added,[4,5,6] and Essential Drugs Lists (EDLs) were derived from them.[7] The guidelines are now widely available and used in facilities throughout the country. The public sector STG and EDL approach can only reach its full potential if adequate information is made available about the medicines themselves. Providing this information has never been the purpose of the guidelines; they need to be supported by a medicines formulary.

The medicines formulary used most frequently in South Africa is the *South African Medicines Formulary.*[8] This well-known and comprehensive reference is currently in its 6th edition. However, as it contains information on medicines used in both the public and private sectors as well as at all levels of care, there has been a need for a more limited reference applicable to primary health care, particularly in the public sector. The *Primary Health Care Formulary*[9] was intended for this purpose. Its third edition was published in 1996, and it continues to be in demand.

In June 2003, the South African National Department of Health posted draft revised *Standard Treatment Guidelines for Primary Health Care* on the Internet for comment.[10] At the same time, new legislation related to medicines control came into force.

In the light of these developments, we decided to adapt the *WHO Model Formulary* to produce an up-to-date *Formulary for Primary Health Care,* which provides information on the medicines on the Government's revised Essential Drugs List for Primary Health Care. The process of compiling the formulary started in October 2003, and the printed book was available in January 2004. This article describes the approach followed in producing the formulary.

Compiling the South African formulary

Four main steps were involved: extracting relevant information from the *WHO Model Formulary,* editing the information, indexing and formatting, and review.

Extracting information

For the 1998 edition, the National Department of Health had made use of a database to derive essential drugs lists from its *Standard Treatment Guidelines.*[7] For the revised draft guidelines posted on the Internet, this step had not been taken. We therefore started by listing the 172 medicines mentioned in the revised draft.

We then used the CD version of the 2002 *WHO Model Formulary* and navigated to each of its 27 sections using the tree structure provided. From the sections, we copied the monographs for the 172 medicines on the South African provisional list, and for all antiretrovirals and antimalarials. At the same time, we extracted any relevant clinical information. We transferred the text of the relevant monographs and clinical sections into an MS Word document using the Copy and Paste commands.

The *WHO Model Formulary* contains monographs for most medicines on the draft South African list. It does not cover some simple remedies, such as aqueous cream or sulphur ointment. Moreover, it generally contains a single generic example of a drug class, (for example glibenclamide, but not gliclazide). In one case, the generic example was not the locally recommended medicine; enalapril is used in South Africa rather than captopril because of its longer-acting properties.

Adaptation of medicine monographs

The monographs taken from the *WHO Model Formulary* were adapted in the following ways.

We removed information not applicable to primary health care, such as references to certain dosage forms (e.g. salbutamol tablets and injection), secondary-level indications (e.g. amoxicillin for surgical prophylaxis), and indications not corresponding to local morbidity patterns (e.g. Lyme Disease).

South African brand names and scheduling status in accordance with recently revised legislation were added for each medicine.

From the *WHO Model Formulary's* annexes on the use of medicines in pregnancy, breast-feeding, and renal and liver impairments, we incorporated information relevant to each medicine directly in each monograph. From the annex on drug interactions, we included those interactions marked as "potentially hazardous". In a next step, we combined similar entries for interactions with several medicines of one class (for example, carbamazepine, ethosuximide, phenobarbital, phenytoin, valproic acid) under one generic heading (antiepileptics), and listed the drug names in brackets. Interactions with medicines unlikely to be used by primary care patients (such as anaesthetics) were left out. However, interactions with other secondary level medicines, such as warfarin, were included, as they are applicable to patients down-referred from a higher level of care.

Monographs for medicines not found in the *WHO Model Formulary* were written up from locally available information (e.g. loperamide, for the relief of diarrhoea in HIV/AIDS patients). References used to adapt and supplement the information included *Martindale*[11] (33rd edition), the *South African Medicines Formulary,*[8] the South African formulary *Daily Drug Use,* which emphasises information on drug interactions and their clinical significance, the South African edition of *MIMS* and *MIMS Desk Reference* 2003.

Adaptation of clinical and prescribing information

Information on clinical management, existing treatment options and characteristics of various drug classes was included at the beginning of each section. The clinical sections taken from the *WHO Model Formulary* were shortened considerably and partly re-written to reflect South African guidelines.

Emergency treatment protocols included in the *WHO Model Formulary* were adapted in a similar way, and a number of emergency protocols were added (e.g. management of seizures).

Other additional information added to the body of the formulary included a section on cold chain management, a tabulated overview of options for family planning, instructions on the correct use of condoms, the South African EPI vaccination schedule, national guidelines for the treatment of tuberculosis, and information on poison information centres in South Africa. Additional sources of this information were our own training manuals as well as national manuals and guidelines.

Introductory section

The introductory section of the *WHO Model Formulary* itself and its annexes on drug interactions, pregnancy, breast-feeding, and renal and liver impairment were included in virtually unchanged form. We adapted the cytochrome P450 drug interaction table by including antiretrovirals. To this general section, we added information on medicines schedules, generic prescribing and adverse drug reaction reporting in South Africa (including a report form); examples of how to calculate doses prescribed per kg or m^2 bodyweight and drip flow rates; and a body surface nomogram.

Format and presentation

The information was rearranged to match the ATC classification, which is used in the current South African EDL as well as other local medicines formularies. We emphasised the different sections with headers and with black marker tabs on the right edge of all right-hand pages. On the front cover of the formulary, these tabs are repeated down the right-hand edge, mapping out the sections.

We included instructions on "How to use this book" in the inside front

RATIONAL USE

Figure 1
A sample view of the South African *Formulary for Primary Health Care*

cover, and a list of abbreviations and emergency protocols in the inside back cover. In the body of the book, the emergency protocols were emphasised by putting them into boxes. We added a table of contents, a foreword and a disclaimer.

Throughout the book, generic names of medicines for which a monograph was included are set in bold characters.

An important aspect of any reference book is its index. It may be the most frequently used section of the book. We indexed generic names, brand names, clinical entities and other relevant keywords. The resulting eight-page index contained approximately 1000 entries. As in the body of the text, generic names of medicines included in the formulary were bolded in the index. Where applicable, we included alternative drug names or abbreviations (e.g. EFZ – see efavirenz) and secondary entries (for example atropine: eye drops, 174; in organophosphate poisoning, 181).

Likewise, we provided extensive cross-references in the text to point to clinical information and to minimise duplication of information for medicines which appear in more than one section (e.g. doxycycline as an antibacterial and an antimalarial).

A sample view of the formulary is shown in Figure 1.

Internal review

While the compiling of the formulary to produce an initial draft took about three weeks, the review stage was more time-consuming and took about two months.

The task of reviewing sections of the draft formulary was divided between 12 staff members of the MEDUNSA School of Pharmacy. The sections were allocated according to reviewers' individual expertise. Comments were invited on the correctness and completeness of the information, not on redesigning the book. The reviewers pointed out further local recommendations (for example, for emergency contraception) and identified some gaps and inconsistencies.

After correction of the reviewed copy, the editors once again read the entire formulary to check the overall scope and coherence.

At a very late stage in the process of compiling the formulary, one week before going to print, the National Department of Health circulated its draft

revised *Standard Treatment Guidelines*. In general, the formulary corresponded very well to this draft. Some minor adjustments were made (e.g. inclusion of spironolactone). The final formulary contains monographs on 185 medicines. At the time of writing, the South African Department of Health has made available the revised EDL for primary health care. All 173 essential medicines on the list are covered in the formulary.

Printing

The final A4 MS Word document (approximately 1.6 MB) was supplied electronically to the printer. From this file, transparencies reduced to A5 format were produced directly for use in the printing process. The book, which contains just over 200 pages, was printed on 80 g/sqm white bond paper and bound with a full-colour laminated card cover.

Conclusion

The *WHO Model Formulary* was a very useful starting point for the production of a local formulary for primary health care. It provided information on most of the medicines on the South African *National Essential Drugs List for Primary Health Care*, as well as valuable evidence-based clinical information. The electronic format in which the *WHO Model Formulary* is made available was very useful in finding and selecting relevant information, and avoided much retyping, which minimised the possibility of mistakes. The sections of text copied were readily useable in a styles-based MS Word document layout.

New legislation in South Africa requires that from May 2004 non-pharmacists who dispense medicines need a dispensing licence. The formulary is used as a resource for the approved dispensing course, which is one of the requirements for the issue of such a licence. It is also on sale to anyone interested.

Information on the MS Word and MS Excel functionality used to compile the formulary is available from the authors on request. ❑

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2004 edition of WHO Model Formulary

Since its publication in 2002, the *WHO Model Formulary* has become an important source of independent information on essential medicines for pharmaceutical policy-makers and prescribers worldwide. For each medicine on the WHO Model List of Essential Medicines, the new edition of the *Model Formulary* provides details of use, dosage, adverse effects, contraindications and warnings, supplemented by guidance on selecting the right medicine for a range of conditions.

New manual facilitates Formulary adaptation

A CD-ROM of the new edition of the WHO's formulary is available and is intended as a starting point for developing local or national formularies. National or institutional committees can use the text of the *WHO Model Formulary* for their own needs by adapting it, and adding or deleting entries to align the formulary to their own list of essential medicines. To facilitate this task English, Russian and Spanish language versions of the formulary have been included on the CD-Rom.

A new manual is included on the CD-ROM, *How to Develop a National Formulary Using the WHO Model Formulary,* which explains how best to use or adapt WHO's electronic files of WHO's formulary to prepare a local or national formulary.

For more information contact: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva, Switzerland.
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RATIONAL USE

Experience of a community-based antiretroviral Buyers' Club in Thailand


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The XV World AIDS Conference was held in Thailand in July 2004, under the slogan 'Access for all', at a time when the Thai Public Health Ministry was rolling out access to antiretroviral (ARV) treatment across the country. By October 2005 the goal of universal coverage had almost been achieved, with over 63,000 people were receiving treatment.

This is a very different situation from a few years ago, when most people with HIV/AIDS in need of treatment were unable to access the necessary drugs: triple therapy began to become available in large urban centres from the beginning of 2000, but was often absent from community hospitals, being viewed as too expensive for the health system as a whole. Poor availability led to poor understanding: doctors lacked knowledge and willingness to prescribe, while those affected by the virus had little idea of what medicines they needed, and those who did know could rarely afford them.

People with HIV/AIDS (PHA) responded by establishing a Buyers' Club, in May 2000, as a collaboration between patients and health care staff, with PHA taking a leading role to ensure that medicines were given appropriately. By centralising purchases and managing drug supply, PHA ensured that affordable medicines reached patients. At the same time, by establishing a role for PHA as co-providers of care, the Buyers' Club demonstrated that ARV treatment could be provided through the public system.


Photo: MSF

Discussion between MSF medical staff, hospital staff and patient group's representatives: one step in establishing a Buyers' Club branch

Over the last four years a Buyers' Club network has helped over a thousand people gain access to correct ARV therapy. At its peak, there were 21 branches across the country supporting a total of 1081 PHA. Without the Buyers' Club, most of these beneficiaries would have gone without treatment and many would have died. This article describes how the Buyers' Club was established and how it evolved.

Access to ARVs in Thailand

Thailand is a lower-middle-income country with a population of 63.5 million, of whom 670,000 have HIV/AIDS (adult prevalence 1.8%). The Thai Public Health Ministry began providing ARV monotherapy in 1992 and dual therapy in 1995. This programme was wound down after experts from the World Bank, World Health Organization and Thai Public Health Ministry concluded that continuation would be costly with minimal effectiveness.[1] (The possibility of lower drug prices through generic production was not considered). The approach shifted to clinical trials, mostly of dual therapy, as a way to provide treatment.[2]

The Public Health Ministry began to promote triple therapy as the norm in 2000 with the launch of an 'Access to Care' programme, using mostly brand name drugs, for 1,600 adults in 109 hospitals.[3] But for the majority, accessing ARV treatment was impossible. The cost was prohibitive for most, and often much higher in the provinces than in the capital. Correct information about ARV therapy among providers and patients was generally lacking; hospital personnel often had little experience of prescribing and monitoring ARVs and because of the high degree of stigma attached to AIDS, patients were afraid to go to hospital and reveal their status.

The result was a vicious circle, with ARVs regarded by hospital pharmacies as "high-cost low-demand drugs", and not stocked. Families got into debt from private purchase of expensive but sub-optimal (and hence ineffective) ARV regimens, the high price of the drugs leading to incomplete or inconsistent prescribing. Treatment was often discontinued after only a few months through lack of funds.

Evolution of the Thai Buyers' Club

The Buyers' Club concept first evolved in Rayong Province, in the east of the country, in May 2000. At that time, Rayong Province ranked third in the country in terms of HIV prevalence.[4] The cost of treatment in Rayong was similar to other places in Thailand at that time: local hospitals stocked few ARV drugs and these were unaffordable by most, costing more than US$500 per month – over four times the average wage of an office worker.

An MSF nurse working in Rayong found that a number of PHA were buying brand name ARVs at high prices, and often only being able to afford dual or monotherapy. The lack of affordable treatment was discussed with senior staff in the Provincial Hospital. The director did not want ARVs stocked in the hospital pharmacy because they could then be prescribed to any patient registered with the hospital's health insurance scheme, while the pharmacist questioned the legality of holding 'non-hospital' stock in the hospital pharmacy. However, both director and pharmacist saw the importance of increasing access to ARVs and the hospital's PHA group was designated responsibility for storing ARVs and for treatment counselling. The hospital made two rooms available to the PHA group for these purposes, with the pharmacist ensuring that one of the rooms was suitable for drug storage. MSF initially agreed to supply ARV drugs that would be prescribed by hospital doctors to five patients. Numbers quickly increased to 10 people per month in the first few months.

It became clear that increasing demands could only be properly met by a system dedicated to managing drug supply and assisting with patient follow up, and that activities should not be limited to one province. Under the umbrella of the Thai Network for People Living with HIV/AIDS (TNP+), the Buyers' Club was established on 13 October 2000, as a partnership between TNP+, AIDS Access Foundation, the Camillian Social Centre (a local NGO) and MSF (see Box 1). TNP+ would coordinate activities across the country and be responsible for overall management of the Buyers' Club. Medicines would be prescribed by hospital doctors and supplied, together with peer support, via local hospital-based PHA groups (these have been established in Thailand since the early 1990s and are mostly funded by the Ministry of Public Health). MSF and AIDS Access Foundation trained the PHA peer group counsellors on ARV treatment and adherence counselling. Social support to the PHA groups would be given by AIDS Access Foundation, while MSF provided ongoing technical support.

How the Buyers' Club works

The Buyers' Club aims to increase access to a limited range of essential HIV/AIDS medicines. Generic drugs are purchased directly from the Thai Government Pharmaceutical Organization (GPO), which has also given advice on drug storage. It has also successfully negotiated a preferential price for Efavirenz from Merck, Sharp & Dohme by requesting access to the same preferential price as the company offered to sub-Saharan African countries in March 2001.[5] In more than five years, the Buyers' Club has not experienced a single drug supply problem.

Medicines are made available within a supportive environment. Doctors give a prescription to patients, who then take

Box 1

Principles of the Buyers' Club

Empowerment of clients
- Helping them make informed treatment decisions based on their own needs
- Providing unbiased information
- Encouraging them to seek qualified medical supervision and advice

Provision of quality services at lowest possible cost
- Being committed to the principles of a not-for-profit organization and reinvesting all profits into the organization
- Ensuring no individual benefits unreasonably
- Maintaining operating costs at the lowest possible level
- Involvement of trained PHA peer group counsellors

Transparency and accountability
- Making complete information regarding revenues and expenses available publicly
- Having a representative board
- Public disclosure of the decision-making process

RATIONAL USE

Box 2

How the Buyers' Club works

1. A person who is interested in taking ARVs goes to their local hospital and discusses this with the doctor who gives medical advice and, if appropriate, a prescription.
2. The person takes the prescription to the PHA group who gives the patient information and counselling about ARVs, explains how the Buyers' Club works and tells them how much their prescription will cost each month. The need for long-term commitment is explained and patients are asked how long they can pay for the medicine.
3. If the person can make a long-term commitment and still wishes to start ARV therapy they register as a member of the club and pay for their prescription
4. The PHA group sends the prescription to the TNP+ Buyers' Club office in Bangkok by fax or registered post.
5. The Buyers' Club dispenses prescription, with clear instructions, by registered post.
6. The PHA group gives drugs to the patient. Adherence counselling, other necessary support and follow-up is provided.
7. A surcharge of 5% is added to the cost of the medicines to contribute to the running costs of the Buyers' Club. Some of this money was also loaned to patients with financial problems who could not afford their treatment.

The entire process should take a maximum of five days.

this to the PHA group, which dispenses the medicines together with appropriate treatment information, including the importance of good adherence, coping with possible side-effects, assistance in planning dosage schedules and other counselling. Follow-up support is provided, including active follow up of people who miss a prescription. Referral to other support agencies is also given where needed (see Box 2).

Initially, prescribing doctors often asked for advice on monitoring of treatment. MSF helped those doctors with little experience of ARVs to become familiar with drug prescription and disease management.

Acceptance by the health care system

The Buyers' Club works to improve the health of individuals, but also to improve the health care system by making medical treatment for PHA more widely available within the public hospital system. It has encouraged improvements in drug supply and prescribing practices within the system, better treatment literacy and peer support for PHA.

Most doctors who encountered the Buyers' Club had previously been frustrated by the lack of availability of affordable medicines and were therefore very supportive. Some were uncomfortable with the idea of patients taking charge of their own treatment (some still are). The most frequent concerns related to the complexities of treating AIDS and the risks of developing drug resistance. But the association between patient groups, MSF medical staff and NGOs helped gain acceptance, and doctors were encouraged by the level of information and support that patients were receiving (see Box 1).

From the outset the Buyers' Club's activities were undertaken in total transparency and accountability. The initiative was presented at public meetings[6] and given public support by leading HIV physicians. The fact that medicines are purchased directly from the Government, through the GPO also provides evidence of tacit endorsement.

Future of the Buyers' Club

The Buyers' Club in Thailand is an organized effort by PHA to ensure that appropriate, effective and affordable treatment gets to a modest number of people. It helped to disseminate treatment together with correct information, improving prescribing practices and offering a peer support system.

Today, the Buyers' Club is winding down as Government services scale up and ARV drugs become more widely available. Access to ARVs through Ministry of Public Health treatment programmes has expanded 35-fold in the past five years and six Buyers' Clubs branches have closed in the last two years. PHA group members continue to offer treatment counselling within the hospitals, playing a key role in the Ministry of Public Health's national ARV programme.[7] They also continue to advocate for increased access to affordable medicines.[8]

Currently, 360 people continue to buy their medicines through the Buyers' Club. The majority of former members now receive their medicines directly from their hospital pharmacy: 568 former members through the MOPH programme, and 62 through a social insurance scheme.

The Buyers' Club concept has spread to PHA and doctors in other countries in the region. In Japan, a Buyers' Club with four Thai members was established in January 2002 for unregistered migrant workers. The club has been able to close as these are now enrolled in the Thai Ministry of Public Health's national programme and receive treatment through the Thai Embassy in Tokyo. Clubs have been established in the Islamic Republic of Iran, Malaysia and the People's Republic of China.

International efforts such as the WHO 3 by 5 initiative are currently focusing attention on high burden countries. More flexible, smaller scale, community-based action might be more appropriate for lower burden countries and will certainly be necessary if unregistered populations are to access treatment. While the global response to AIDS is increasing, every indication suggests that people in other countries will continue to be excluded from accessing treatment, and similar efforts will be needed for some time to come. ❑

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Uruguay's first Information and Evaluation Centre for Medicines

THE Information and Evaluation Centre for Medicines (CIEM) is part of a project promoting rational use of medicines. It is an initiative of the Pharmacology and Therapeutics Department of the Faculty of Medicine and the Pharmacy Department of the Hospital Centre Pereera Rossell (CHPR) in Montevideo. The Centre came into being when specialists in a number of disciplines became increasingly concerned about problems of medicines use that they were discovering in the course of their work. They carried out the first studies on the therapeutic and economic impacts of antibiotic use, subsequently developing and disseminating therapeutic guidelines and planning educational interventions to improve practices. It became clear that there was a need for a unit to provide independent information on medicines and to evaluate their use.

Created in 2001, CIEM is based in the Pharmacology Department of CHPR, a tertiary level teaching hospital and the national maternity and gynaecology referral centre. Run by clinical pharmacologists and pharmacists, CIEM promotes rational use of medicines by studying those who consume, prescribe, dispense and administer them. Among its tasks are providing appropriate information to health staff and patients, contributing to the development of formularies and pharmacotherapeutic guides, undertaking medicines use studies and carrying out evaluations to ensure improvements in practices. The Centre also develops professional training, including continuing education courses and advises the therapeutics and hospital infection committees, as well as acting as an "outpost" of the National Pharmacovigilance Centre.

Photo: CIEM

All the members of the CIEM: Gustavo Giachetto, Luciana Nanni, Hector Telechea, Noelia Speranza, Silvia Kegel, Ismael Olmos, Celia Hackenbruch

In 2003 CIEM successfully organized the first Rational Use of Medicines Day in Uruguay, and to reach the next generation is currently implementing a new educational programme on medicines, which is targeting school pupils. ❑

RATIONAL USE


J. Nwokike

Baseline data and predictors of adherence in patients on antiretroviral therapy in Maun General Hospital, Botswana

➢ Jude I. Nwokike

Very high levels of adherence to antiretroviral (ARV) drugs are a prerequisite for a successful and durable virological and immunological response, while low adherence increases the risk of treatment failure and disease progression, and contributes to the development of resistance.[1] It is known that in antiretroviral therapy (ART), above 95% adherence is required for adequate virological and immunological response. Adherence plays a critical role in the success of HIV/AIDS treatment plans and is the most important factor that can jeopardise expected treatment outcome. Such 'perfect' adherence poses numerous treatment challenges to the patient, including life-long pill-taking, pill burden, frequent dosing intervals and food restrictions.

Before the Botswana launch of ARV treatment there were genuine concerns about the adherence potential of Africans and the prospects of them being able to follow a complicated regimen like that of Highly Active Antiretroviral Therapy, HAART. It was realised that the kind of adherence that we were advocating requires more than the efforts we had historically placed on other chronic diseases like hypertension and diabetes. Yet the few things that we knew about adherence were learnt from those same chronic diseases. The complex thing in all these is the subjective nature of medicine adherence behaviour, the ability to measure adherence and the ability to develop strategies that can improve poor levels of adherence.

In Botswana, there is a lack of baseline data to determine the level of adherence to ARVs, particularly after the introduction of free national access to these drugs. In their Botswana Adherence Study, Weiser et al[2] identified factors that promote non-adherence. However, that study was done when patients paid for their pills and had no formal adherence education/counselling sessions, and it used only self-report and provider assessment adherence measurement methods. At Maun General Hospital in Botswana an institution-based, quantative and retrospective study was undertaken to determine baseline adherence values and identify predictors of adherence among treatment-experienced patients. These patients received formal adherence education/counselling sessions which include Pre-Treatment Antiretroviral Drugs Adherence Counselling (PADAC) and ongoing "per refill visit" adherence counselling. Using four adherence measurement methods, the study set out to answer the following questions:

- is the level of adherence optimal for viral suppression?
- what are the factors that predict adherence/non-adherence?

The study objectives were:

- to establish adherence monitoring and measurement tools for patients on antiretroviral therapy
- to obtain baseline data on the level of adherence
- to identify the predictors of adherence.

Study design

The study involved 176 patients [74 men and 102 women] on treatment for a minimum of three months. The adherence monitoring and measurement tools included:

1. PADAC, Pre/Post PADAC questionnaires and adherence monitoring standard operating procedures.
2. Self-completed questionnaires to establish predictors of adherence.
3. Measurement tools– pill count, 7 – day recalls questionnaire, pills identification tests, structured interviews and a monthly pill calendar.

PADAC: This is a two-hour drug information and adherence counselling session for patients and their adherence partners. PADAC sessions are held within the week patients are to begin ART and attendance at a session, held in Setswana, is mandatory before treatment begins.

PADAC sessions cover the following:

1. How ARV medicines work
2. How resistance occurs
3. The relationship between adherence, resistance and treatment failure
4. How to take the medicines: dosage reminders, use of concurrent orthodox or traditional medicines and other special restrictions
5. Possible side-effects
6. What treatment hopes to achieve.

The Pre/Post PADAC questionnaire is made up of 12 self-completed questions that aim to assess the understanding of the contents of the PADAC session and establish the usefulness of the session. Adherence monitoring standard operating procedures come in the form of a manual for health care providers for the provision of adherence support for individuals on ART. It details on the need for adherence support that is repetitive and ongoing. The SOP is presented as a way to expedite rather than force completion of treatment.[3]

Self-complete questionnaire: We also designed a self-complete questionnaire with 34 questions to determine the predictors of adherence. The questionnaire was administered in the respondents [182 Patients] preferred language [English or Setswana].

Measurement tools: Pill count, 7 days recall questionnaire, pills identification tests and monthly pill calendar

Pill count– Patients are usually requested to come to their reviews/refills with their pill containers. Pharmacy staff physically counted the pills and/or estimated the volume of the liquid preparations brought back. The Pharmacy records are used to calculate adherence after factoring-in returned quantities. Adherence was reported in adherent days/month percent. The pill count method employed zero tolerance to non-adherence – missing out 1 dose in a 4 dose/day regimen translates to non-adherence for that day.

7 day – recall questionnaire– This method may over-estimate adherence.[4] Structured interviews and probes were used to validate the findings of the 7 – day recalls.

Pills identification tests– This method may correlate with validated self-report adherence measure.[5] Pharmacy staff assigned value to indicate adherence based on patients ability to identify their own pills from other pills that also included look-alike pills.

Monthly pill calendar– Patients are issued monthly pill calendars which they return on their refill days. It has the advantage of establishing which specific doses are missed (more critical information in calculating adherent days/month).

Study findings

From the 176 patient records reviewed, there was a determined average adherence per month value of 24.5 days [83.16%]. Most patients [54.39%] were on a Combivir/Efavirenz combination. This patient group had 24.99 adherent days/month [upper 95% confidence interval of 25.72]. Adherence to a Combivir/Nevirapine combination was 29.82 adherent days/month. Adherence promoters were found to be: adherence partners (51 patients out of 182 [28.02%]); pharmacy counselling (48 or 26.37%) and pill count at 32 [17.58%]. Non-adherence predictors included: forgot (49 patients [26.92%]), access (37 [20.33%]) and lack of privacy (33 [18.13%]).

Figure 1
Adherence in different treatment regimens

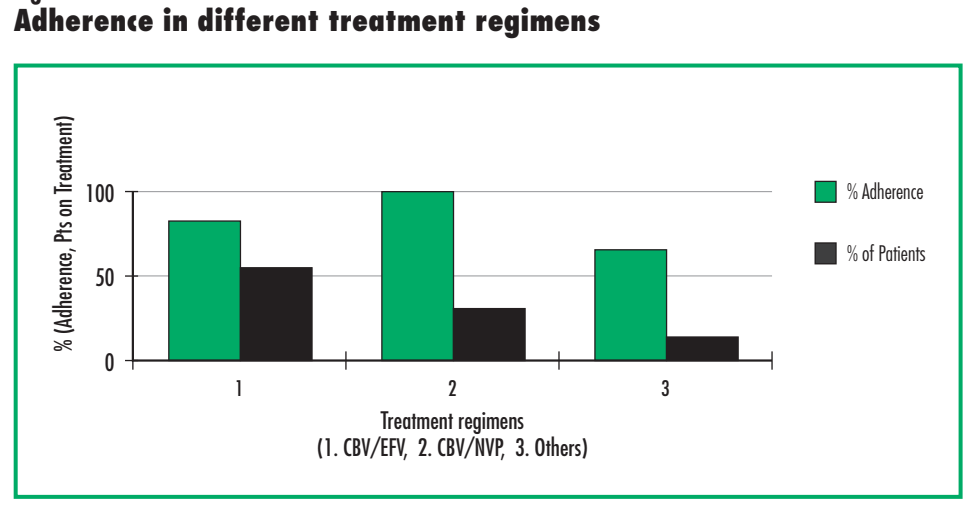
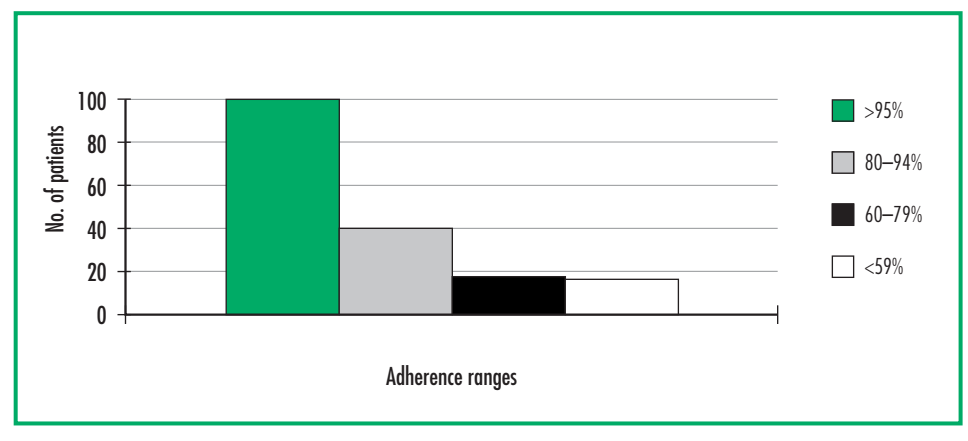


Figure 2
Number of patients in different adherence ranges



RATIONAL USE

Discussion

The average adherence of 83.16% obtained is the composite adherence using the adherence measurement methods listed. This is relatively high compared to projections. Weiser et al[2] predicted 74% if cost were removed as a barrier. Adherence varied with respect to regimen. Patients on CBV/NVP achieved highest adherence [99.4%].

The majority of the patients [101 or 57.4%] achieved 95% and above adherence (Fig. 2). Over 95% adherence is required for virological suppression.

Having an adherence partner was the most critical factor that promoted adherence.

Most of the patients [26.92%] missed their medications because they simply forgot to take them (Fig. 4). Problems with access [not financial] was another non-adherence predictor and relates to when patients found themselves far away from their pills.

Recent developments

Even after the study period Maun General Hospital has made efforts to further strengthen its adherence measurement and monitoring strategies. Some of those strategies are:

- the production of a draft manual for health care workers on monitoring and measuring adherence
- greater emphasis on warning new patients to guard against the identified non-adherence predictors
- issuing two months' supply of medication as an incentive for excellent adherence
- graded weighting of adherence measurement methods to improve sensitivity of the measurement instruments
- capturing adherence values in the new Integrated Patient Management Systems, IPMS.

Conclusions

Adherence is below optimal in Botswana, there is a need to develop enablers and incentives to improve adherence.

Simple and non-electronic adherence measurement methods should be standardized as they are crucial in developing countries.

There is a need to evaluate the efficacy of formal institution-based comprehensive adherence education and counselling programmes.

Health care facilities should develop adherence monitoring plans that are ongoing and multidisciplinary.

There is a need for a modified DOT programme for orphans and other special and vulnerable groups.

Access to medicines does not guarantee adherence, national free ARV programmes need to develop and build adherence measurement and monitoring guidelines into the national treatment protocols. ❑

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Figure 3
Adherence promoters

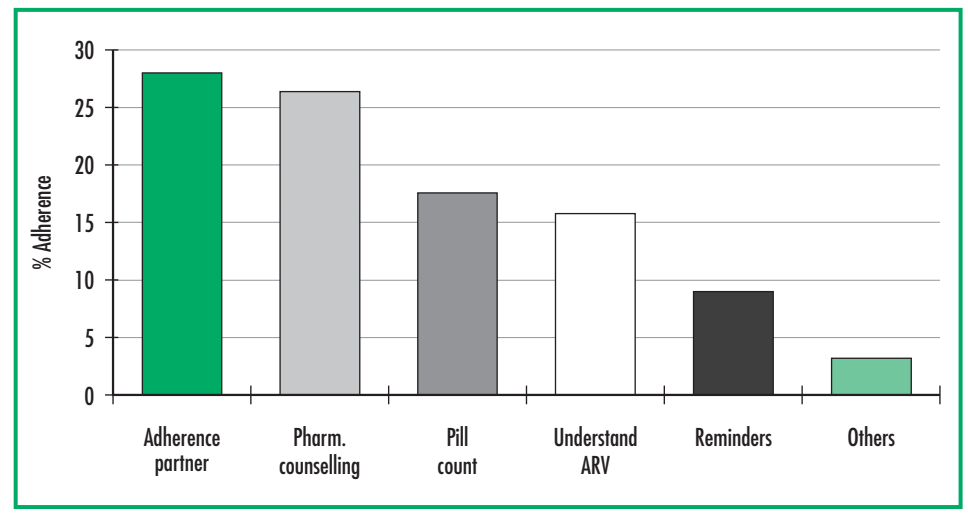
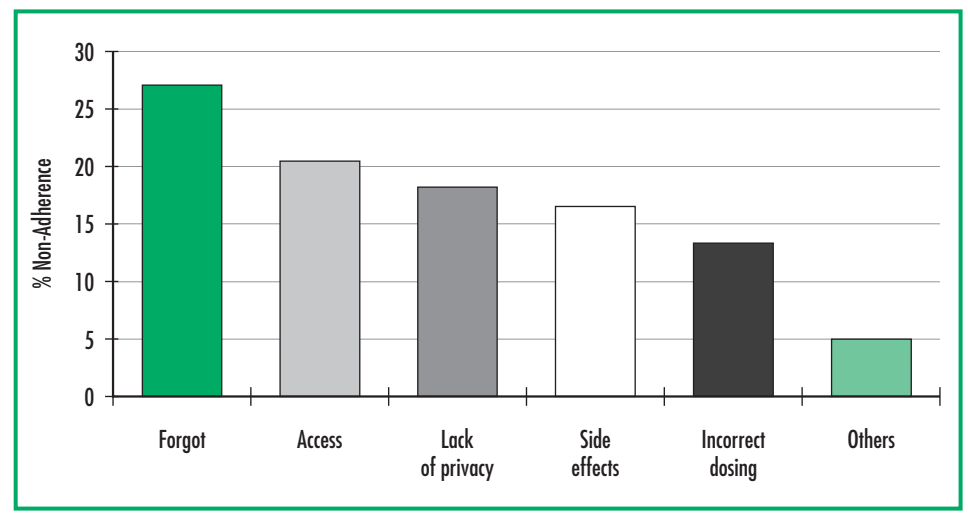


Figure 4
Non-adherence predictors



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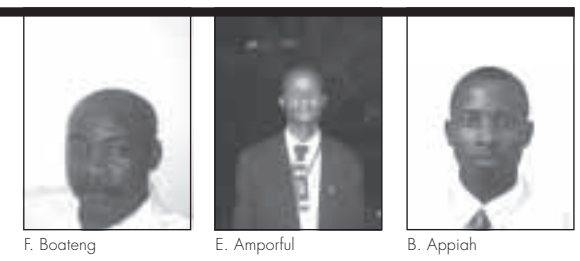
"Let's talk about drugs" – The Pharmaceutical Society of Ghana takes to the screen


F. Boateng E. Amporful B. Appiah

➢ Frank Boateng, Edward Amporful, Benard Appiah

The Pharmaceutical Society of Ghana (PSGH) has introduced a television serial – a "docu-drama" – aimed at portraying the pharmacist as indeed "a true friend of society" in line with it's motto, "Amicus Humani Generis." The aim was to represent the pharmacist as an important public health practitioner; an educator, a health promoter and a counsellor. The serial presents the everyday issues brought up at the pharmacy, and how they are handled or may be handled.

The Project

A number of proposals were written to seek donor support and sponsorship for this important public health initiative, and it took us almost two years to succeed. When the funding was certain, the Public Health Committee of the PSGH was quick to assemble and roll out the plan for the project. Amongst the many titles that came up, "Let's Talk About Drugs (LTAD)" was finally chosen. Although we were mindful of the use of the word "Drugs" instead of "Medicines", this title was a reminder of a popular song in the 1970s.

The Society decided to move away from the very typical style where a pharmacist or a health professional is invited to a studio for a question and answer session, or for a presentation/lecture. Since it is established that dramatization is more effective in leaving a lasting impression, it was agreed that we should look at the opportunity of presenting a drama but one interspersed with local facts.

LTAD is shown on Sundays at 7:30pm on Ghana Television (GTV) and has nationwide coverage. The first episode, shown on 24 July 2005, highlighted patients rights, with the title: ***"Patients too have Rights"***. Other programmes shown include ***"Misuse of Antibiotics"***, ***"Malaria in Children"***, and ***"Generic Prescribing"***. The programme is billed to run for 15 weeks for the first round. It will be resumed in January 2006, to run for 26 weeks in a second round.

An attentive audience

As an evaluation tool, a live programme with a panel of pharmacists was broadcast to respond to various questions from the public. The response was overwhelming, with the five phone lines provided jammed for the 30 – minute programme. The questions asked were clearly indicative that viewers had been following the series attentively.

The programme has been a real success and an image booster for the Society. We have had several requests to reproduce LTAD in the local languages, and also a request to adapt the programme for radio. We think LTAD will be an effective tool for others in a similar situation to that in Ghana: very high patient/doctor ratios, high patient/pharmacist ratios and countries where irrational use of medicines is the norm. ❑

Frank Boateng is managing Director of Fabby Chemists Ltd., Community Pharmacy Practice and President, Pharmaceutical Society of Ghana. Edward Amporful is Chief Pharmacist, Cocoa Clinic, Ghana and Benard Appiah is Drug Information Pharmacist/Publications Manager, National Drug Information Resource Centre, Ghana.

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RATIONAL USE

Priority Medicines for Europe and the World


R. Laing


W. Kaplan

➢ Richard Laing, Warren Kaplan

The Priority Medicines for Europe and the World Report was commissioned by the Government of the Netherlands at the time of its Presidency of the European Union. The report identifies a priority list of medicines for Europe and the rest of the world, taking into account Europe's ageing population, the increasing burden of non-communicable illnesses in developing countries and diseases which persist in spite of the availability of effective treatments. The report looks at the gaps in research and innovation for these medicines and provides specific policy recommendations on creating incentives and closing those gaps.

At present, pharmaceutical research and development are based on a market-driven incentive system relying primarily on patents and protected pricing as a prime financing mechanism. As a result, a number of health needs are left unaddressed.

The report identifies gaps for diseases for which treatments do not exist, are inadequate or are not reaching patients. Threats to public health such as antibacterial resistance or pandemic influenza, for which present treatments or preventive measures are unlikely to be effective in the future, also require immediate action.

In addition, the report addresses obstacles where effective medicines could be better delivered to the patient. It emphasises fixed-dose combination medicines (medicines which include more than one active ingredient in one pill) as worthy of further research and development. Finally, it looks at particular groups such as children, women and the

elderly, who have frequently been neglected in the scientific or medicine development process.

The 17 priority conditions identified by the report are:
Future public health threats: infections due to antibacterial resistance; pandemic influenza;
Diseases for which better formulations are required: cardiovascular disease (secondary prevention); diabetes; postpartum haemorrhage, paediatric HIV/AIDS; depression in the elderly and adolescents;
Diseases for which biomarkers are absent: Alzheimer disease; osteoarthritis;
Diseases for which basic and applied research is required: cancer; acute stroke;
Neglected diseases or areas: tuberculosis; malaria and other tropical infectious diseases such as trypanosomiasis, leishmaniasis and Buruli ulcer, HIV vaccine;
Diseases for which prevention is particularly effective: chronic obstructive pulmonary disease including smoking cessation; alcohol use disorders: alcoholic liver diseases and alcohol dependency.

The report suggests that Europe can and should play a global leadership role in public health, as reflected by its history of social services provision and social safety nets for all citizens. In many developing countries, the poor are increasingly affected by the chronic diseases that are widespread in Europe, including cardiovascular disease, diabetes, tobacco-related diseases and mental illnesses such as depression.

Innovative solutions

The report suggests that efforts to shorten the medicine development process without compromising patient safety would greatly assist in promoting pharmaceutical innovation. For instance, the EU could create and support a broad research agenda through which the European Agency for Evaluating Medicines (EMEA), national regulatory authorities, scientists, industry and the public would critically review the regulatory requirements within the medicine development process for their relevance, costing, and predictive value.

Health authorities are responsible for medicines reimbursement decisions that aim to ensure safe and effective treatment for all patients, while reconciling this with budgetary constraints. Health and reimbursement authorities and manufacturers should agree on general principles for the evaluation of future medicines. For example, the EU Commission and national authorities should support a research agenda on the various methods of rewarding clinical performance and linking prices to national income levels. The report authors believe that these measures will help encourage industry to invest in the discovery of innovative medicines that address priority health care needs.

The report maintains that where the market is strong and the problem is poor understanding of the basic biology of the disease, investment in basic research and in facilitating innovation by the pharmaceutical industry will be needed. Where the biology is well understood but the market is weak, public support for breaching the gap between basic and clinical research – possibly through public–private partnerships and other not-for-profit product development initiatives – will be the preferred solution. Where the biology is not well understood and there is also a weak market, then biological research can be supported while market incentives are created for the pharmaceutical industry, through reducing barriers to innovation and through improving reimbursement rewards.

The report points out that major pharmaceutical gaps have been closed in the past. For example, until 1975 the main treatment for severe peptic ulcer – a common ailment – was surgery. Following a long period of focused research in biological mechanisms underlying ulcer disease, effective medical treatments were discovered. These breakthrough discoveries, combined with the discovery that most ulceration was caused by a bacteria treatable with antibiotics, made surgery unnecessary. ❑

The report was presented at a High-Level Meeting in the Hague on 18 November 2004.

The report, can be accessed at: http://mednet3.who.int/prioritymeds

Accessing antiretroviral drugs: dilemmas for families and health workers


S.R. Whyte


M.A. Whyte


L. Meinert


B. Kyaddondo

➢ Susan Reynolds Whyte, Michael A. Whyte, Lotte Meinert, Betty Kyaddondo*

The price of antiretroviral (ARV) medicines has fallen dramatically in recent years. In Uganda, triple combination therapy costs about US$500 per month in mid-2000. By March 2003, the same treatment, using generic drugs cost US$28, bringing fee-for-service treatment within reach of more families. Free treatment is offered to some, as more donor initiatives and research projects provide ARVs for specific target groups. By mid-2003 the Uganda AIDS Commission estimated that there were about 10,000 people accessing the drugs out of about 157,000 who should be taking them.[1]

The rise in number of people on treatment is welcome. But in this rapidly changing situation, often characterised by hype and promises, the way towards free and equal treatment for all is rough and uneven. The fall in prices creates dilemmas for those families, still a small minority in a poor country, who can now almost afford treatment. Projects and programmes providing free treatment are increasing awareness about antiretroviral drugs, while still providing them only in

RATIONAL USE

certain geographical areas and to selected people.

In a qualitative and exploratory study completed in mid – 2003, we asked how a range of Ugandans perceive and manage the current situation of unequal access to ARVs. We started by mapping out the channels through which people actually are getting the drugs in today's Uganda. Then we explored the dilemmas that uneven access poses for families and health workers.[2]

Four channels of access to ARV medicines

ARV medicines, whether generic or branded, found their way to people who needed them through four more, and less, well demarcated channels.

1) Medicines were provided free in structured research and treatment programmes funded by donors, but only to those who lived in a defined catchment area and met inclusion criteria. A prime example is the Prevention of Mother-to-Child Transmission Programme (PMTCT), available at some, but far from all, public maternity units.
2) Authorised treatment centres provided drugs on a fee-for-service basis; these urban-based institutions account for the largest number of ARVs dispensed. They include the Joint Clinical Research Centre as well as clinics at some major hospitals.
3) Private practitioners, mainly based in Kampala, provided discrete treatment for those who could afford it. Their prescriptions could be filled at pharmacies.
4) Finally, medicines were 'facilitated' along informal networks, supplying friends and relatives on a less regular basis, sometimes for free, sometimes for cash. This included ARVs being brought in from abroad.

While the first two channels had a public character (signboards, documents, clinic hours for AIDS patients), the last two were less formal and more discrete. By their nature they are less amenable to professional supervision.

Inequity and support for treatment

Since most public health facilities do not provide free antiretroviral therapy (ART), health workers must refer patients to authorised treatment centres. But telling poor people where they can go to buy life-saving drugs they cannot afford is a bitter task. Some health workers felt it was kinder not to tell families who were evidently destitute. The dilemma faced by doctors was illustrated by the head of the medical ward at the national hospital who explained how they used the 'blanket sign' to decide whom to inform about ARVs. (In-patients who brought nice bedding and were visited by well-dressed family members showed signs of being able to afford the medicine).

In 2003, the PMTCT programme provided free nevirapine to minimise the risk for the baby but left the HIV-positive mother asking 'What about me?' When mothers were told that they could purchase treatment for themselves, they were terribly disappointed. As one said: *'It is too much…we have that hope but how many can afford?'*

For individuals and families the decision to start ART involved painful prioritising. Since family members are usually economically dependent on one another, supporting ART for one person meant not being able to help someone else with money for school fees or some other important life project. Rarely is there only one person sick with AIDS within a family. When resources are scarce, people must decide which individual to help. This can mean weighing not only needs, but also abilities to stick to treatment and become a productive family member once again.

Unequal access to ARVs poses questions of social justice in a country where most people live in rural areas and cannot afford treatment, even at the reduced price. It poses dilemmas for health workers and for middle class families who have to make tough decisions. Even when a decision is made to initiate treatment, it is difficult to maintain the regimen for months and years, in the face of many other needs. So in the end unequal access is also a problem for improving the use of medicines, since the main reason for discontinuing treatment is economic.

Uganda's new policy on ARVs recognises that even though priority groups may receive free treatment, many will still have to meet full or subsidised costs themselves.[3] In Uganda, as in most other countries, uneven access to ART will be the reality for some time to come. In order to confront this situation, researchers should examine the whole range of ARV access channels, the associated patterns of social differentiation and exclusion, and the dilemmas these pose for health workers and families. ❑

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Editor's Comment

This short article highlights some of the non-drug supply issues in access to ARVs. Even if ARVs are provided "free", patients have costs such as transport or time. Families may have to make difficult choices about starting treatment for a family member. These choices may impact on adherence and should be discussed during pre-treatment counselling.

Nicaragua's Ministry of Health promoting rational use of medicines to health post nurses

In many Nicaraguan health posts, especially rural ones, patient care and medicines use are the responsibility of nursing staff, probably because of the difficulty of ensuring the availability of other medical personnel for such units. The Ministry of Health had developed a range of capacity-building tools, but the official functions of care staff in health posts had never been defined. In an initiative aimed to change this, on 19 June 2003, the Minister of Health, Dr José Antonio Alvarado, presented a strategy to improve health care and rational use of medicines by health post staff. The launch meeting attracted a wide range of organizations, and was followed up by a training of facilitators workshop to help ensure that the correct messages were disseminated to nursing staff.

The main elements of the strategy include defining activities related to patient care, selecting medicines appropriately, developing and distributing information and educational materials, promoting continuing education and monitoring and evaluation. Now in its implementation phase, the strategy is being promoted at local level by supervisory staff and coordinators from CURIM, the committee for rational use of medicines, in each municipality. In 2003, 10 of the 17 health regions had implemented the strategy, training 169 municipal facilitators, with the support of various cooperation agencies, such as the Pan American Health Organization and the European Union. In 2004 work was done to complete the capacity-building stage in another seven regions and to monitor the development of activities in places capacity had already been increased.

Self-learning module on rational use of medicines for health staff – Ministry of Health, Nicaragua, 2003

In another initiative a module consisting of a workbook and a trainer's guide has been published by the Ministry of Health. The aim is to improve the application of treatment standards and medicines use, promote self-learning and make optimal use of existing awareness raising/educational materials disseminated by health units. Although designed with the needs of health centre staff in mind, the module is a permanent education tool. It can be used to reinforce learning on the Ministry's patient treatment standards for primary health care personnel, and for students and staff in nursing and medical schools. The module has been distributed to all nursing personnel. ❑

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RATIONAL USE

There's hope – early observations of ARV treatment roll out in South Africa

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In September 2004, a Promoting Rational Drug Use in the Community Course involving 33 participants from 14 countries was held in South Africa. It was organized by WHO, the University of Amsterdam and the Medical University of South Africa, (MEDUNSA), Pretoria. A major activity of the course was field visits to ARV treatment sites. The report of these visits is included below. Following the course, groups prepared proposals for follow-on activities. Groups in Botswana, South Africa, Uganda and the United Republic of Tanzania have undertaken studies on factors related to ARV adherence. A full course report is available at: http://mednet3.who.int/prduc/coursereport/PRDUC_Report.pdf

In 2002, the rate of HIV infection in South Africa in the 15–49 age group was estimated at almost 30%.[1] The public sector roll-out programme for the prevention of mother-to-child transmission with nevirapine started at 18 pilot sites in 2002. An antiretroviral (ARV) treatment plan was published in 2003 and roll-out of treatment started at 32 accredited sites in April 2004, aiming to treat all South Africans needing therapy (an estimated 1.4 million by 2009). Although stigma, discrimination and cultural beliefs still affect voluntary testing and recognition of HIV and AIDS, in 2004 many more patients were initiated on ARV therapy.

Twenty ARV products are currently available in South Africa. Current first-line treatment is a twice-daily triple ARV regimen including two nucleoside reverse transcriptase inhibitors and either nevirapine or efavirenz. At least 95% adherence is required for this regimen to be fully effective and not induce resistance. Achieving this high level of adherence remains a concern. At all the sites, a multidisciplinary team does the assessment of patients. Patients are enrolled in the ART programme when they have a CD4 count below 200 and/or WHO stage III or IV AIDS-defining illness, and are committed to following the regimen strictly.

Here we present data from an exploratory study on adherence to ARVs undertaken as a field exercise for the Promoting Rational Drug Use in the Community Course (see http://mednet3.who.int/prduc/) held in Pretoria in September 2004.

Methodology

Six health facilities dedicated to ARV therapy were included in the qualitative study undertaken in Gauteng and North-West Provinces. These units consisted of three public clinics – one primary, one secondary and one tertiary – two NGO-based primary clinics, and a private-for-profit primary clinic.

Different qualitative methods were used to study factors influencing non-adherence to ARV treatment. Thirty-eight people, 22 women and 16 men, living with HIV and AIDS (PLWHA) were interviewed using exit questionnaires (17 people) and semi-structured interviews (21). These interviews aimed to study: PLWHA's history of ARV treatment; experience in taking medicines; cost of treatment; perception of the quality of care given at the clinics; and availability of social support. In-depth interviews were also conducted with 24 health workers including five doctors, 11 counsellors, five nurses and three pharmacists. The purpose of the interviews was to study the functioning of the ARV programme, information provided to PLWHA receiving ARV treatment, availability of ARVs and other resources, perceived job satisfaction, problems and possible solutions, and other relevant information. In addition, two focus-group discussions were conducted, one with PLWHA and one with health workers. Structured observations were conducted on 13 consultations, to study the interaction between the providers and PLWHA. Availability of ARV stocks in the six clinics was also assessed. Information was collected on data collection forms and tabulated into a matrix using word processing software. These matrices were then synthesized across facilities to produce summary result tables. The heads of individual facilities, health workers and the PLWHA gave their permission prior to the study.

One female responded to the question of how she felt she was being treated by health staff, with the following: *"Nice! Even the doctors, they are nice to you".*

Patients in the study were between 20 and 60 years old, and their educational backgrounds ranged from those who had reached Grade 3 up to diploma and degree holders. Most lived in areas surrounding the facilities, and the reasons for their visits ranged from initiation of treatment to follow-up and other illness. Among the 21 PLWHA interviewed using a semi-structured format, 16 started therapy in 2004 while five had started more than one year previously. The length of treatment as recorded at the time of the survey ranged from three months to four years. One female PLWHA had not started treatment after being diagnosed nine months previously due to a fear of being on ARVs for life. Nineteen of the 38 PLWHA had never used ARVs and 10 people in the study had been diagnosed in the previous year.

Results

Facility profiles

All six facilities have a treatment guideline, although their sources varied (WHO, Catholic Society, etc.). Three facilities have diagnostic facilities in their hospital while another three send their specimens to other facilities for analysis. The criteria for all sites for starting ARV treatment are HIV+, a CD4 count of <200, and WHO stage III or IV of AIDS. All the clinics have a "preparedness for ARV treatment" programme, which varies in intensity and duration. Some of these programmes work with PLWHA on an individual basis, others prepare their PLWHA in groups. Some clinics require proof of adherence to prophylaxis against opportunistic infections, usually cotrimoxazole and in some cases isoniazid. All the clinics carry out pre-training for new ARV users, which includes history-taking, adherence courses of varying lengths and some form of contract agreement.

Photo: WHO

Participants at the Promoting Rational Drug Use in the Community Course

Two clinics have a pharmacist. In one clinic the prescription is filled in another facility and the nurse then dispenses the ARVs. In another clinic, the pharmacist comes to dispense ARVs on fixed clinic days. In clinics that have a pharmacist, s/he counsels the patient and issues leaflets on drug schedules and in some cases a leaflet on side-effects and a pill intake card. Counselling is conducted at all clinics, either by medical doctors (in two clinics) or by trained HIV counsellors (in four clinics). Where a nutritionist is available counselling on dietary needs is given to PLWHA.

ARVs are issued free of charge in all public clinics visited, however PLWHA pay a registration fee which ranges from 17–30 Rand[2] per visit. The cost in the private clinic ranges from 800–2000 Rand most of which is covered by insurance, according to the PLWHA interviewed.

At the time of the survey, all the drugs needed for treatment of PLWHA were available and there were no stock-outs reported over the previous two months. With regard to support to health workers, debriefing sessions are carried out in four of the six clinics, three have in-service training for staff, and nothing was provided at one clinic.

Quality of care

Perceived quality of care may be a crucial issue affecting adherence to ARV treatment in the long–term. Data on this were collected from in-depth and exit interviews with PLWHA, and observations on health worker – PLWHA interactions.

Privacy. In all six clinics visited, PLWHA's privacy was respected and they were attended by health workers in a private setting. In one clinic, privacy was seen as a major issue, even during the study interviews, which were carefully planned so that the PLWHA would not meet each other. The doctor in charge stressed the importance of privacy by giving an example of one person who lived around the corner from the clinic, and had started ARV treatment there, but then decided to continue the treatment elsewhere for fear of meeting someone who knew him. In another clinic PLWHA could meet, have tea, and support each other on a daily basis. They felt knowing, supporting and sharing experiences with each other made it easier to follow the treatment. Clearly, the importance of 'privacy' depends on the overall set up of the ARV treatment centres.

Respectful treatment. Almost all interviewed PLWHA expressed their satisfaction about the way they are being treated by the health workers. Most are greeted cordially and feel that they can express their concerns and ask questions. For example, one woman was pregnant

RATIONAL USE

Table 1
Components of information received by PLWHA initiating ARV treatment at two different facilities

Component of information	From exit interviews (n=4 females)	From observations (n=3 males)
1. How ARVs work	4	2
2. How to use them	4	2
3. Why need continuous treatment	4	2
4. What possible interaction may occur with other treatment	4	3
5. What to do when they forgot to take medicines	4	2
6. Which side-effects may occur and what to do if they occur	4	2
7. What requirements for (breast)feeding	4	N/A
8. When and where to get ARV re-supply	4	2

and she asked about the implications of her pregnancy for her treatment, and the risk of transmitting her illness to the baby.

Information given to PLWHA. This is reportedly a major influence on increased adherence. In this study the information given to PLWHAs on their initial visit was observed, and questions were also asked in the exit interviews as well. In particular, PLWHA were asked: whether health workers provide information about how the medicines work; how to administer the medicines; why continuous treatment is needed; what possible interactions can occur; what to do when they forget to take medicines; what possible side-effects may occur; and where to get ARV re-supply.

All PLWHA interviewed said that they get a substantial amount of information, and this was supported by the findings from observations (Table 1). One PLWHA only received information about the possible interaction of the ARVs with alcohol. This person showed low self-esteem and exhibited defensive behaviour.

Waiting time. Avoiding long waiting times is crucial in maintaining high adherence levels over a long period. Waiting times ranged between 30 and 90 minutes, and some PLWHA reported that the time they had to spend waiting for treatment was a problem for them.

Factors influencing (non) adherence

Almost all PLWHA in treatment reported feeling better. Only one person said that the treatment made him more sick, and another was unsure due to the limited period of treatment. Fifteen out of the 21 PLWHA on ARV treatment reported no missed doses, while six reported missing at least one dose.

Both health workers and PLWHA mentioned several factors that complicate adherence to treatment, sometimes leading to non-adherence for a period, but often just making adherence more difficult.

Costs. Both PLWHA and health workers said that the cost of ARV treatment and blood tests, especially in the case of private facilities, was a major constraint to adherence. Even the PLWHA who are covered by Medical Aid complained of costly treatment since the insurance does not cover all expenses. Cost was found to be a major factor that in reality affects adherence. One man said: *".. It can take three months for me before I come back when I don't have money..."*.

Food. Both the health workers and PLWHA reported that food complicates or contributes to non-adherence. In a number of cases therapy made people hungrier, but the cost of food is often a problem. Some centres recommend and/or provide nutritional food, such as fortified high protein supplements.

Family support. Family support is an important factor in supporting adherence, and was mentioned by most of the health workers interviewed. However, PLWHA are usually shocked when they first realise they have contracted HIV, and often find it difficult to disclose to family members, and so do not receive support.

Family support
A 47-year old male PLWHA who had been under ARV treatment for four years whispered in pain: *"I have to keep this in to me... I do not tell anybody..."*. In contrast, another teenage PLWHA was very optimistic: *"I told my mother, I told my brother, they all support me..."*.

Commenting on the beneficial effects of treatment: *"I have power, I have energy, can even sweep..", "I could not walk last week, today I can walk"*.

Side-effects. Health workers at two centres mentioned side-effects as a serious problem. Sometimes PLWHA report that they experience side-effects initially but that these passed with time. Of the 21 people interviewed, 11 reported not experiencing any adverse or side-effects at all. Others complained about various problems, such as rash, nausea and pain in the feet.

PLWHA's knowledge and conflicting information. Some health workers reported limited information about ARV treatment, especially the urgency of the treatment. While this factor, in itself, may lead to failures in adherence, this may be even more problematic in those cases where PLWHA have received conflicting information from different sources.

Food
As one woman said with a sigh: *"...if we have no money to buy food, then this medicine is a problem..."*.

In addition to the factors described above, various health workers from two centres mentioned 'depression due to HIV status' as a factor complicating adherence to ARV treatment. Health workers also reflected that the concomitant use of traditional medicines is a factor influencing treatment. In terms of adherence to ARV treatment, most health workers observed that females appeared to be more adherent than males. People aged over 30 were thought to adhere better to treatment. Educational level seems to be an influence as well. PLWHA also admitted that they sometimes simply forgot to take the medicines, especially when beginning the treatment.

Efforts to enhance services

All clinics have taken several measures to enhance adherence to ARV treatment. Written information (leaflets) are available in all clinics. Follow-up programmes vary in intensity from a daily direct observation of treatment, to weekly and to monthly clinical reviews. Some clinics keep a diary of appointments while others use phone calls and short messaging services. In one clinic, the pharmacist issues the PLWHA with leaflets on the treatment schedule, and in some cases provides a diary card, or an alarm clock.

PRDUC course participants were impressed by the high quality of counselling provided by health workers at all clinics. From the observations of 13 counselling episodes, it was reported that most patients were greeted in a friendly way, and were listened to carefully. Results from the exit interviews with 17 PLWHA also supported this finding. Most of them were satisfied with the services, and said that they respected and trusted the health workers. In the private clinic, participants admired the efforts to ensure privacy by establishing procedures which minimised the chance of PLWHA meeting each other during the visit.

To support the health workers, most clinics have conducted a pre-service training programme, a Care-for-Carer training programme, or debriefing sessions, which varied in intensity, frequency and length. Interviews with health workers indicated that most of them were extremely enthusiastic and passionate, although some health workers complained about the heavy workload and tiring counselling process, low remuneration, or the inadequate recognition by the Government of certain aspects of the work. Some health workers expressed their hope that the Government would assist in creating a more enabling environment for ARV treatment by providing a community-focused sensitising programme, to positively influence the support system needed by PLWHA on ARV treatment.

Discussion

Although this was a small study, the use of in-depth interviews and observation provided comprehensive information about behaviour and practices. Many of the observations and comments were consistent across the range of different facilities.

Most of the sites visited had an ARV roll-out programme for less than six months, so availability of ARVs seemed not to be a problem. However, sex, age and level of education were observed to influence adherence. The national ARV programme uses the multidisciplinary approach where different health workers in the team and other patients and support groups care for patients. Written information and materials to reinforce adherence are available.

The patients interviewed were generally happy with the outcomes of therapy although in some facilities side-effects and dosage regimens were said to be an issue. Patients commented that they trusted the health care workers and felt that they were listened to, respected and given a chance to ask questions. Health workers were enthusiastic and seemed to enjoy their work.

Counselling
A teenage PLWHA expressed her feelings during the interview: *"...they are very, very, very supportive..."*.

Transport costs seemed to be a burden for some of the patients and an increase in appetite associated with the use of ARVs posed a challenge where there is poverty. However, Government provides some nutritional support if needed. In most of the sites, health workers expressed concern about the expected increase in numbers of patients to be treated, which could result in overloading existing facilities and human resources. Lack of Care-for-Carer Programmes in institutions was said to be shortcoming.

A shortage of social workers and counsellors in the facilities was noted. The need for a broader range of ARVs to provide treatment for all categories of patients requiring ARVs, especially paediatric forms, was also noted. Concerns were widely expressed about the limited existing staff capacity and numbers needed to cope with an increase in patient load, as well as the need for capacity building to improve service delivery.

Conclusion

This study was undertaken in a small number of health facilities, over a single day by participants attending a training course. The facilities visited were among the first to provide ARVs to the general population. The staff were enthusiastic and committed to their patients. The patients appreciated the care they were receiving and generally felt better on therapy. Health workers expressed concern as to the present and expected future workload. Patients were concerned about hunger associated with treatment and the need to take treatment regularly and for life.

These are early days for the roll-out of ARV therapy in South Africa but there appears to be hope that many more patients could be treated. Many problems related to workload, promoting adherence, availability of food for patients and other factors exist but there is also a feeling of enthusiasm among staff and hope among patients, suggesting that the roll-out of ARVs has begun successfully in these health facilities. ❑

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1. National Household HIV Prevalence and Risk Survey of South African Children, 2002.
2. Exchange rate at time of interview: US$1 = R 6,35

RATIONAL USE

ISafE and the evidence-based approach for essential medicines selection in Thailand


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THAILAND adopted the WHO concept of essential medicines and began to publish a National List of Essential Medicines (NLEM) in 1981, revising it periodically since then. In 1998, when Thailand faced an economic crisis, the NLEM was used as a reimbursement list for the first time, mainly in order to cut down unreasonable expenditure in the large Civil Servants Medical Benefit Scheme.[1]

The 2004 NLEM

The aim of the NLEM 2004 is to cover the essential medicines needs of the Thai people in an economic and cost-effective manner. The selection criteria include health need, safety, efficacy, efficiency, equity, treatment cost, national affordability, availability, compliance, and quality.[2] The steps for selecting drugs are shown in Figure 1.

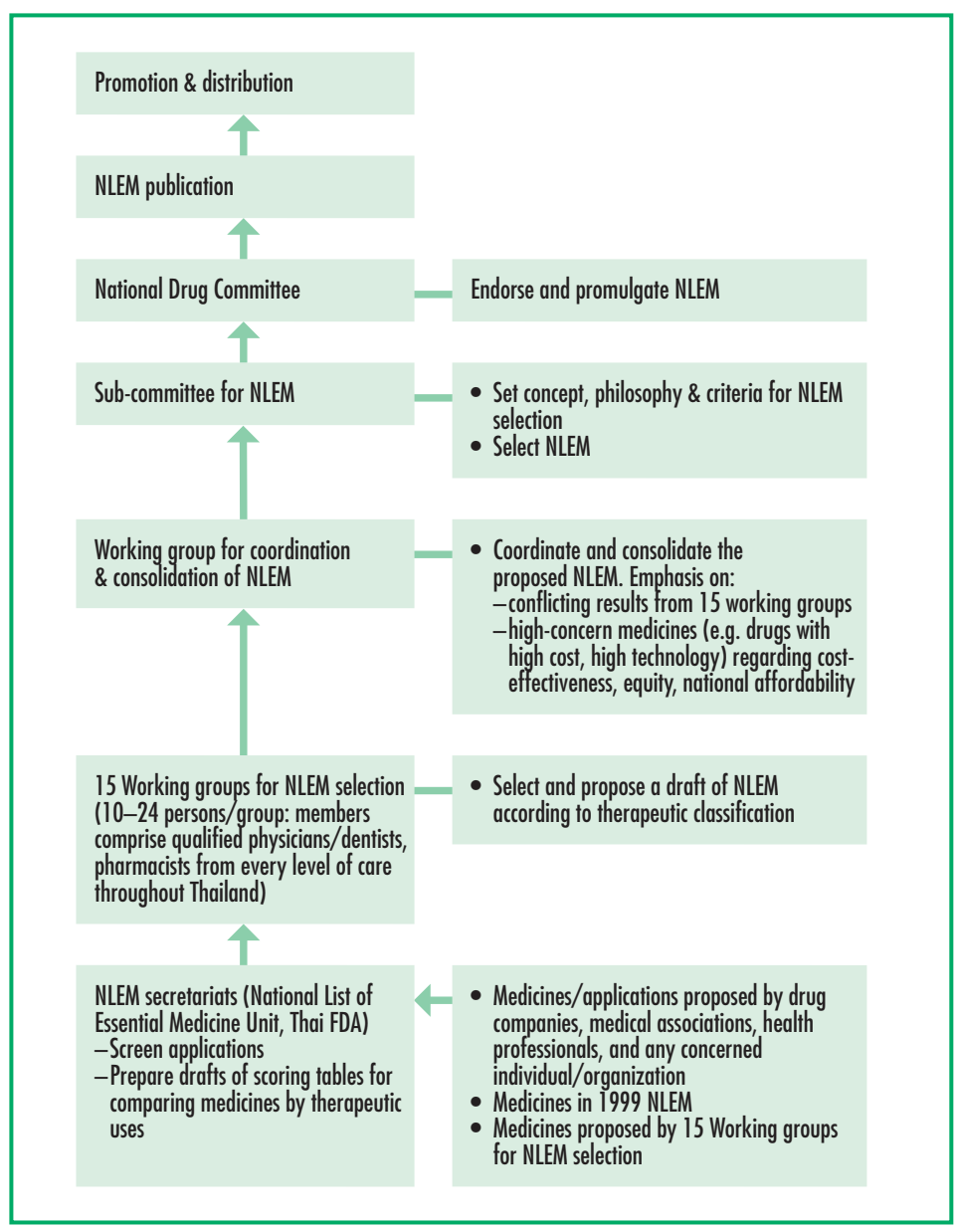
The highlight of the 2004 revision is an attempt to create an evidence-based selection system that is explicit, transparent, explicable, and free from commercial influence. To achieve this goal, the following important measures were developed and implemented:

- ethical criteria for NLEM selection and declaration of conflict of interest
- the invention of the ISafE computer-based system for comparative evaluation of products.

The ISafE scoring system

The scoring system used for the drug selection process in Thailand's 2004 NLEM uses four criteria – **I**nformation, **E**fficacy, **S**afety and ease of use (patient adherence) – of the medicine, as the basis for a scoring calculation. The scoring system is known as **ISafE** – the acronym of all the criteria used in this method. Details of how ISafE scores are derived are discussed below.

Figure 1
Steps in selection of medicines for the Thai National List of Essential Medicines



Scoring "I" for Information

The scoring process begins by searching the free PubMed services on the Internet. All relevant articles are counted for each medicine. The counts are compared using percentile ranking and points between 0.5 and 1 are assigned to each medicine (quantity points). Next, Micromedex's DRUGDEX drug evaluation database was searched. The database assesses the quality of documentation for each indication of a medicine. Quality points are given to each medicine as follows 1, 0.9, 0.8 and 0.7 for Excellent, Good, Fair, Poor or No Assessment, respectively. The final point for I (Information) is the average of quantity and quality points (adult and paediatric).

Scoring "E" for Efficacy

Micromedex DRUGDEX evaluation gives an assessment on efficacy of a drug. The final E score is the average of the adult and paediatric assessments each scored on a 0–1 scale.

Scoring "S" for Safety

Data on the risks of a drug were searched from 3 databases, Medscape DrugInfo, Micromedex Drug Interaction Database and Gold Standard Multimedia Clinical Pharmacology CD-ROM. The final S score is the weighted average of the different assessments.

Scoring af (administration restriction and frequency of drug administration)

The **a** and **f** scores attempt to quantify patient adherence to a medicine. Textbooks are searched for information on whether the medicine has to be taken on an empty stomach, with food, at night (such as simvastatin), has special instructions for use, needs a special device for administration or has to be injected. If a medicine has no restriction on administration it is given an **a** score of 1.0 otherwise its score is 0.9. For the **f** score, a score of 1, 0.95, 0.90 and 0.85 is assigned to a medicine that has to be given once, twice, 3 or more than 3 times per day respectively. The final **af** score is the average of the sum of the **a** and **f** scores.

The final ISafE score

A point is assigned to each of the criterion, ranging from 0.6 to 1 for **I**, 0.8 to 1 for **S**, 0.9 to 1 for **af** and 0.8 to 1 for **E**. The final ISafE score is the product of all the points. The best possible score

Table 1
How the I (Information) score was derived

1	2	3	4	5	6	7
Generic Name	**N° of Pub.**	**QN point**	**MM Adult**	**MM Ped.**	**QL point**	**I**
Betahistine hydrochloride	9	1.00	F	N	0.80	0.90
Betahistine mesilate	9	1.00	F	N	0.80	0.90
Cinnarizine	6	0.90	G	N	0.85	0.88
Dimenhydrinate	2	0.70	F	N	0.80	0.75
Flunarizine hydrochloride	1	0.70	P	N	0.75	0.73
Meclizine hydrochloride	2	0.70	E	G	0.95	0.83
Almitrine + Raubasine	1	0.70	N	N	0.70	0.70

Explanation: Column 2 is the number of publications conforming to the criteria found for each drug. Column 3 is the quantity point translated from column 2 using percentile ranking. Columns 4 and 5 are the Micromedex database's quality assessment of documentation for each drug (E, G and N represents Excellent, Good and No Assessment respectively). Column 6 is the average of adult and paediatric assessment.

RATIONAL USE

Table 2
Scoring table for antivertigo preparations

Generic Name	I	E	S	af	ISafE
Dimenhydrinate	0.75	1.00	0.90	0.90	0.61
Cinnarizine	0.88	0.90	0.85	0.90	0.60
Flunarizine hydrochloride	0.73	0.90	0.80	1.00	0.53
Betahistine mesilate (6mg)	0.90	0.90	0.90	0.81	0.59
Meclizine HCl	0.83	0.90	1.00	0.90	0.68
Betahistine HCl (8mg)	0.90	0.90	0.90	0.81	0.59
Betahistine mesilate (12mg)	0.90	0.90	0.90	0.81	0.59
Almitrine + Raubasine	0.70	0.80	0.90	0.95	0.48

using this scheme is 1 and the lowest possible score is 0.35. All medicines used for a specific purpose are compared by their relative scores.

Drugs with an ISafE score below the 50th percentile of the group are initially excluded from the NLEM. In Table 2, the 50th percentile score is 0.59, so flunarizine and almitrine + raubasine are discarded from antivertigo use (although flunarizine passed the 50th percentile for use in migraine prophylaxis). The medicines that pass this 50th percentile comparison are deemed to have acceptable overall quality to be considered for inclusion in the NLEM. These medicines are further compared for their treatment cost by the NLEM adjusted cost index (EMCI) in order to ensure that the medicines are economical and cost-effective.

Determining the treatment cost of medicines

The WHO DDD (defined daily dose) is used to calculate the number of unit doses (i.e. tablets or capsules) needed for one day (UD) for the drug in question. Based on the actual Thai costs we calculated the Baht per Patient Day cost for the Essential Medicine Cost Index (EMCI).

The NLEM adjusted cost index (EMCI)

The EMCI is the treatment cost for a medicine divided by the ISafE score (Table 3). The EMCI is used to rank only those medicines above the 50th percentile in the overall quality assessment (based on the ISafE score). The medicines with low EMCI are ideal for inclusion in the NLEM, because they are assessed as providing acceptable quality at low cost.

The basis of the NLEM selection process

The ISafE scoring system and EMCI data as shown in Table 3 are the primary tools used by all involved in the compilation of NLEM (15 working groups for NLEM selection, the working group for coordination and consolidation of the NLEM and the subcommittee for the NLEM). All the medicines listed are then scrutinized to see whether they merit inclusion in the NLEM.

Rules for inclusion/ exclusion

Several rules are applied before a medicine can be included in the NLEM. Firstly, the medicine must have been cleared by the safety monitoring programme (SMP) implemented by the Thai Food & Drug Administration (FDA). All new chemical entities approved for use in Thailand are subject to mandatory 2-year SMP status. Medicines under the SMP are restricted to use in hospitals and clinics, to ensure that the medicine is not harmful to the Thai population before its inclusion in the NLEM. Secondly, only one medicine from the same chemical classification should be included in the NLEM, except when there are valid reasons to justify the inclusion of others in the same class. Thirdly, medicines with high potential for misuse are generally excluded. Fourthly, high-cost medicines without clear-cut proof of their cost-effectiveness over similar products are not included.

Table 3
Ranking antivertigo preparations using the NLEM adjusted cost index (EMCI)

Generic Name	I	E	S	af	Baht/PD	ISAFE	EMCI
Dimenhydrinate	0.75	1.00	0.90	0.90	0.63	0.61	1.0
Cinnarizine	0.88	0.90	0.85	0.90	1.76	0.60	2.9
Flunarizine hydrochloride	0.73	0.90	0.80	1.00	2.58	0.53	4.9
Betahistine mesilate (6mg)	0.90	0.90	0.90	0.81	5.63	0.59	9.5
Meclizine HCl	0.83	0.90	1.00	0.90	9.69	0.68	14.3
Betahistine HCl (8mg)	0.90	0.90	0.90	0.81	9.33	0.59	15.8
Betahistine mesilate (12mg)	0.90	0.90	0.90	0.81	11.40	0.59	19.3
Almitrine + Raubasine	0.70	0.80	0.90	0.95	19.34	0.48	40.3

Expert panels' opinions of the scoring approach

Of the 15 expert panels, 10 panels and one sub-group (a total of 201 members) adopted the scoring approach as a tool for essential medicine selection. The expert panels that could not adopt it were referred to as non-score users, (60 members) and the main reasons for non-use included: the complexity of medicine preparations (e.g., nutritional and multivitamins); lack of information for score formulation (e.g., radiopharmaceuticals and nuclear pharmaceuticals); and being the only medicine in a therapeutic class (e.g., antidotes).

A survey was conducted to assess expert panels' opinions about the essential medicine selection process.[3] Two different sets of self-administered questionnaires were mailed to score users and non-score users separately, and the overall response rate was 46.6%. Overall, respondents thought that the drug-related information and the evidence-based databases used in the selection process are appropriate. Score users suggested that the scoring system could be improved thorough the use of drug-related information obtained from proper evidence-based databases. Both score users and non-score users agreed that a combined approach – the scoring approach together with expert opinion – was the most appropriate for the medicine selection process, as neither was sufficient alone.

Factors influencing essential drug selection are relatively similar in both score users and non-score users. Basically, the NLEM philosophy and the community's health care needs are the most influential factors in selecting essential drugs, followed by concerns about treatment costs (for example, reimbursement and the Government budget). The influence of opinion leaders and pharmaceutical companies were reported as rarely affecting essential drugs selection.

Implications of the scoring approach

The scoring approach (together with other evidence-based materials) has proved useful as a tool for essential medicine selection. The goal is to assure that high-priority medicines (e.g., higher ISafE score with lower cost) should be considered first, and only the essential ones should be selected for the List.

The 2004 NLEM contains more drug items than the 1999 one, so it was important to eliminate items that provide low benefit-cost ratios. Examples of low priority drugs (or drugs with low benefit-cost ratios) that were excluded from the 2004 NLEM are tenoxicam, sulindac and loxoprofen.

Promoting the availability of essential medicines

The evidence-based approach with a systematic review on therapeutic indications alerts the panels and public health agencies to the crucial issue of essential medicine shortages. Specifically, the reviews carried out indicated that there were some drugs that have yet to be made available in Thailand, but are essential.

Conclusion

The essential medicines concept promotes the rational use of medicines. Its effectiveness depends on the essential drugs selection process. In 2004, Thailand attempted to create an evidence-based selection system that is explicit, transparent, explicable and free from commercial influence. We created the ISafE computer-based system for comparative evaluation of products based on predefined criteria for NLEM selection. We can now assure that high-priority medicines – those with a higher ISafE score and with a lower cost – are considered first, and that only the essential ones are selected for our National List of Essential Medicines. ❑

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Editor's Note

Two presentations were made at the ICIUM 2004 which provided more details of this impressive process they can be found at:

Scoring System for the Development of the National List of Essential Drugs (NLED) in Thailand Pisonthi Chongtrakul: http://mednet3.who.int/icium/icium2004/resources/ppt/O_AC015.ppt and at:

Assessment of the Selection Process for the 2003 National List of Essential Drugs (NLED) of Thailand, Worasuda Yoongthong: http://mednet3.who.int/icium/icium2004/resources/ppt/O_AC089.ppt

RATIONAL USE

Monitoring antibiotic use and resistance – a pilot project in South Africa


A. Gray


S. Essack

➢ Andy Gray, Sabiha Essack

Resistance to antimicrobials is a problem in all parts of the world. This has been recognised by WHO, which has proposed the "WHO strategy for containment of antimicrobial resistance". High priority has been given to the development of appropriate surveillance methodologies that can show the association between antimicrobial use and resistance. Such surveillance systems exist in other parts of the world. An example is the Swedish Strategic Programme for the Rational Use of Antimicrobial Agents (STRAMA). However, such systems rely on access to large medicine sales databases and to well-developed laboratory services. In most developing countries these two systems are lacking. Medicines are supplied through a wide variety of outlets and no single computer system captures these sales. Laboratories are usually attached to hospitals and therefore do not routinely study organisms obtained from the community. WHO has funded a number of pilot studies in developing countries to test the feasibility of setting up simple surveillance systems. One of these is in Durban, South Africa. The Durban pilot project has tried to show whether or not it is possible to set up a system to track microbial resistance in a community, while at the same time tracking the use of antimicrobials in the same setting. The project was conducted in one of the sub-districts of the Durban metropolitan area.

Sputum samples were collected from patients 12 years of age and older presenting with a febrile illness and productive cough. Initially it was hoped that two public sector and two private sector sites could be used. However, difficulties were encountered with getting permission to obtain sputum samples from private doctors' patients. A third public sector site had to be included later. Despite this, the number of sputum samples that grew organisms was small. A total of 311 *Haemophilus influenzae*, 184 *Streptococcus pneumoniae* and 30 *Moraxella catarrhalis* were isolated and tested for sensitivity to commonly used antibiotics (ampicillin, chloramphenicol, ciprofloxacin, cotrimoxazole, erythromycin and rifampicin). Of particular concern were the high levels of resistance to cotrimoxazole seen among *S. pneumoniae*. However, this did not vary during the year, so could not be directly linked to any changes in the use of cotrimoxazole.

Antimicrobial utilization data could not be obtained from a single source. Fieldworkers had to visit 21 facilities each month to capture all prescriptions containing an antimicrobial that had been written in two weeks of the previous month. In order to cover all possible sources of such medicine, prescriptions were examined at seven public sector primary health care clinics, seven pharmacies in the private sector and seven dispensing medical practitioners in the private sector. The pharmacies would issue antimicrobials on prescription from non-dispensing doctors. In South Africa, antimicrobials are not available without a prescription. Antibiotic usage was expressed as the number of Defined Daily Doses (DDD) per 100 patients seen or prescriptions dispensed.

The project aimed to see at least 30 antimicrobial prescriptions per site per month. However, even with 2 weeks' data, this was not possible in some of the smaller practices. Of the 96,369 prescriptions reviewed, 14.8% were for antimicrobials (see Table 1). No time trends could be seen in any of the classes of antimicrobials monitored. However, there were major differences between the three types of practices. The public sector facilities used more antimicrobials than did the private sector facilities, but were restricted to older agents. South Africa's public sector uses an Essential Drugs List with Standard Treatment Guidelines. Private sector prescribers were more likely to use the newer penicillins, macrolides and quinolones. For all facilities together, the monthly use of cotrimoxazole varied from 5.5 to 11.7 DDD/100 patients. However, because there are no data on the size of the population served by these facilities, it is impossible to compare them with data generated elsewhere. For example, in 2003, outpatient use of cotrimoxazole in Sweden was 0.2 DDD/1000 patients/day. What can be done in Durban, though, is to compare use over time. In the last two months of the pilot project, use of cotrimoxazole increased. The increase was due to the public sector clinics applying a policy regarding the use of cotrimoxazole as prophylaxis in HIV-positive patients.

The Durban pilot project has shown that surveillance can be done in a developing country setting, but that there are many problems that need to be overcome. The real challenge will be to make this a routine part of the health care system, so that ongoing efforts to improve antimicrobial use and to limit the spread of resistance can be planned and monitored. ❑

Table 1
Antimicrobial prescribing levels

	Prescriptions	Antimicrobials	%
Pharmacy	14,565	1723	11.8
PHC	59,926	9640	16.1
Dispensing Docs	21,878	2854	13.0
Total	96,369	14,217	14.8

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Mercy Ships: an NGO's experience with the WHO Essential Medicines List and Formulary

How does one decide what medicine and dose to stock and use, with the diversity and limitations on the relief aid field? Thankfully, the concept of an essential medicines list (EML) is not new: since 1977 WHO has been advocating a systematic approach to medicine selection tailored to local populations. Mercy Ships International (www.mercyships.org) is a humanitarian relief organization operating a fleet of hospital ships, staffed by international volunteers with diverse prescribing experiences. To minimise errors and optimise resources, we adopted the EML concept when the WHO Model Formulary 2002 was published. Involving volunteers with experiences from weeks to over 15 years, originating from Africa, the Americas, Asia and Europe, our EML working group included administrators, anaesthetists, surgeons, physicians, nurses, pharmacists and laboratory technicians. Our first list was established in July 2002 based on 20 years experience of the M/V Anastasis in Africa. After a pilot in Togo, the list was distributed in booklet format in late 2003.

We chose a basic Word format following the WHO and British National Formulary models, prioritising generic name prescribing, because with international volunteers brand name prescribing would be too confusing and error-prone. The Mercy Ships Formulary booklet is designed as a rapid 'bedside' pocket reference, indicating medicines available on our EML and their basic dose information. In its preparation, we are indebted to information and advice from the Micromedex Healthcare database, Médecins Sans Frontières' Essential Drugs Practical Guide (www.msf.org), and online networks "HIF-net at WHO" (www.inasp.info), E-DRUG (www.essentialdrugs.org/edrug), AFRO-net and SATELLIFE (www.healthnet.org).

After many requests, the formulary is now downloadable online at: www.drugref.org and www.ms-information.org/medical/formulary. A step-by-step article on its preparation is on the Mercy Ships website and the Aid Workers Network (www.aidworkers.net). ❑

Report by Kae Ting Trouilloud, a Mercy Ships pharmacist and formulary editor. E-mail: kaecherie@yahoo.co.uk

RATIONAL USE

Patient and carer membership of NICE clinical guideline development groups


M. Kelson

➢ MARCIA KELSON

THE National Institute for Health and Clinical Excellence (NICE) produces national guidance on the promotion of good health and prevention of ill health.

NICE produces guidance in three areas of health:

- health technologies – guidance on the use of new and existing medicines, treatments and procedures within the National Health Service (NHS) in England, Wales and (for interventional procedures guidance only) Scotland;
- clinical guidelines (guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales;
- public health – guidance on the promotion of good health and prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector in England.

NICE is committed to involving patients, carers and the public in the development of its guidance and has a dedicated Patient and Public Involvement Programme (PPIP) to develop and support that involvement. This paper focuses on NICE clinical guidelines, describing how patients and carers are involved as members of the groups that develop those guidelines.

Production of NICE clinical guidelines

NICE clinical guidelines make recommendations about the best ways of treating and managing patients with a particular condition, based on the best available research on clinical and cost effectiveness rather than on opinion.

NICE commissions one of seven National Collaborating Centres (NCCs) to develop a guideline on a given topic. The commissioned NCC then convenes a guideline development group (GDG) whose members include clinicians, people with a research interest in the topic and at least two (and up to four) patient/carer members. The patients and carers are paid for their attendance at GDG meetings.

Recruitment and selection of patient members

The NICE PPIP has responsibility for identifying people interested in joining a GDG as patient or carer members.

The PPIP recruits applicants from a number of sources:

- Direct approaches to patient and carer organizations that register an interest with NICE in a specific guideline topic
- Adverts in patient organization newsletters
- Adverts on the NICE website.

The PPIP sends interested people an application pack which includes:

- a job description – this describes what a clinical guideline is, the role of a GDG, and the role of GDG patient/carer members
- a person specification – this is not intended to be prescriptive but aims to give people an idea of the types of skills and experiences a person may need to play an effective role on a GDG
- an application form which asks applicants about their skills, experiences and why they would like to join the GDG.

Applicants are not expected to have any formal qualifications and NICE and the NCCs do not have a rigid view of the types of applicants they are looking for. However, the person specification suggests that people may need some of the following experiences and skills to play an effective role:

- Experience of the condition: this may have been gained directly, for example as a patient with the condition; or indirectly, for example as an employee or member of a patient organization who works with patients or carers with the condition
- An understanding of the views of a wider network of patients or carers (for example as a member of a patient group, local self-help group etc)
- Time to commit to group meetings (GDGs generally meet monthly for 12 to 18 months)
- Some familiarity with medical and research language
- Communication and team working skills.

To date, applicants have included individual patients with a condition, carers, but also patient organization employees (ranging from chief executives to policy and information staff).

The NCC selects patient/carer members on the quality of the written application and discussion with the applicant, either by telephone or in person. Because the NCCs want to get a mix of skills and geographical spread (from all GDG, not just the patient/carers) these additional factors may sometimes also influence selection of one applicant over another.

Training of patient/carer members

Patient and carer members have full access to the training offered by the NCC to all GDG members. In addition, the NICE PPIP also runs one-day training workshops specifically aimed at the patient/carer members. Ideally, people attend the workshop before the first GDG meeting although staggered starting dates mean that some people have already attended a GDG meeting by the time they come to the training.

The training day is run by PPIP staff and external expert speakers. The programme, which has been revised following early feedback, now consists of the following sessions:

- An overview of the NICE Guideline Development Process
- Stages of guideline development;
  - setting clinical questions
  - appraising and evaluating evidence
  - the hierarchy of evidence
  - key statistical terms

  drawing up recommendations.
- Experiences of other patient/carer members: an opportunity to hear from and question people who have completed their work on a GDG
- Health economics: its role in NICE guideline development plus worked case studies
- Evaluation of the day.

Interactive sessions provide participants with practical experience of tasks they will do on the GDG. The workshops are not intended to turn the patient members into clinical experts or researchers but focus on working with them to identify ways of ensuring that a patient or carer perspective informs the guideline development process.

Ongoing support for patient/carer members

The PPIP also offers ongoing support and contacts patient/carer members at key milestones of the guideline development process to see how they are getting on. Some request more intensive PPIP support. In rare instances, the PPIP facilitates meetings between the patient/carer members and the NCC or GDG chair, for example, where the patient members have felt that patient-centred issues are ignored by a professionally dominated agenda.

At the end of the process, each NICE guideline is published after a press launch which usually involves a panel of three or four speakers drawn from the GDG. Recent launches have routinely included one of the patient/carer members as panel members.

Evaluation of patient/carer membership of GDGs

By March 2004, NICE had published 20 clinical guidelines produced by GDGs with patient/carer membership. As each guideline was published, a freelance researcher, commissioned by the PPIP, carried out semi-structured interviews with both the GDG patient/carer members and the professional chairs. The project collected feedback on:

- how patient/carer membership was working
- how actual participation matched both patient and professional expectations
- the contribution participants felt they had made to the guideline
- areas for improvement.

Overall, both patient/carer members and GDG chairs were very positive about patient/carer membership of GDGs and felt that the guidelines produced were more patient-centred as a result:

'What we did was to give a point of view that couldn't be given by anyone else on the group…' (a patient)

"Some of the best contributions to what we've ended up with came from the patient/carer members" (GDG Chair).

However, some people also identified areas of concern, including the organization and conduct of some GDG meetings, the hierarchy of evidence used and patient/carer member research skills. The findings are being used to refine and improve the effective involvement of patients and carers in the guideline development process.

Summary

Membership of GDGs is just one way that patients and carers can contribute to NICE clinical guideline development. Opportunities also exist for national patient and carer organizations to comment on draft scopes and final draft guideline recommendations. Some NCCs have also collected additional information on patient and carer views, for example, through focus groups, to inform the GDG. However, in contrast with these additional methods, GDG membership means that patients and carers contribute directly, rather than indirectly, to both the process and the final product.

We hope that our attempts to develop and document formal processes to recruit, train and support people, and to evaluate the outcomes of such involvement, will provide a model to help others develop more systematic and effective opportunities for patient and carer involvement in their own work. NICE itself is drawing on the experiences of involving patients and carers in clinical guideline development to create opportunities for patients, carers and the public to contribute to the development of its new programme of work producing public health guidance. ❑

For more information about NICE, the PPIP and the evaluation project described above, visit www.nice.org.uk

For more information about opportunities for patient, carer and public involvement in the production of NICE technology appraisals, interventional procedures, clinical guidelines or public health guidance, please contact Marcia Kelson, Associate Director, NICE Patient and Public Involvement Programme, e-mail: marcia.kelson@nice.org.uk

RATIONAL USE

Workshop boosts rational use activities in Jordan


R. Bader


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➢ Report by Rania Bader, Salah Mawajdeh and Ken Harvey

Jordan, like all countries, is faced with the difficult problem of how to provide equitable, evidence-based and cost-effective health care within the limits of its ability to pay. About 9% of the Jordanian GDP is spent on health, with one-third of this spent on medicinal drugs, while drug expenditure is growing at 17% per annum compared to GDP growth of 3.3%. This makes the pharmaceutical sector a high priority for the first phase of Jordanian health reform. While the country has a published and endorsed National Drug Policy implementation, especially the rational drug use component (RDU), left much to be desired. To help remedy this situation, the Jordanian Food & Drug Administration (JFDA) joined forces with WHO, the Australian HIC and the U.S. Agency for International Development Partners for Health Reform*plus* (PHR*plus*) to hold a strategy development workshop on RDU.


Photo: Ronia Bader

A lively group session at the Workshop

Organized in September 2004 by the JFDA, the two-day workshop brought together some 100 participants representing organizations from key sectors (see Box 1) to the Dead Sea Valley. In order to stimulate debate, participants had previously been provided with background material including keynote presentations and a policy paper that outlined the history of RDU in Jordan; analysed its strengths, weakness, opportunities and threats, and provided an action plan for their consideration.

The workshop was introduced by Dr Ken Harvey (a consultant with the Australian Health Insurance Commission). He noted that all countries have problems with RDU and that they can learn from each other, from WHO, and from other international agencies working in this area. He stressed the need for all sectors to be involved; government, health professionals, consumers and the pharmaceutical industry. Each had competing needs; only by working together could an outcome be achieved that was fair to all. Dr. Harvey listed a number of concerns about RDU in Jordan. These included evidence of excessive and wasteful prescribing but also of under treatment of certain diseases, such as hypertension, increasing levels of antibiotic resistance, the escalating cost of valuable new drugs and the additional cost of preventable medication-related adverse events. He then introduced the workshop objectives, to:

- review progress and revitalise the RDU component of Jordan's NDP;
- share local and international experience with respect to implementing RDU;
- present local data relevant to RDU (including WHO indicators, drug utilisation data and information on antibiotic resistance);
- discuss and prioritise the strategies suggested by participants and consultants to stimulate RDU in Jordan;
- encourage organizations and individuals to commit to undertaking particular RDU activities.

On behalf of the WHO Representative, Dr Mohammed Khan welcomed the Minster of Health, other distinguished guests and participants to the workshop. He noted that WHO had much to contribute to improving rational use in terms of expertise and technical materials. The speaker from PHR*plus*, Dr Dwayne Banks, discussed some of its main activities in Jordan, including the National Health Accounts Project, which provided the Government with a systematic method for tracking and estimating health care expenditures, and had found pharmaceutical expenditure to be around one third of health GDP. PHR*plus* was also supporting the introduction of pharmaceutical inventory software, hospital accreditation and an update of the Jordan National Formulary and Essential Drug List.

The Director General of the JFDA, Dr Salah Mawajdeh, reminded participants of the goal of Jordan's NDP; "To develop, within the available financial and human resources, the potential that drugs have to improve and maintain the health of the population". He noted that the JFDA had worked closely on pharmaceutical policy studies within the larger World Bank-supported Health Sector Reform Project, with the current workshop part of the Project.

Formally opening the workshop, Eng. Saed S. Darwazah, Minister of Health of Jordan, raised the issue of conflict between two competing policy goals. The first was to make all new drugs quickly available on the Jordanian market in order to provide freedom of choice for health professionals and consumers. The second was to choose cost-effective therapy appropriate to the economic resources of the country. He noted that new drugs are not necessarily better but are always more expensive than older multisourced products. He was concerned that doctors too often switched to new products; and believed they required guidance, which was the task of this workshop.

Dr Harvey presented an outline of RDU activities in Australia. A small group of people concerned about antibiotic resistance initially created guidelines for antibiotic use, conducted antibiotic audits and targeted education at the gaps between what was recommended and what was actually practiced.[2] These initiatives spread to other therapeutic areas and were eventually formalised as the Australian Quality Use of Medicines (QUM) Policy. A National Prescribing Service (RDU coordinating unit) was funded by the Australian Government to support and encourage the development of QUM activities in both the public and private sectors. Evaluation has shown that these activities have improved the prescribing, dispensing and consumption of medicinal drugs and have been cost-effective. In short, spending money saved more money! Other countries have had similar experience.

Presenting the overall WHO Medicine Strategy for 2004–2007,[3] the Special Adviser to the WHO Regional Director for Medicines, Dr Abdel Saleh, stressed that NDP should be an integral component of National Health Policy which, in turn, should be an integral component of National Socioeconomic Policy. He noted that the problem with RDU is not lack of technical knowledge,[4] rather it lies in implementation. Problems include poor organization and management of health services at all levels, limited allocation of funds, relatively low salaries, the working conditions of public employees and the weakness of health

Box 1

Organizations represented at the Jordan RDU Workshop

- Australian Health Insurance Commission
- Drug Store Importers
- Drug Store Owners Association
- Food and Drug Administration
- IMS
- Joint Procurement Administration
- Jordan Association of Pharmaceutical Manufactures
- Jordan Pharmaceutical Association
- Jordan pharmaceutical companies
- Jordan University
- Jordan University of Science & Technology
- King Hussein Cancer Centre
- Ministry of Health
- National Society for Consumer Protection
- PHR*plus*
- Royal Medical Services
- World Bank
- World Health Organization

RATIONAL USE

information systems. Globalization presents another challenge, and in particular free trade agreements, which may have had the potential to undermine health policy. He stressed the need to adhere to important basic values, especially the right to health as a human right.

The Country Manager for IMS, Mr Al-Khuzai, provided local data on drug utilisation from the Jordan Pharmaceutical Index (JPI). This commercial venture estimates the national quantity of all pharmaceutical products sold through retail pharmacies. The data showed that drug consumption (units) was growing at 12% per annum compared to a population growth rate of 2.8%, while drug expenditure in Jordanian Dinar (JD) was growing at 17% per annum compared to a GDP growth of 3.3%. Antimicrobials account for the largest market share (23% by JD; 15% by unit) and foreign companies supplied 63% of the market (JD).

Consumer practices

Dr Leone Coper (Consultant, Australian Health Insurance Commission) reported on qualitative research conducted with Jordanian consumers. A number of focus groups had revealed that doctor "shopping" was common; pharmacists were viewed primarily as dispensers of medicines (but were also used for the treatment of minor illnesses) and many consumers believed medicine was a "last resort" in treating illness, although less so in cases of chronic illness. Many misunderstandings about medicines were revealed, such as, "60% of the sample believed more is known about side-effects of newer, more expensive medicines".

Consumers also lacked knowledge about their own medicine. Researchers noted that doctors and pharmacists usually waited to be asked rather than automatically giving consumers the information they needed to about their medicines. Non-compliance was commonly reported. Only 47% of people interviewed with chronic conditions always took their medicine; 50% stopped taking medicine without notifying a doctor or pharmacist. Many people had taken antibiotics over the previous 12 months, especially for coughs, colds and flu; 19% had taken three or four courses, 8% 5 or 6 courses and 6% used antibiotics chronically. If an antibiotic was required 59% went to the doctor first; 25% asked the pharmacist which one to use; and 16% asked pharmacists for a brand that had worked well for them before (self selection).

Need for antibiotic control policies

A presentation of local data on antibiotic resistance by Dr Asem Shehabi, highlighted a dramatic increase in penicillin resistance to *Streptococcus pneumoniae* (an important community pathogen causing meningitis, pneumonia, otitis media, etc) over recent years. High levels of antimicrobial resistance in urinary and faecal pathogens were also reported with similar rates of resistance occurring to antibiotics commonly used in both out-patients and in-patients (a reflection of high community use of antibiotics). There were also severe problems of antibiotic-resistant nosocomial infection in tertiary hospital neonatal and adult intensive care units. Increasing antibiotic resistance required the use of newer, more expensive and sometimes more toxic antibiotics; it also raised the real danger that physicians will run out of effective antibiotics to treat certain infections. The data highlighted the need for antibiotic control policies.

Ken Harvey presented a local study on antibiotic use, conducted in 1999 by Jordan University of Science & Technology staff who evaluated drug prescribing practices in 21 randomly selected primary health care facilities in the Irbid Governorate using WHO indicators. At least 30 prescriptions were analysed from each centre. The mean number of drugs prescribed was 2.3; the mean percentage of drugs prescribed generically was 5.1%; the percentage of drugs from the essential drugs list prescribed: 93%; prescriptions involving injections: 1.2% and prescriptions involving antibiotics: 60.9%. The percentage of drugs prescribed generically was low by international standards and the percentage of prescriptions involving antibiotics very high.

A representative from the Essential Drugs and Medicines Policy Department at WHO Headquarters, Dr Guitelle Baghdadi, introduced participants to the WHO Ethical Criteria for Medicinal Drug Promotion.[5] While these were written in 1988 they were seen to be even more relevant today, as a result of the large amount of money spent on pharmaceutical promotion and its corresponding influence on the prescribing, dispensing and consumption of medicinal drugs. She advocated training health workers in critical appraisal of pharmaceutical promotion and introduced participants to the WHO/Health Action International drug promotion database as a useful educational resource.[6]

The final presentations were on Drug and Therapeutics Committees (DTCs) and were made by Dr Saleh and Dr Imad Treish. It was noted that a DTC in a hospital was responsible for implementing locally the same broad range of functions required under the NDP, including establishing systems for the rational selection, use and monitoring of drugs. Participants were given copies of the WHO/MSH manual, *Drug and Therapeutics Committees – A Practical Guide.* The need for a clear administrative mandate for the DTC was stressed, as was the important role of pharmacists. The King Hussein Cancer Center had shown that not only could an effective DTC be set up in Jordan but it could also achieve cost-savings by RDU interventions (for example, omeprazole has been successfully targeted).

On the second day of the workshop, participants were divided into five groups to discuss a number of questions, formulate a group response to each and later present these in a plenary session. All groups agreed that a national RDU Unit with responsibility for addressing RUD issues should be set up in Jordan. Considerable detail was provided by the groups as to how the various strategies proposed might be implemented. There was less consensus on where such a unit should be situated with the JFDA, the Ministry of Health and the Joint Procurement Directorate all being suggested as possible sites. Others wanted a unit independent from the above (but still receiving Government money).

Subsequently, given the unanimous support from all sectors represented at the workshop, a steering committee has been set up under the auspices of the JFDA to establish the RDU Unit (initially within the JFDA) and decide on its infrastructure, personnel and functions. ❑

Rania Bader and Ken Harvey are consultants, and Salah Mawajdeh is Director General Jordanian Food and Drug Administration.

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Interactive HIV/AIDS training course for South African pharmacists

SOUTH Africa has an estimated 5.3 million people living with HIV/AIDS, the highest caseload in the world. Most health care professionals have not learnt about HIV and antiretroviral therapy during their studies.

The MEDUNSA School of Pharmacy contributed to a FIP manual on the role of the pharmacist in safe and effective HIV/AIDS therapy. The material was adapted into a South African course consisting of a manual and an interactive CD. This self-paced distance learning course was approved by the South African Pharmacy Council for Continuous Professional Development in 2003.

The course was tested on pharmacists from two South African provinces. Questionnaires were designed to evaluate knowledge, attitudes and preparedness to offer HIV-related services. At pre-test, only a third of all respondents (188) would have scored 60% or more in their knowledge test; the average score was 47%. Six to eight weeks after distribution of the course material, all the scores had improved in the study group (n=66), while no corresponding changes were seen in the control group (n=46). The increases in attitude and preparedness in the study group were correlated. Twelve to 16 weeks after completing the course, all 44 study group respondents "passed" their knowledge test, the average score was 85%. However, knowledge changes were not correlated with either attitude or preparedness. Less than a third of pharmacists actually offered HIV-related services at any stage of the study.

In 2004, the public sector, which caters for 80% of the population, started providing antiretroviral treatment. Encouraging early observations were made during field visits by participants of the 2004 PRDUC course in Pretoria (see p. 16). There has been a renewed interest in the training course in recent months. Pharmacists are keen to acquire a basic knowledge of HIV and its treatment as they become involved in the roll-out. ❑

RATIONAL USE

Drug safety surveillance – a concern for everyone


S. Olsson

➢ Sten Olsson

Commitment to pharmacovigilance has increased enormously since the first systems were set up in the 1960s. Then, following the thalidomide disaster, 10 developed countries, under the leadership of WHO, saw the need for international collaboration in drug monitoring to prevent a similar disaster recurring. Now there is worldwide recognition of the importance of the early detection of potential drug hazards and the sharing of information.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.[1]

The scope of pharmacovigilance

From an exclusive concern for physicians to report only serious and unexpected pharmacological or immunological adverse reactions (ADRs) to modern medicines, pharmacovigilance has grown. It now encompasses a broader range, such as blood products, vaccines and traditional medicines, and additional safety issues, including:

- quality defects
- unexpected therapeutic failure (may be due to resistance, interaction, inferior product quality)
- substandard or counterfeit products
- drug dependence
- overdose and poisoning
- medical error.

It is now well known that many drug-related problems result from health system failures (procurement and logistics, for example) or irrational prescribing and use and are, therefore, preventable. The cost of such failures to health systems around the world, and the burden on patients, are enormous.[2–4] Pharmacovigilance systems are designed to detect early signs of a wide range of failures, to prevent harm to patients, waste of resources and the repetition of avoidable harm.

Figure 1
Number of member countries in the WHO Programme since the start in 1968

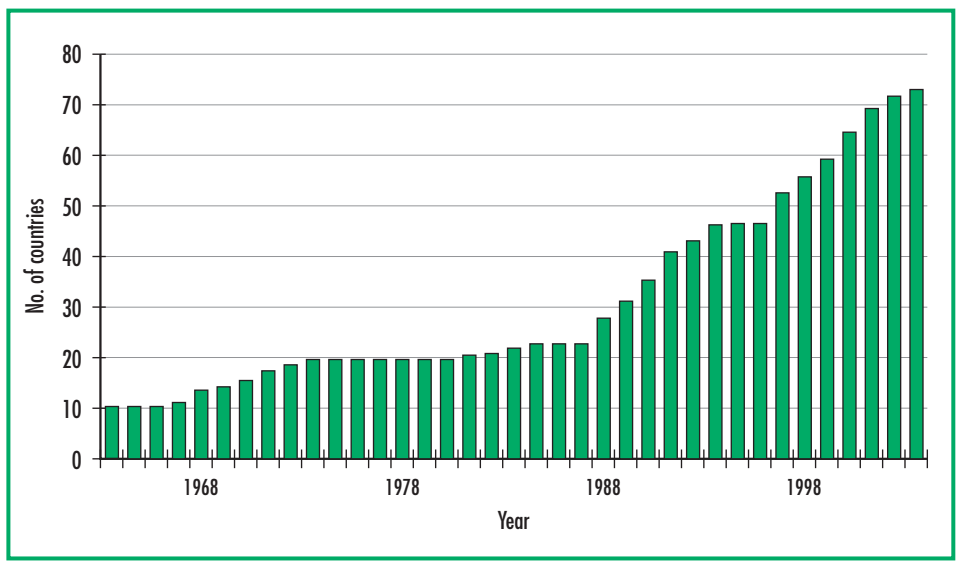

Figure 2
Members and associate members of the WHO Drug Monitoring Programme

The WHO Programme

Over seventy countries, all full members of the WHO International Programme for Drug Monitoring, have pharmacovigilance systems for the collection of ADR data. A further 14 associate member countries are in the process of setting up their systems (see Figures). The Programme is coordinated by PSM's Quality and Safety of Medicines unit at WHO Headquarters, while the operational aspects are managed by *the* Uppsala Monitoring Centre (*the* UMC) whose formal title is the WHO Collaborating Centre for International Drug Monitoring.

Countries send their ADR data to the WHO ADR database, known as Vigibase. This unique resource, managed by *the* UMC, holds more than three million case reports. Around 250,000 new reports are added each year. The primary purpose of the Programme is to detect information about potential new drug hazards, especially those that are unexpected, serious or rare and which have not come to notice previously or are little documented. Signals of such suspected new hazards are then communicated throughout the network of member countries. *The* UMC was the first organization to use data mining and pattern recognition for pharmacovigilance, a leading-edge technology whose results are routinely available for all countries.

The UMC also produces a number of world-standard tools and resources, such as the WHO Drug Dictionary and the WHO Adverse Reaction Terminology, for use in international drug safety activities. Another important role is to maintain a communications network between pharmacovigilance centres throughout the world. Member countries each have a designated national pharmacovigilance centre, responsible for communicating with health care professionals, collecting adverse reaction reports, submitting case reports to the WHO database, and often, a range of other activities.

For up-to-date information please visit the UMC website at www.who-umc.org or the main WHO website at www.who.int and www.who.int/medicines/areas/quality_safety/en for information about quality and safety issues from the Quality and Safety of Medicines (QSM) team in the Department of Medicines Policy and Standards (PSM).

Increased global engagement

Many factors have contributed to a greater interest in pharmacovigilance in emerging countries over the last decade, including the direct influence of the WHO Programme. Some of these are:

- Following the success of essential medicines programmes, medicines are now more widely available and it is recognised that the desired results in terms of improved public health are obtained only if medicines are of good quality and are used rationally
- Epidemiological and other studies have revealed the enormous scale of medicines-related problems in health care [2, 4]
- It is now recognized that, although the majority of medicines-related safety problems are universal, many are unique to the local setting. Each country therefore needs to have in place its own system for detecting and following-up medicine treatment outcomes.

RATIONAL USE

➤ Training courses and guidelines in pharmacovigilance practice have been more readily available and strongly supported.[5, 6] The first international course was organized by *the* UMC in 1993. The ninth UMC course was held in Canberra, Australia, in November, 2004. So far 205 health professionals from 86 countries have participated in these two-week courses. WHO Regional Offices and national authorities have arranged regional and national courses. The four courses arranged in Bolivia, Colombia and Guatemala by the Spanish Medicines Agency 2000 – 2003 are particularly significant for that region.

➤ Drug safety issues have been increasingly recognised by public health programmes (see box).

Special challenges

Countries with less well developed health care systems, where record keeping and documentation are often poor, require methodological innovation. ADR reporting must be extended beyond trained physicians to all health professionals. Widespread self-medication and the use of traditional medicines mean that traditional healers and patients also need to report adverse drug experiences. The mass media need to be involved in creating awareness of drug safety issues. In countries with less well-regulated drug markets, pharmacovigilance has an important part to play in identifying drug-related risk areas that should have priority from a public health perspective. The overall aim is to enter into an active dialogue with all health care providers and the public about their experiences with medicines and about how to use them safely and rationally.

Setting up a centre

Resources needed to set up and run a national pharmacovigilance centre are relatively limited. Political support, professional commitment, basic reference sources, office facilities and means of communication are indispensable however. All come at a cost far below that of the problems they aim to prevent. Particularly in developing countries, is beneficial for pharmacovigilance activities to be associated with other vital functions like drug information and/or poison centres, or located in hospitals or medical schools.

The long-term challenge is to educate health professionals, patients, the media and the general public that

➤ no medicine, including herbal and traditional medicines, is 100% safe for all people in all circumstances

➤ it is everybody's business to be critical prescribers or users

➤ the reporting of suspected drug-related problems will help improve public health and reduce harm to patients and wastage of resources.

We can avoid drug-related problems only when we know that they exist, and their detection is the fundamental purpose of the WHO Programme and of worldwide pharmacovigilance. ❑

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Pharmacovigilance and public health programmes

In recent years new drug therapies have been introduced in the treatment of the major tropical diseases. Since large populations, often with complicating co-morbidity, are exposed to these new medicines, there need to be systems for follow-up of possible adverse consequences.

The antimalaria programmes in sub-Saharan African countries are recent examples of public health initiatives where safety has been seen as a priority.

Because of severe resistance to older medicines, many countries have introduced *artimisinin*-based products as first– or second-line treatment of malaria. These preparations have not been used on a large scale in Africa before. The WHO Roll Back Malaria Programme is now collaborating with the WHO Drug Monitoring Programme in establishing pharmacovigilance systems, particularly for antimalarials, in several African countries. The starting point was a training course in Zambia in 2003.

A similar approach is now followed by providing training for representatives of pharmacovigilance centres and HIV/AIDS programme managers in Africa. A first course was held in South Africa, 1–10 September, 2004.

A further example is the ambitious approach of the Expanded Programme on Immunization to record Adverse Events Following Immunization (AEFI). The WHO Global Training Network on vaccine quality has so far carried out twelve training courses on AEFI. The global programme on eliminating lymphatic filariasis has also increased its efforts in collecting information on adverse effects to the medicines used.

Ways to strengthen Drug and Therapeutics Committees in Thai hospitals


A. Sripairo


K. Harvey

➢ Araya Sripairo, Ken Harvey

At the 2nd International Conference on Improving Use of Medicines (ICIUM) held in Thailand in 2004, a number of papers emphasised the importance of hospital Drug and Therapeutics Committees (DTCs). In addition, a practical guide to DTCs, produced by WHO in collaboration with Management Sciences for Health, was distributed to conference participants. The practical guide (and papers presented at ICIUM) noted that while it was relatively easy to set up DTCs, it was much harder to make them work effectively. This is in line with our experience.

In Thailand, hospitals under the Office of the Permanent Secretary, Ministry of Public Health, were first required to establish DTCs (called Pharmacy and Therapeutics Committees) in 1987. At that time, a Manual of Drug Administration and Management outlined the structure and responsibilities of DTCs. Despite policy and structural change in Thailand's health system, there is no mechanism for updating the manual.

In the light of these events, we explored the functioning of Thai DTCs in 17 hospitals (2 regional, 3 provincial and 12 district). The methodology included document review, in-depth interviews, a questionnaire survey, a focus group, and participant observation. We found that meetings mainly focused on drug selection, and consumption and budget problems, while members usually played only a passive role, and subcommittee reports received little discussion.

A number of barriers that prevented DTCs from functioning better were identified. Because DTC Chairpersons were also Hospital Directors they were very busy; hence the number of DTC meetings was few. The DTC Secretary was also very busy, and preparation and minutes of meetings suffered. There was lack of clarity with respect to the roles and responsibilities of DTC members, which was sometimes compounded by conflict between doctors and pharmacists about drug selection and use. Externally, there was no organization supporting DTC performance, no recent guidelines on DTC activities and no educational programmes to assist DTC members.

To revitalise and extend the functions of Thai DTCs in areas such as rational drug use, we suggest that an updated DTC manual is needed. The WHO/MSH manual *"Drug and Therapeutics Committees: A Practical Guide"* provides an excellent resource in this regard.

Topics that our research have shown to be particularly relevant to an updated Thai manual include:

➤ the list of DTC functions;

➤ structural models of DTCs and their various sub-committees or working groups;

➤ the drug management cycle;

➤ rational drug use activities;

➤ performance indicators;

➤ a yearly plan of DTC activities;

➤ sources of information and organizations to assist DTCs.

There will be a need to translate, shorten and localise these topics to the Thai situation in order to provide a more succinct manual aimed at Thai DTC members.

In addition, the roles of DTCs need to be included in education programmes in the universities and colleges that produce Thai health workers, and a DTC network is also suggested in order to share experiences between Thai DTCs. ❑

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ACCESS


P. Carlevaro

Multidrug resistant-tuberculosis: together we can fight it

The Lilly MDR-TB Partnership

➢ PATRIZIA CARLEVARO

In many areas of the world, tuberculosis (TB) is re-emerging as a serious public health threat. TB hits hardest among the working age population, therefore also contributing to a loss of economic productivity. Multi-drug resistant tuberculosis (MDR-TB) is a virulent, mutated type of TB that is much more difficult to treat. Its spread is often accelerated by HIV infections. Each year there are about 400,000 new cases of MDR-TB, although very few of these are diagnosed and treated.

For the last 50 years Lilly has been producing two of the essential medicines* for treating MDR-TB: cycloserine** and capreomycin***. Until recently the market for these drugs has been small, with no more than 1000–2000 patients receiving this treatment per year. Now, however, with the successful implementation of the WHO DOTS (directly-observed treatment short-course) strategy, the TB community has decided that the time has come to address MDR-TB and develop the DOTS-Plus strategy.

In 2000, Médecins Sans Frontières (MSF) (www.msf.ch) and some other NGOs in the former Soviet Union were facing a surge in MDR-TB, particularly in prisons. This posed a serious threat, due to an increased risk of transmission in closed areas and the spread of infection into the community when prisoners were released. Because of these serious challenges, Lilly became more engaged in the development of second-line TB drug supplies for poor countries. During the same year, Lilly agreed to provide cycloserine and capreomycin at subsidised prices, if WHO, MSF and other key partners could ensure that the medicines were properly used.

With this in mind, the Green Light Committee (GLC) was born. WHO successfully gathered all the key MDR-TB players and developed a structure whereby countries could submit project proposals to the Committee. If they met certain criteria, they could purchase Lilly medicines and all other second-line drugs via the MSF procurement process at a special highly discounted price. From a few projects in 2000, the GLC has now reached an approval level of more than 30 projects covering more than 7,000 patients and is expected to reach about 20,000 patients by the end of 2006.

This was just the beginning of Lilly's commitment to tackling MDR-TB. Cycloserine and capreomycin are difficult products to manufacture because of complex chemical synthesis or fermentation and freeze-drying processes. Due to these technical complexities, this small market had been unable to attract generic producers – despite the fact that there were no patents on these drugs. Lilly decided to proactively embark on a major initiative that was launched in June 2003. This US$70 million MDR-TB initiative is a first of its kind partnership, which brings together committed NGOs, academia, international organizations and the pharmaceutical industry (http://www.lillymdr-tb.com/).

Covering prevention, treatment and care of MDR-TB patients, and transfer of manufacturing technology to developing countries, this programme can be considered a model one. The components of the Lilly MDR-TB partnership are outlined below. Apart from the transfer of technology, all the activities are implemented directly by partners.

Transfer of technology

The unique aspect of this component is that Lilly is transferring the manufacturing know-how to produce the active ingredients and finished dosage forms of its two off-patent drugs, critical to treating MDR-TB. Lilly has established a partnership with state-of-the-art companies in China (Hisun) and India (Shasun) to produce these drugs at international standards, by the end of 2005. The active pharmaceutical ingredients (API) will be transferred to the Lilly partner in South Africa (Aspen), where the two medicines will be converted into final form, consistent with international manufacturing and quality standards. This will result in 250 mg capsules of cycloserine and 1-gram vials of capreomycin being available for the treatment of MDR-TB.

In addition to capital investment in the plants, Lilly has committed up to 10 full-time staff over a period of four years to assist and train local staff, and to ensure long-term success of the manufacturing partnership. These partners were chosen because they have the manufacturing skills, and especially because they were fully supportive of participating in this public health battle by committing to limit their profits. Considering the high prevalence of MDR-TB in the former socialist countries, Lilly is currently actively pursuing opportunities to convert facilities in Russia for the production of these drugs as well.

Training staff in manufacturing and good business practices

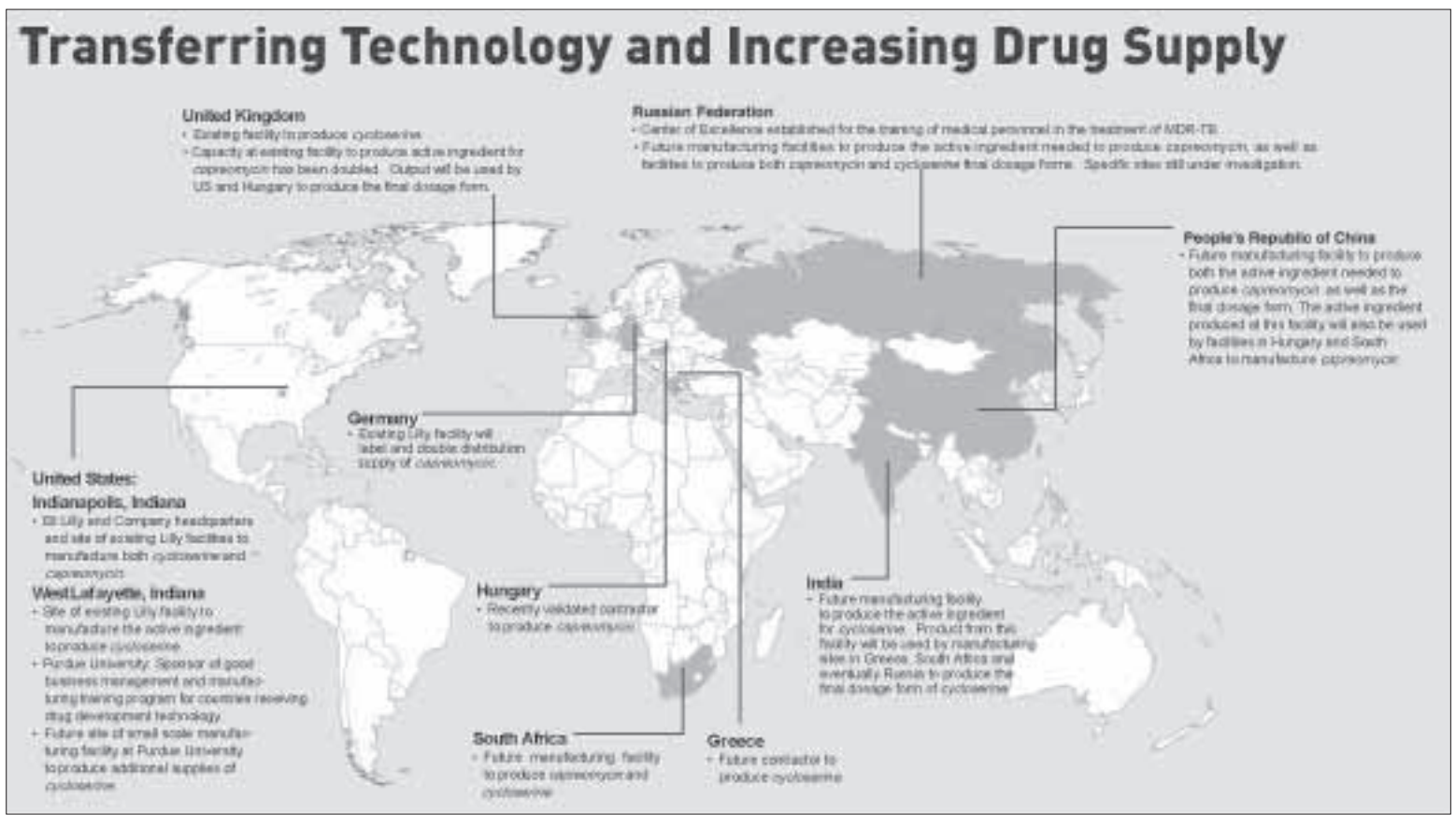
One of the concerns of the Lilly MDR-TB partnership is to ensure the sustainability of the local production and to nurture a class of skilled and committed staff. Thanks to a long-standing relationship, Purdue University, located close to Lilly Headquarters in the USA, (http://www.purdue.edu/) has agreed to develop training courses in Good Manufacturing Practices (GMPs) and sound business management for each of the partner facilities. Lilly expects that the contribution will prosper well beyond the production of these two drugs. By strengthening local skills, Lilly aims to facilitate the quality production of other needed drugs and create a viable South-to-South business.

Increasing our drug supplies to GLC approved projects

The availability of cycloserine and capreomycin has always been a challenge, due to manufacturing complexity. Lilly has invested in its UK plant to increase capreomycin production and has renewed and doubled, for an additional two years, its commitment to supply WHO/GLC approved projects. Countries must apply to the GLC in order to obtain cycloserine and capreomycin at the subsidised price of US$0.13 per capsule of cycloserine and US$0.98 per vial of capreomycin. Lilly delivers the products to the procurement agent in the Netherlands, the International Dispensary Association, which in turn distributes the product to GLC-approved projects.

Training health professionals in TB prevention and management

Lilly has linked with Partners in Health (PIH) and Brigham and Women's Hospital, Boston, USA, (www.pih.org) to create a centre of excellence for training health care workers in selected Russian oblasts (regions). PIH is one of the pioneer NGOs working in MDR-TB. Its pilot project in Peru has given hope to many other countries that MDR-TB can be



ACCESS

contained and treated. PIH is also a co-founder of the GLC. Core activities are centred in Tomsk, Siberia. Doctors from several regions participate in the training provided by PIH, and it is now an officially certified government course. The centre was developed in Tomsk as a result of the many years of PIH experience in clinical activities supported by the Open Society Foundation.

Based on my experience when working at UNICEF, I was very aware of the key role of nurses and assistant nurses in the delivery of health care. Sad to say that often they were not fully appreciated as key contributors to health care. Having spoken with the Geneva-based International Council of Nurses (ICN) (www.icn.ch) and explored their interest in engaging nurses in fighting MDR-TB, I found them very enthusiastic. In 2004 ICN launched the Nurses' Pocket Guide for TB and MDR-TB and will deliver training courses in several parts of the world; they will also advocate including TB and MDR-TB modules in nursing school curricula. The first training of trainers course has been completed in South Africa and another will soon be carried out in the Philippines. ICN – with more than 12 million nurses around the world – will play a pivotal role in the delivery of TB and HIV/AIDS services.

Recently we have established partnerships with The World Medical Association and the International Hospital Federation to develop similar tools for physicians and hospital managers. This is to ensure that professional working in the private sector also receive training in line with DOTS and DOTS Plus policies.

Community support to MDR-TB

The International Federation of Red Cross and Crescent Societies (www.ifrc.org) has a long tradition of working with vulnerable groups in poor countries. Volunteers will provide psychological and home support to MDR-TB patients to ensure better access to care and to improve compliance. In addition, educational programmes have been developed to improve community awareness of preventive measures and to reduce stigma. The model is being piloted in Kazakhstan and will be replicated in other regions.

Support for setting up surveillance systems and an MDR-TB database

One of the key problems in treating MDR-TB is poor or a lack of clinical laboratory and drug susceptibility data. Despite the recent establishment of the DOTS-Plus strategy there is a lack of resources for these tasks. Lilly has provided a grant to the US Centers for Disease Control (CDC) Foundation (www.cdc.gov) to develop a model surveillance database which is undergoing testing in Russia in a number of MDR-TB projects. The purpose of this surveillance database, according to WHO and CDC is to develop model surveillance software that can be applied to other countries.

Support for technical assistance to GLC projects in developing countries

Although the progress made by the first pilot projects was spectacular and cure rates were over 70%, to ensure correct delivery of MDR-TB therapy, more support is needed to allow WHO and the GLC staff to share their know-how with developing countries. In fact, reductions in the price of second-line TB drugs, the validation of second-line regimens and the additional resources now available through the Global Fund have generated more requests to the GLC for technical support in project planning, implementation and monitoring. Lilly provides funds to WHO to ensure that countries in need can receive such technical support. (http://www.who.int/gtb/policyrd/DOTSplus.htm).

Increasing workplace awareness of TB and MDR-TB

The business community can play a pivotal role in increasing TB and MDR-TB detection, early diagnosis and treatment. In partnership with The World Economic Forum (www.weforum.org), awareness and educational tools are in development to help employees better understand prevention components and to reduce stigma. Workplace health care staff will also be trained on treatment options based on national protocols. The various tools will be tested, first in India, and then adapted for business communities in high burden TB countries.

Lessons learned

Although the partnership is in its infancy, we can begin to assess what we at Lilly have learned. First, we have been fortunate to partner with the right "mates". From the beginning Lilly could focus on the transfer of technology component, allowing its competent partners to deliver the TB health care services. Partners share information and identify synergies in their implementation phases. We still need to improve overall supply planning. DOTS-Plus is complex to implement. The MDR-TB therapy is long, complicated by the combination of different drugs and by individualised protocols. This increases the difficulties in forecasting local needs, developing an adequate procurement plan and consistently delivering supplies. There is a need to strengthen market analysis to engage more reliable suppliers and distributors in this field.

We are very proud that the GLC has created more awareness of MDR-TB and an environment to successfully treat and save lives. The GLC reputation is such that now all MDR-TB projects supported by the Global Fund will be cleared by the GLC in order to receive their grant. We know that everyone can make a difference in the fight against TB. We hope that the decoding of the TB genome and other mycobacterium genomes will bring new and easier solutions.

Meanwhile, we need to work together to ensure that aid to TB continues to grow and that developed countries will stick to their promises. The estimated need for addressing TB in the 22 high burden countries is over one billion US dollars. The funding gap is still large but more and more resources are being devoted to this deadly disease. It is important that donors, while investing in TB control, as in other key diseases, allocate seed money for technical assistance and for strengthening the health care system overall. This is crucial if we want to meet the Millennium Development Goals for TB. ❑

* Reserve anti-tuberculosis drugs: amikacin, capreomycin, ciprofloxacin, ethionamide, kanamycin, ofloxacin, p-aminosalicylic acid, protionamide. (Treatment of Tuberculosis. Guidelines for National Programmes, WHO/CDS/TB 2003.313).
** Seromycin™.
*** Capasatat™.

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Access to insulin in developing countries

➢ DAVID BERAN ON BEHALF OF THE INTERNATIONAL INSULIN FOUNDATION

THE problems faced by people with Type 1 diabetes are a perfect example of the problem of access to medicines. In many poor countries, an effective treatment that has been available in the developed world for almost 80 years still fails to reach those who need it in the developing world. This is because of problems with the distribution, planning and cost of required medicines and medical supplies.

Leonard Thompson, a Canadian teenager, was the first person to receive insulin, in January 1922. Insulin is the only known treatment for Type 1 diabetes, a disease that as yet has no cure. Type 1 diabetes, also referred to as Insulin Dependent Diabetes Mellitus or IDDM, is caused by an autoimmune process that destroys insulin-producing cells in the pancreas. Diabetes is a chronic condition that affects people of all ages in all areas of the world. Improper care can lead to serious health complications and in some cases death.

Over 80 years after the discovery of insulin, access to insulin is still problematic in many parts of the developing world. To address this issue the International Insulin Foundation (IIF) was established in 2002 by leading academics and physicians in the field of diabetes. The IIF is a nongovernmental organization established to improve sustainable, affordable and uninterrupted supply of quality insulin in areas of need for people with Type 1 diabetes. The IIF's view is that increasing the supply of insulin, through donations or other means, offers only temporary relief and that the roots of the problems need to be identified and tackled.

In order to achieve this aim, a clear, locality-specific, analysis of the constraints to insulin access and diabetes care is needed. This led the IIF to develop the Rapid Assessment Protocol for Insulin Access (RAPIA). It was developed based on the principles of Rapid Assessment Protocols (RAP), which have been used in assessing infectious diseases, drug abuse and nutrition, for the purpose of applying preventive and therapeutic interventions.

The RAPIA is structured as a multi-level assessment of different elements that influence the access to insulin and care for people with diabetes in a given country. It is divided into three components and 15 specific questionnaires:

- ***Macro*** – ministries of health, trade and finance, private sector, national diabetes association, central medical store and educators
- ***Meso*** – provincial health officers, hospitals, clinics, health centres, etc., pharmacies and drug dispensaries
- ***Micro*** – carers (health care workers and traditional healers) and people with diabetes.

The aim of each questionnaire is to get the interviewee's perspective on the barriers that a person with Type 1 diabetes faces obtaining insulin and proper care.

...cont'd on page 28

ACCESS

Access to insulin... cont'd from pg. 27

The RAPIA provides information in the following categories:

- Health service structure and functioning with regards to procurement of medicines and diabetes management
- Diabetes policies written and enacted
- Reported and observed practice for Type 1 diabetes management
- Availability of insulin, syringes and monitoring equipment
- Existence of distribution networks for insulin
- Insulin supply-related knowledge and attitudes amongst people with diabetes and their carers
- Other problems that hamper the access to proper insulin and care.

Field experience

In collaboration with the respective Diabetes Associations and Ministries of Health the RAPIA was piloted in Mozambique, thanks to a grant from the World Diabetes Foundation. It was also implemented in Zambia, with the financial support of WHO, the Diabetes Foundation and the Barnett & Sylvia Shine No 2 Charitable Trust (UK-based charities). Local teams of interviewers were trained to work in three distinct economic and geographic areas of the country.

Findings in Mozambique and Zambia

Different purchasing policies at the central level lead to different prices paid by these two countries for their insulin. Mozambique purchases insulin by international tender at US$4.50 (€3.95) per 10ml vial of 100IU insulin compared to US$4.62 (€4.07) in Zambia. Zambia also purchases through national tender at US$8.00 (€7.02) and US$10.05 (€8.82) per vial.

Policies exist in both Mozambique and Zambia by which care for chronic conditions is subsidised in part or in full. However, in practice, patients have to pay for their insulin, either because this policy is not applied or there is a lack of insulin at public facilities. In Mozambique the average price, for a patient, per vial was US$1.60 (€1.40) in the public sector compared to US$10.20 (€9.00) in the private sector. Prices for insulin in Zambia were slightly higher with a vial costing US$2.00 (€1.80) in the public sector and US$12.80 (€11.20) in the private sector. In both countries some 40–50% of patients are estimated to get at least half of their insulin supplies through the private sector – which can consume up to one third of a family's income.

Insulin alone is not enough. Syringes and needles are needed for its delivery. In both countries syringes were in short supply and prices varied considerably between the public and private sector. In Mozambique patients were able to obtain syringes at public pharmacies at US$0.04 (€0.04) each, but as was often the case, when these were out-of-stock they had to pay as much as five times this price in private pharmacies.

In parallel to the need for insulin and syringes, patients with Type 1 diabetes need constant monitoring of their blood sugar. Testing facilities are therefore needed for patients, as personal testing equipment is too expensive for most. These facilities need supplies of testing strips and other reagents to help diagnose patients and also for continued monitoring.

The work carried out by the IIF showed that the main problem of the drug supply system was the consequence of problems in quantifying needs at both the central and peripheral areas. As the number of patients with Type 1 diabetes is not known, supplies are ordered based on a mix of estimates, past consumption trends and past orders. This leads both to surpluses and to shortages, and also to erratic distribution of insulin throughout the country. For example, in Mozambique 77% of the total insulin ordered was used in the capital city, Maputo, a city which accounts for only 11% of the population. In the end these problems impact patients in the most peripheral and poorest areas of a country.

RAPIA – the larger implications

The RAPIA, besides enabling the IIF to collect the data presented above, has raised awareness about the challenges that people with Type 1 diabetes face in two developing countries. It has acted as a catalyst around the issues of management of diabetes and other chronic conditions. It has shown that health care delivery for these conditions – be they Type 1 diabetes or HIV/AIDS or tuberculosis, are complex issues that can be successfully managed and treated in poor country settings. A comprehensive and functioning health care system is necessary, as well as supply of drugs and monitoring facilities. These components of a comprehensive infrastructure might enable people with Type 1 diabetes to enjoy a full and healthy life. ❑

David Beran is the Project Coordinator for the International Insulin Foundation. For more information visit: http://www.access2insulin.org

NEWSDESK

WHO/UNICEF Technical Briefing Seminar: increasing understanding of the pharmaceutical sector in developing countries

THE ninth Technical Briefing Seminar for International Staff Active in Pharmaceutical Support Programmes was held at WHO in Geneva from 19–23 September 2005, and was once again very well received. This annual event is organized jointly by the Department of Medicines Policy and Standards (PSM) and the Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM), in collaboration with UNICEF Supply Division, Copenhagen.

Over five challenging days of presentations and discussions, the 28 participants from 23 countries were exposed to a wide range of information, providing an overview of current technical issues. Sessions covered developing national drug policies, selection of essential medicines, access to medicines and the impact of globalization and trade agreements. Other presentations dealt with drug regulation and quality assurance, procurement and supply systems, promoting rational use of medicines, and coordination between international agencies. The programme also included updates on the Global Fund, the UN Prequalification Project and the 2005 Meeting of the Expert Committee on the Selection and Use of Essential Medicines.

Regional perspectives

Sessions were led by senior staff members of the WHO Medicines Departments and UNICEF staff. This year's seminar was greatly enhanced by joint facilitation by Richard Laing (PSM), Zafar Mirza (Regional Adviser, WHO Regional Office for the Eastern Mediterranean and Jean-Marie Trapsida (Regional Adviser, WHO Regional Office for Africa. The interventions and regional perspectives provided were greatly appreciated by the participants.

The seminar is intended for technical advisers and field staff of WHO, and of other UN and bilateral agencies, and governmental and nongovernmental organizations active in pharmaceutical and health sector support programmes in developing countries. It is also open to medicines experts working in the public sector, academic institutions and civil society organizations. The seminar has become increasingly popular, and although participants have to pay their own travel and accommodation expenses it was once again oversubscribed.

The content of the seminar has evolved based on participant feedback and developments within the pharmaceutical sector. Course evaluation is taken very seriously and every day participants evaluated sessions on relevance and quality of presentation on a scales of 1–5 and were also asked to provide comments. The session on rational use of medicines proved the most popular with participants, and has consistently received high ratings in recent years.

At the end of the seminar, an 'image' of the specially created seminar web site (including the PowerPoint presentations, key readings, etc.) was burnt on CD-ROM and copies were provided to all participants. Planning for the 2006 seminar has already begun. ❑

Further information is available at: http://mednet2.who.int/tbs/

NEWSDESK

Restructuring of WHO's medicines departments in Geneva

WHO carries out its work in the area of medicines at global, regional and country levels. At WHO HQ 2005 brought changes that mean activities are now planned and implemented by two new departments. The Department of Essential Drugs and Medicines Policy was restructured to create the Department of Medicines Policy and Standards (PSM) and the Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM). Hans Hogerzeil was appointed Director of the former and Malebona Matsoso (see box) Director, and Germán Velásquez Associate Director of the latter. ❑


H. Hogerzeil


G. Velásquez

A new face at WHO HQ


M. Matsoso

Malebona Matsoso is known to many in the medicines world as a staunch supporter of access and a strong developing country voice. She has just taken the helm of a newly created medicines department of WHO Technical Cooperation for Essential Drugs and Traditional Medicine. "Our work will concentrate on countries and what they need to move forward, particularly on access", she explained when asked how she saw her new job at WHO. "Of course you need policy work, and you need some parameters, but ultimately impact can only be measured by how successful those policies have been for countries and their people."

Before taking up her post at WHO in March 2005, Ms Matsoso was the Registrar of Medicines at the Medicines Control Council in South Africa and for eight years served as a senior official in the South African Government. She also served as Secretariat of the Southern African Development Community (SADC) harmonization initiative and coordinated all medicines registration-related activities for the region.

Ms Matsoso has been in the forefront of drug policy development and implementation in South Africa for a long time. She has worked in both the public and private sectors as a pharmacist and is a member of various advisory panels in South Africa and internationally to improve access to antiretrovirals.

WHO Health Technology and Pharmaceuticals Newsletter, Jan.–May 2005.

14th WHO Model List of Essential Medicines published

THE WHO Expert Committee on the Selection and Use of Essential Medicines met in Geneva from 7 – 11 March 2005, with members noting the careful and timely presentation of evidence-based applications for addition, deletion or changes to the Model List. Early posting of most documents on the web site together with the rounds of review and comments prior to the meeting ensured the transparency of the process. In addition, an open session was held to allow all stakeholders to comment on issues relating to the Model List.

Significance for public health policies

The on-going review of the core and complementary lists, the use of the "square box" symbol (primarily intended to indicate similar clinical performance within a pharmacological class), and planned reviews of specific sections continue to make the Model List more consistent in its advice. The deletion of many obsolete items and the addition of more relevant ones have increased the practical value of the Model List as a public health tool.

Those medicines with similar clinical performance within a pharmacological class are identified and listed in the web-based WHO Medicines Library, which now incorporates the Model List, the WHO Model Formulary, references to most clinical guidelines developed by WHO, and links to price information, nomenclature and information on quality and standards.

WHO has published the Expert Committee's report (details below), with the first part containing a summary of the Committee's considerations and justifications for additions and changes to the Model List, including its recommendations. This section also gives updates on the Priority Medicines Project and current activities in the field of rational use. There are also progress reports on the review of essential medicines for reproductive health and of the New Emergency Health Kit. Annexes to the main report include the revised version of the WHO Model List of Essential Medicines and a list of all these items according to their 5-level Anatomical Therapeutic Chemical (ATC) classification codes.

The Selection and Use of Essential Medicines. Report of the WHO Expert Committee 2005 (including the 14th Model List of Essential Medicines). WHO Technical Report Series No.933. Price: Sw.fr.25/US$22.50, and in developing countries Sw.fr.17.50. Contact: World Health Organization, Marketing and Dissemination, 1211 Geneva 27, Switzerland, e-mail bookorders @who.int

A new technical report on pharmaceutical preparations

This report presents the recommendations of an international group of experts convened by WHO to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities and pharmaceutical manufacturers, this report discusses the monographs on antiretrovirals proposed for inclusion in *The International Pharmacopoeia.* It also covers specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials. Good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues are dealt with.

The report is complemented by a number of annexes. These include an amendment to GMP: main principles regarding the requirement for the sampling of starting materials, guidelines on GMP regarding water for pharmaceutical use, guidelines on the sampling of pharmaceutical products and related materials, and draft guidelines for registration of fixed-dose combination medicinal products. ❑

WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-ninth Report, WHO Technical Report Series, No. 929. Price: Sw.fr.25/US$22.50, and in developing countries Sw.fr.17.50. Contact: World Health Organization, Marketing and Dissemination, 1211 Geneva 27, Switzerland, e-mail bookorders@who.int

Medicinal plants in tropical countries

ACCORDING to WHO estimates, 80% of the world's population rely primarily on traditional methods of healing, which use empirical knowledge based on the use of medicinal plants. In many rural areas of developing countries there are no alternatives to these traditional methods, as neither the financial means nor the necessary infrastructure are in place to allow the use of imported pharmaceuticals.

Pharmaceutical and pharmacological studies of many of the commonly used plants have already been done. There are, however, insufficient data available regarding the efficacy and side-effects of using medicinal plants to treat disease, according to the criteria of evidence-based medicine. The result is that many medical practitioners who have been trained in modern medicine mistrust the widespread use of traditional plant remedies in rural areas in developing countries.

The authors, Markus Mueller and Ernst Mechler, have undertaken a study and written the monographs contained in *Medicinal Plants in Tropical Countries* to overcome this contradiction – common usage on the one hand and lack of knowledge on the other. They present information and critical analysis of 25 important medicinal plants, chosen from an initial list of 4776 medicinal plants which are predominantly used in Africa. Fifty-four of these plants were described in ethno-pharmacological reports from five or more African countries, and from this list 25 of the most frequently reported plants were chosen for this collection. The monographs present a summary of the often contradictory information on the use of medicinal plants in traditional medicine in a way that is helpful, in the first instance, to doctors, pharmacists and other health practitioners. ❑

The book is only available for health workers etc. in African countries and can only be ordered there. The cost of the book is US$2 plus postage. Please contact: Legacy Bookshop Nairobi (info@legacybooks.com), MEDS Nairobi (sahibu@africaonline.co.ke), JMS Kampala (store@jms.co.ug) or German Institute for Medical Mission in Tübingen, Germany (petersen.amh@difaem.de).

MEDICINE PRICES

9 countries from the WHO African Region meet to analyse data from their price surveys

THIRTY-FOUR participants from the Ministries of Health, WHO and civil society of nine African countries met for three days in Pretoria, South Africa, at the end of January 2005 to review and analyse more than twenty-six thousand pieces of price information collected as part of medicines prices surveys carried out between April and December 2004 in the nine countries. All the surveys were carried out using the WHO and Health Action International methodology: *Medicines Prices: a new approach to measurement.*

The countries involved are Ethiopia, Ghana, Kenya, Mozambique, Nigeria, South Africa, Tanzania, Uganda and Zimbabwe, and the meeting was organized as part of the WHO/Health Action International, Regional Collaboration for Action on Essential Medicines in Africa. A variety of sectors were surveyed in the nine countries including public facilities, private pharmacies, dispensing doctors and private clinics/ hospitals.

The Honourable Minister of Health of the Republic of South Africa, Dr M. E. Tshabalala-Msimang welcomed participants, emphasising the importance of medicine prices surveys to provide evidence on the extent to which prices are one of the important barriers to access to medicines. She stressed the need to intensify country support to make essential medicines more affordable and accessible to contribute to the improvement of the health status of the African population.

Preliminary results were presented during the workshop. Participants further cleaned their data and determined how to best analyse, present, interpret results and to present and make evidence-based policy recommendations in an effective way to stakeholders and policy makers. It was apparent that reliable data and evidence on medicine prices are the first steps to identifying strategies and policies to lower the widely varying and unaffordable medicine prices observed in many African countries and to highlight some of the contributing factors.

Strategic approaches in making medicine prices more affordable were discussed; these included improving availability and appropriate use of generic medicines, providing reliable price information, the need for continuous monitoring of procurement and retail prices, improving efficiency of supply and distribution systems, regulating mark-ups and removing import taxes and levies on essential medicines.

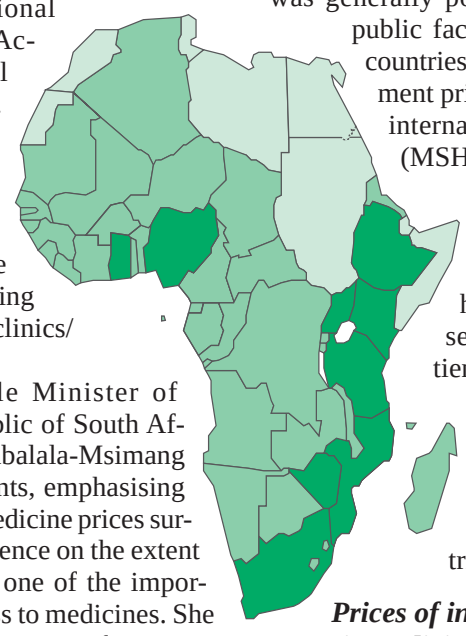
After this meeting, countries returned home to further clean their data and finalise national reports with evidence-based policy recommendations which would then be shared with stakeholders for comment. All countries are also planning how to disseminate the findings and how the various partners can contribute to advocacy work to achieve the recommended change, including policy changes.

Findings from the preliminary data and issues identified by the countries

Some of the findings from analysis of the preliminary data from eight of the countries were:

Public sector procurement prices

Good prices were obtained overall in public sector procurement; however there was generally poor availability in the public facilities. Five of the six countries reported their procurement prices being less than the international reference price (MSH 2003).



Private sector prices

Medicine prices were considerably higher in the private sector. The median patient prices for the lowest price generic were double at dispensing doctors compared to private pharmacies in 2 countries.

Prices of innovator and generic medicines

Prices of innovator brands are considerably higher than the prices of their lowest priced generic equivalents. In private pharmacies, innovator brand medicines were found to be on average 400% more expensive than their lowest price generic equivalent for a basket of medicines; however this varied from around 200% to almost 700% between countries (n=8). The level of implementation of practices of generic prescribing and dispensing therefore has a major impact on the proportion of income that patients have to pay for their prescription or medicines.

Variations in prices within and between countries

There is a lack of consistency in the pricing of medicines within countries: large price variations for the same brand or generic entity within and between sectors; in some countries, there were significant variations in medicine price between public sector facilities. In one country prices varied, on average, by 300% for the same innovator brand or generic entity within the same sector – for quite a number items this variation was greater than 1000%.

There are large variations in prices between countries for the same medicine; the price of innovator brand medicines varied on average by 220% between countries, and for the available lowest price generic, by 217% (n=8).

Affordability

Medicines were generally unaffordable for a large proportion of the population – particularly for chronic diseases. Figure 1 illustrates the affordability of medicines for a family across the 8 countries; within the family, there is an asthmatic child with a respiratory infection, an adult with diabetes and an adult with a peptic ulcer.

In county "C", a lowest paid government worker would need to work 107 days or 17.3 days for innovator and generic medicines respectively to pay for a month's treatment and the course of antibiotics. With 7 out of the 8 countries, it would take (almost) 5 days or more salary to pay for the medicines. It should be noted that many family's incomes are lower than that of the lowest paid government worker and hence these medicines are probably unaffordable to the majority of the population in most if not all of the countries.

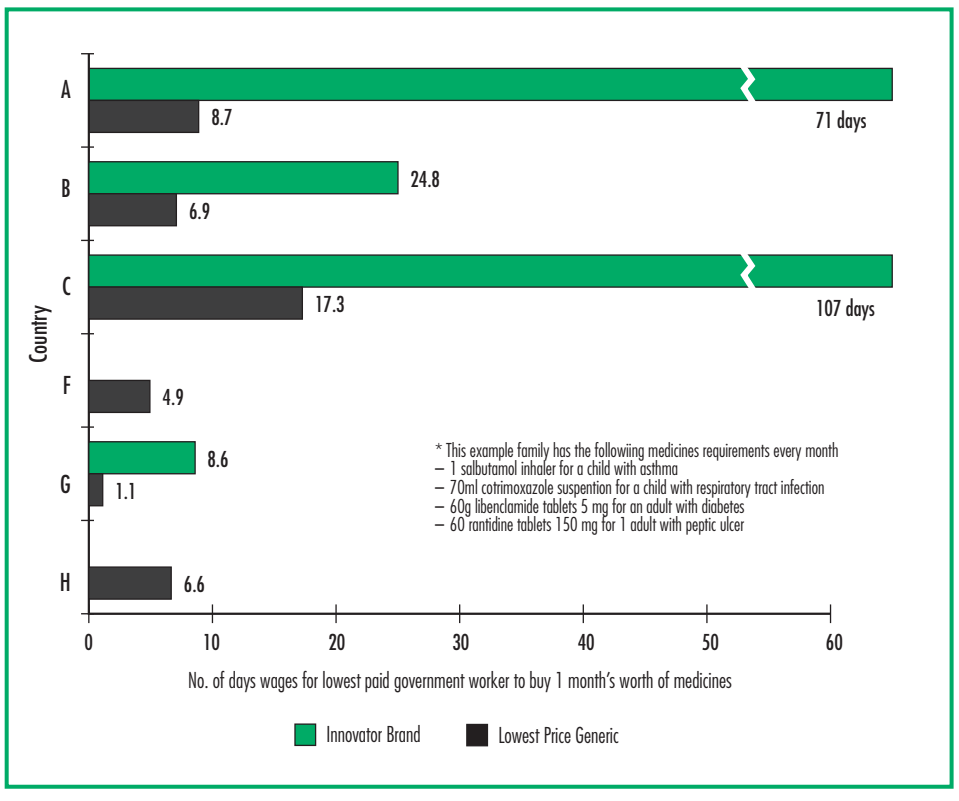
The out-of-pocket affordability of malaria treatments is of critical importance in malaria-endemic countries. The affordability of a course of sulphadoxine-pyrimethamine tablets was found to be as little as 0.1 days and as much as 1.3 days salary for the lowest paid government worker depending upon whether the innovator or generic medicine was prescribed, dispensed and purchased. The variation between countries in affordability was 820% for innovator brand and 1400% for the available lowest priced generic.

Preliminary recommendations identified by the countries

The following preliminary meeting recommendations began to be formulated from the initial analysis of the results:

- Countries need to have a policy on the pricing of medicines which contains elements of ensuring price transparency, price control and enforcement.
- Price transparency through ongoing monitoring and publication of pricing and availability information are important tools to reduce price variations for the same entity, as well as to monitor the effects of any interventions.
- Sharing of price information between countries is an important tool to influence policy change within a country as well as to be able to negotiate better prices – especially within economic sub-regions.
- Increase consumer awareness and acceptance of good quality generic equivalents.
- Legislate for generic substitution and promote and provide incentives for generic prescribing and dispensing in all sectors; stimulate and promote local production of generic medicines.
- Public sector to focus on initiatives to improve availability including better quantification and demand-driven supply systems.
- Removal of all taxes and tariffs including VAT on medicines, especially essential medicines. ❑

Figure 1
Affordability of medicines for a family for a month: illustrative example



MEDICINE PRICES

Conducting a medicine pricing survey: experience and challenges


Z. Baber


M. Ibrahim

➢ Zaheer Ud-din Baber, Mohamed Izham Mohamed Ibrahim

The issue of medicine pricing has always been of great concern for developed and developing countries due to the high costs incurred in pharmaceutical care. Generally, pricing surveys involve many key players including pharmaceutical industry, government agencies, the private health care system and pharmacists. Although various stakeholders recognise the medicine price issue, very few want to reveal the true situation and address it in a systematic manner. However, WHO and Health Action International (HAI) have undertaken the commendable task of developing a simple and robust methodology which has addressed some earlier flaws in pricing surveys.[1]

Learning about drug prices

Systematic work on drug pricing issues in Malaysia is scanty. A pilot pricing survey was conducted on a few drugs using the WHO/HAI methodology. This informal attempt to obtain some baseline price data resulted in the discovery of remarkable differences in the prices of some drugs when compared with Management Sciences for Health reference prices.[2]

The survey was an ongoing project and more drug prices were surveyed. The preliminary data were presented in a WHO/HAI conference on medicine prices in 2004 in Bangkok.[3] The workshop was useful and informative, adding greatly to participants' knowledge. Those attending were encouraged to submit their research proposals for the survey in their respective countries. We were not very sure how we could conduct a well-planned and systematic survey. But we were motivated and seriously started thinking of putting theory into practice.

Undertaking such a survey is beyond the scope of an individual, and requires the commitment of a group of people. We started contacting people-consumer associations, academics, pharmacists, pharmacy and medical associations and NGOs to contribute in one way or another. Initially the response was not very positive. The negative response may have been due to the fact that the survey was not seen as a priority. It took a long time to persuade the various stakeholders to play their part in conducting a successful survey, which could have implications for policy change.

In the meantime, a proposal was submitted to WHO/HAI, and after minor revisions was accepted. The project was now supported and endorsed by WHO/HAI. Our institution assisted in setting up a secretariat for the survey, with an associate survey manager appointed who is responsible for the planning and organization of the survey. Now our efforts were proving successful, with the necessary individuals and organizations consenting to take part. We have principal and co-investigators, a survey manager, and the back up of an advisory group of academics, doctors, pharmacists, representative of NGOs and an economist.

Recently the first meeting of the advisory group was held for discussion and planning, and the training sessions for data collectors were held, using the WHO/HAI training manual. We have also identified the facilities from which data will be collected, and now we are moving forward on data collection.

Lessons learnt

The lessons learnt during this process were interesting and may be helpful for those who want to start a survey. To conduct a medicine pricing survey is not an easy task and it requires a great deal of time, effort and commitment. It also requires good administrative, investigative and analytical abilities with excellent networking skills. Project leaders can pave the way by forming an advisory group of like-minded people working on medicine access issues. The formation of such a group is challenging, and to integrate and convince various stakeholders and involve them in mainstream work is a difficult task.

Ministries of health in respective countries have their own way of working and this has implications for survey findings. NGOs working on access issues have their own interests, i.e., some on consumer issues, others focusing their work on patents. The pharmaceutical industry and others in the business community are very sceptical about these surveys and think of the potential adverse effects they may have on business. Medical and pharmacy associations usually safeguard the interests of their own community so making an independent survey difficult. Merely an endorsement from WHO may not be enough to convince stakeholders to cooperate. A dialogue between ministries of health, consumer groups, HAI and WHO is required. Effective lobbying will make the task of the survey manager much easier.

The survey methodology is very systematic, and takes time and effort to learn. Investigators must make an effort to explain to all the stakeholders what the survey involves. What is written in the medicine pricing manual seems very clear but putting it into practice is a really challenging task.

The involvement and background of the principal investigator also matters. A principal investigator must be well versed on the pharmaceutical pricing situation and have first hand knowledge of the field. However, we believe a medicine pricing survey may be a worthwhile and comparatively minor effort if the price situation is clearly understood, and can lead to the formulation of a pricing policy. The policy can then have a positive influence on the health expenditure in developing countries. ❑

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1. Medicine prices: a new approach to measurement. Geneva: World Health Organization; 2003. WHO/EDM/PAR/2003.2.

2. Baber Z, Ibrahim M Izham M, Affordability of medicines in Malaysia-consumer perception's, Essential Drug Monitor, No 33, Geneva: World Health Organization; 2003.

3. Baber Z. A preliminary analysis of Malaysian drug pricing scenario. Paper presented at WHO/HAI workshop on drug pricing, Chulalongkorn University, Bangkok, Thailand. April 5–7, 2004.

Editor's comment

The article above discusses planning a medicine price survey in Malaysia, but the team has since conducted their survey and produced a very comprehensive report, looking at price, availability, affordability and price components. The survey covered the public sector and two areas of the private sector (private pharmacies and dispensing doctors).

Among the main findings were:

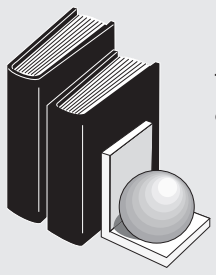
- Public sector prices were reasonable (generally 2.4 times the reference prices for innovator brands, and for different generics between 1.56 and 1.09 times the reference prices.
- Private sector prices: in both the private pharmacies and the dispensing doctors the innovator brands were 15–16 times reference prices and the generics were about 6.5 to 7.5 times reference prices.
- Availability of the surveyed products was generally fairly low, though it appeared that dispensing doctors were more likely to have generics available.
- Affordability was a problem, with many people having to pay the equivalent of 2–7 days' wages for a course of therapy.

Some key findings concerned the price components of atenolol, omeprazole and losartan. What they show is that for public procurement the base price (manufacturers' sale price and CIF (cargo insurance, freight)) components amount to between 69 and 81% with the total mark ups ranging from 26 to 46% for atenolol.

For the private pharmacies the base price only amounts to between 40 and 56% of the final price with mark ups amounting to 150% for generic and 80% for innovator atenolol. The situation in the dispensing doctor sector is even more striking, with the base price of generic atenolol being only 30%, and 43% for the innovator brand, of the total price. The combined mark ups are 234% for the generic and 129% for the innovator brand. The final price of the generic version is still less than the innovator brand but the profit margin is substantial.

The study shows that in an unregulated market such as Malaysia, the mark up on generics is much greater than for the innovator brands and that the final cost paid by the consumer may be two or three times the base price. In these circumstances reducing the base price without controlling mark ups may only increase the profits for the wholesalers, retailers and particularly the dispensing doctors.

PUBLISHED LATELY



Important

The Department of Medicines Policy and standards cannot supply the publications reviewed on these pages unless stated otherwise.

Please write to the address given at the end of each item.

How to Investigate the Use of Medicines by Consumers, A. Hardon, C. Hodgkin, D. Fresle. World Health Organization, University of Amsterdam, KIT Royal Tropical Institute, the Netherlands, 2004

This manual is a practical guide to the use of research methods for investigating medicines use by consumers, particularly those in developing countries, in order to identify problems, design interventions and measure changes. It will help health workers, policy-makers, administrators, researchers, educationalists, medical and pharmacy students, and many others to go beyond the individual and to study the community as a focus. By understanding why people take medicines as they do, it is possible to design interventions that are sensitive to the particular beliefs, practices and needs of their community.

Topics covered include the reasons for studying medicines use by consumers, what influences consumer choice, and how to prioritize and analyse community medicines use problems. There are chapters on sampling and data analysis, and the manual concludes by looking at the important issues of monitoring and evaluating interventions.

The publication is an update of the manual developed by WHO, *How to Investigate Drug Use in Communities – Guidelines for Social Science Research.* It also builds on session notes developed for the international training course, Promoting Rational Drug Use in the Community, jointly organized by WHO and the University of Amsterdam.

Readers are encouraged to "learn by doing". Health workers are trained to diagnose and treat individual patients. The manual aims to help health workers and many others to go beyond the individual and to study the community as a focus.

Although resources and the capacity to do studies are limited in many settings, it is hoped that this book will encourage readers to undertake research on medicines use pratices, if only on a small scale, and to report the results. The editor of the *Monitor* is keen to receive such reports with a view to publication.

Available, free of charge, from: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland. Also at: http://www.who.int/medicines/publications/en

National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO global survey. World Health Organization, 2005

Various types of traditional medicine (TM) and medical practices referred to as complementary or alternative medicine (CAM), are increasingly used in both developing and developed countries. One of the major components of the WHO Traditional Medicine Strategy is to promote the integration of TM and CAM into national health care systems where appropriate. Development of national policy and regulations are an essential indicator of the level of integration of such medicine within a national health care system.

The use of medicinal plants is the most common form of traditional medication worldwide. Regulation of herbal medicines is a key means of ensuring safety, efficacy and quality of herbal medicinal products. WHO has been receiving an increasing number of requests from governments for guidance on how to regulate herbal medicines.

During the last four years, many countries have established, or initiated the process of establishing national regulations regarding herbal medicines. WHO has been conducting a global survey on national policy on traditional medicine and on the regulation of herbal medicines; aiming to:

- Collect updated and comprehensive information on TM/CAM policies and regulation of herbal medicines.
- Clarify the current situation, in each country, on the TM/CAM national policies and regulation of herbal medicines, and their major challenges on these particular area.
- Identify the specific needs on capacity building for TM/CAM policy development including establishment of regulations on herbal medicines, and the type of direct support WHO should provide to Member States.
- Monitor the impact of the WHO Strategy for Traditional Medicine in relation to present national policy and regulation on TM/CAM/herbal medicines.

WHO received completed survey returns from 141 countries. The raw data of the survey results were fed into a database specifically designed for this project, to create basic country profiles. This document provides a summary of the results of the WHO global survey with information from 141 Member States.

The baseline information gathered is the first of its kind, and will be valuable not only to help countries compare and learn from each other's experiences in strengthening their current TM/CAM system, but also for guiding WHO on its support to Member States.

Available, free of charge, from: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland. Also at: http://www.who.int/medicines/publications/en

International Nonproprietary Names (INN) for Pharmaceutical Substances CD-ROM List 1–91 of Proposed INN and List 1–52 of Recommended INN. Cumulative List 11. World Health Organization, 2004

The aim of the INN System has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.

This 11th Cumulative List CD-ROM is intended as a reference source for national drug regulatory authorities, the pharmaceutical industry and health professionals. It supersedes the10th list published in 2001. It contains over 7633 INNs for individual pharmaceutical substances, including about 455 new names proposed since the previous Cumulative List was prepared. It is produced in a multilingual format: English and French introductory texts, together with a listing of INNs in Latin, English, French, Russian, Spanish, Arabic and Chinese.

The CD-ROM also includes references to other generic names, such as national nonproprietary names and names used by the International Organization of Standardization, pharmacopoeial monographs, the List of Narcotic Drugs under International Control, and other sources. Indexes of molecular formulae and of Chemical Abstracts Services registry numbers are also included.

Internet access to International Nonproprietary Names (INN) for Pharmaceutical Substances Regular updates of published proposed and recommended INNs Information on Proposed and Recommended International Nonproprietary Names (INNs) can also be consulted on the following website: http://www.who.int/medicines/services/inn/en/index.html

Available from: Marketing and Dissemination, WHO, Geneva, Switzerland. E-mail: bookorders@who.int

Price: Sw.fr.350.00/US$315.00, and in developing countries Sw. fr.100.00.

Antimicrobial Resistance Surveillance and Containment CD-ROM, World Health Organization, 2005

This CD-ROM contains the WHO Global Strategy on Containment of Antimicrobial Resistance, as well as a wealth of information relating to the Strategy. Topics covered include antimicrobial resistance surveillance, assessment tools, antibiotic use, hospital infection control and antimicrobial resistance in farm animals. All the documents are in English, with some also in French, Spanish or Russian.

Available, free of charge, from World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland. E-mail: edmdoccentre@who.int

For further information see: http://www.who.int/drugresistance

The WHO Medicines Bookshelf CD-ROM Version 4

This contains a selection of over 350 medicines-related publications, in English, French and Spanish, taken primarily from WHO information materials and covering the entire field of interest of WHO medicines work, including access to essential medicines, rational use of medicines, national medicines policy, quality and safety issues, and traditional medicine.

Core publications from other sources are also included on the CD-ROM, with the kind permission of the organizations concerned.

The Bookshelf links to the Essential Medicines Library, which contains the WHO Model Formulary and provides links to WHO clinical guidelines and United Nations price information resources, among many others.

The Bookshelf is available free of charge: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland. E-mail: edmdoccentre@who.int

Determining the Patent Status of Essential Medicines in Developing Countries. World Health Organization, Health Economics and Drugs Series No. 17, 2004

Now that the Doha Declaration has confirmed the inherent flexibility within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that allows governments to take measures to protect public health, it is up to governments to ensure that patents do not constitute a barrier to access to medicines. There are a range of policy options for countries, depending on the particular circumstances and needs. However, a crucial factor to ensure effective decision-making in such issues must be the availability of accurate and up-to-date information about the patent status of essential medicines. The question of whether or not a medicine is under patent protection is clearly of great importance for drug procurement decisions. Unfortunately, such information is not always easily accessible or available in an easily understood form.

In 2000, WHO and UNAIDS jointly published a report, *Patent Situation of HIV/AIDS-Related Drugs in 80 Countries.* The aim of the report was to assess the patent situation of HIV/AIDS-related medicines in countries for which data was available. Since the report's publication, a number of new medicines have become vital in the treatment of HIV/AIDS, as well as the treatment of opportunistic infections. The information included in this report, which is largely presented in the form of a patent table is an attempt to update the previous work.

Available, free of charge, from: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland. Also at: http://www.who.int/medicines/publications/en

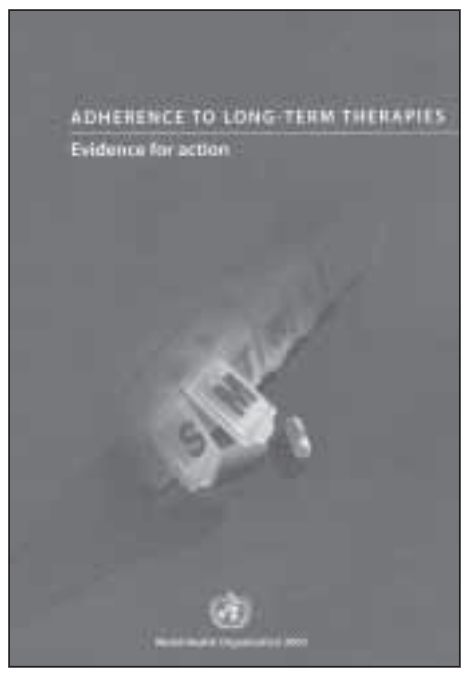
PUBLISHED LATELY

Adherence to long-term therapies. Evidence for action. World Health Organization, 2003

➢ JENNIE CONNOR

Huge investments are made in the development and testing of pharmaceuticals and in training health care providers to use them appropriately. However, the therapeutic effectiveness of long-term medications is compromised by poor adherence, resulting in preventable morbidity, poor cost-effectiveness and antimicrobial resistance. Improving adherence is therefore a key component of improving control of both communicable and non-communicable diseases worldwide.

The report, *Adherence to long-term therapies – Evidence for action,* makes two very important contributions to this effort. First, it gathers together evidence and expert opinion on determinants of adherence to long-term medications, both in relation to general principles and more specifically to nine major chronic conditions. Second, it promotes a systems approach to understanding adherence and to improving it. The adherence of a patient to his medication is conceptualised as the result of five interacting dimensions: social and economic factors, therapy-related factors, patient-related factors, condition-related factors and health systems/health care team factors. This framework acknowledges that the commonly encountered adherence rates of around 50% are not simply determined by the failings of individuals, and that this must shape our response.



Despite the wider theoretical framework, much of the report is focused on physician-patient relationships in developed countries, as this is where the available research has been conducted. So although the disproportionate burden of disease in poor populations is acknowledged, the difficult conditions under which good adherence to multi-drug regimens must be promoted for much of the world's population are not really discussed. Successive chapters on adherence in nine important conditions reiterate common themes and outline disease-specific issues, but the possibility of different approaches for resource-poor settings is only touched on.

Evidence for effective interventions is sparse and research in high-income countries indicates that even complex and tailored individual approaches usually result in only small improvements in adherence. Even less research has been conducted in resource-poor environments, but for these settings useful interventions will need to be simple, systematic and, wherever possible, passive. They are therefore more likely to be population-based interventions, rather than individual ones. An example is the use of fixed-dose combination (FDC) pills and simplified dosage regimens as a component of treatment strategies for HIV/AIDS, TB and malaria. The clinical experts contributing to this report consistently identified too many pills and complex regimens as barriers to adherence. The FDC strategy aims to reduce the size of the task the patient faces, and has stimulated discussion about other aspects of health systems that could be modified to make adherence easier.


J. Connor

This report provides an important summary of adherence research and a useful way to conceptualise this important problem. Our improved understanding of the barriers to adherence resulting from this work is a good starting point for action, and I hope it will inform the development of both practical guidelines and new research.

Jennie Connor is an epidemiologist, in the School of Population Health, University of Auckland, New Zealand.

Copies of Adherence to Long-term Therapies are available from World Health Organization, WHO Press, 1211 Geneva 27, Switzerland. E-mail: bookorders@who.int Price: Sw.fr.30/US$27, and in developing countries, Sw.fr.15.00.

Also available at: http://www.who.int/medicines/publications/en/

Medicines out of control? Antidepressants and the conspiracy of goodwill. Charles Medawar, Anita Hardon. Aksant Medical Publishers, 2004

➢ JIM SABIN

Medicines out of control? tells the story of how public agencies and the medical profession have responded to emerging awareness of the potential for Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants to cause disturbing withdrawal symptoms and trigger suicidal impulses. The primary focus is on the UK, but the authors put UK experience into a broad historical and cultural context. Charles Medawar, a specialist in pharmaceutical policy, drug safety, and corporate accountability, is Executive Director of Social Audit in the UK (http://www.socialaudit.org.uk). Anita Hardon, Professor of Anthropology of Care and Health at the University of Amsterdam, the Netherlands, has written and taught widely about use of medications in Asia, Africa and Europe.

Readers will either love this remarkable work or fume at it. Few will be neutral. This is the authors' intention. In the preface they tell us that the book is being "offered for peer-review and consultation, and is meant to promote comment and debate." They invite feedback to help them prepare what they envision as a revised, popular edition sometime after 2004.

I identified five primary themes in the 11 highly readable chapters:

- Although the title – *"Medicines out of Control?"* – has a question mark after it, the authors' answer is clearly "yes," and they use the SSRI story to argue that governmental regulation in the UK does not provide adequate control or accountability.
- The authors use the term "conspiracy of goodwill" as a label for what they see as a historical tendency to turn to medications as ***the*** solution for mental distress. In a chapter titled "Sedative hell" they contend that the cycle of unbridled optimism followed by disillusionment that occurred with opiates, cocaine and barbiturates is happening again with antidepressants.
- The authors' central assertion is that the drug oversight process is undermined by commerce (the pharmaceutical industry) and culture (the conspiracy of goodwill), with the most notable shortcoming being failure to collect, respect and apply narrative evidence from users of medications.
- The authors believe that the quest for "blockbuster" drugs for what they see as "routine life management" squeezes out attention to essential medications. In this way they link their argument about failures of accountability in the developed world to failures of access in the developing world.
- Finally, the authors delineate what they call the "crisis" of SSRIs, focusing on discontinuation or withdrawal symptoms and the possible triggering of suicidality. In their view this "crisis" ranks at the same level as thalidomide!


J. Sabin

Medicines out of control? ultimately sees robust democracy – transparency, readiness to listen to and learn from the experience of individual users of drugs, and public accountability – as the antidote to highly distorted pharmaceutical practices. Readers interested in public values and policies regarding medicines in developed countries should take up the authors' invitation to join a dialogue on creating a healthier healthcare system.

Jim Sabin is Clinical Professor of Psychiatry, Harvard Pilgrim Health Care, Boston USA. Available from: HAI-Europe, Jacob von Lennepkade 334-T, 1053 NJ Amsterdam, the Netherlands. Fax: +31-206855002. Price: Euro27.50 + shipping

PUBLISHED LATELY

Recent Ph.D theses from Scandinavia

➢ RICHARD LAING

One of the pleasures of working at WHO is receiving materials from all over the world. I have recently read six Ph.D reports from Scandinavian universities. In most cases, Goran Tomson from the Division of International Health (IHCAR) at the Karolinska Institute in Stockholm, Sweden, has been one of the supervisors. The students are from Asia, Africa and Europe and have all undertaken research related to pharmaceutical use or policy. These theses are made up of a series of papers, some already published before and some after submission, with a relatively short and easy to read summary. They are bound in paperback style and often contain photos and easily understood tables.

The first study is by Lamphone Syhakhang from Lao People's Democratic Republic,[1] who examined both private pharmacies and public pharmacies in Laos, and measured the effect of a regulatory intervention in private pharmacies. The study used qualitative and quantitative methods and included an intervention with inspections, information, distribution of regulation documents to drug sellers and sanctions. The main findings of the study were that most private pharmacies were managed by non-pharmacists, and the quality of practices was low, with no significant difference between public and private pharmacies. Essential drugs and essential materials were significantly more available in private than in public pharmacies. More antibiotics and injections were dispensed in public pharmacies. ***After 18 months of regulatory intervention, the pharmacies in the active intervention districts showed improvements.*** The major conclusion of the study was that the quality of private pharmacies was low and included the dispensing of a high proportion of substandard drugs. ***It was however possible to improve the practice of private pharmacies including the provision of better quality drugs through regulatory interventions.***

The thesis by Chuc, Nguyen Thi Kim described the quality of private pharmacy practice and assesses the effects of an intervention package on knowledge and practice of private pharmacy staff in Hanoi, Viet Nam.[2] The study involved a case study and a randomised controlled trial. For the case study, two private pharmacies were studied intensively using a variety of methods. Sixty-eight private pharmacies participated in the intervention study. A Simulated Client Method ("mystery patients") was used to assess practice and interviews were used to assess knowledge. Three interventions were applied sequentially: regulatory

enforcement, education and peer influence.

The major results from the case study showed that less than 1% of customers came with prescriptions. Antibiotics were sold to 17% of clients and 90% were broad spectrum. According to pharmacy staff, antibiotics gave them the best financial benefit.

The intervention package resulted in improved knowledge and practice of pharmacy staff in the intervention pharmacies. ***This study shows that it is possible to improve the knowledge and practice of pharmacy staff with a multi-component intervention.*** It also shows that if pharmacy staff get appropriate support to fulfil their public health role, more rational provision of drugs may follow.

The next thesis by Kristina Jönsson studied the evolution of National Drug Policies in Viet Nam and Laos.[3] This study examines from a political scientist's perspective how foreign ideas are translated into national policies elsewhere, and the different influences which determine how well the policy is actually implemented.

Mattias Larsson wrote a thesis which aimed to assess drug provision in the public and private sectors, antibiotic use and resistance in the community, as well as the effect of an intervention package aimed at improving case management in private pharmacies in Viet Nam.[4] He assessed drug utilization using prescription and medical record reviews and interviews with doctors. Community antibiotic use and bacterial resistance were assessed among children using a questionnaire and laboratory tests. The same randomised control trial as described by Chuc assessed the effect of an intervention package on case management of childhood acute respiratory infection, male sexually transmitted diseases and dispensing of prescription-only drugs in private pharmacies in Hanoi. The main findings of the study were that essential drugs were available in remote areas, the average number of drugs per prescription was high, and injections were common. Of the pharmacy staff, 20% stated that they would dispense antibiotics for a child with cough, in practice 83% of the pharmacies did. Fifty-three percent stated that they would ask the patient questions related to breathing, in practice 10% did; eighty-one percent stated that antibiotics are not effective in short courses, in practice 47% dispensed for courses of less than five days. Compliance with prescription regulation was weak. ***The intervention pharmacies improved significantly compared to the control pharmacies.*** The study's major conclusion was that promoting Good Pharmacy Practice standards to improve case management in private pharmacies is likely to have a major public health impact.

The next thesis by John Chalker, represents a saga over time and place.[5] The first study in Nepal occurred in 1990 and 1991 and evaluated the effect of a drug supply scheme. The remaining intervention studies occurred in Viet Nam and Thailand. He replicated the Viet Nam study described by Chuc and others in Bangkok, and compared the effect of supervision and incentives on antibiotic prescribing in rural Viet Nam. Of particular interest was the fact that while the three-phase intervention in Hanoi was successful, the same intervention in Bangkok failed to change practices. ***The main conclusion was that the effect of any intervention is dependent on the context.***

Public Health in Private Hands by Knut Lonnröth is a study of private and public tuberculosis (TB) care in Ho Chi Minh City, Viet Nam. The study examined the attitudes towards public and private TB care among physicians and patients using qualitative methods. Cross sectional surveys of patients receiving care in both sectors were combined with another cross sectional survey of private pharmacies. Finally, the quality of care and treatment outcomes were assessed in a cohort study. The results of the study showed that while patients perceived that private providers provided better quality care, the reality was that the public providers used better diagnostic

procedures and case management and had substantially better outcomes.

These results are similar to those reported by Uplekar from India.[7] ***The implication of this study is that where private doctors do treat TB the National TB Programme needs to focus efforts on improving the quality of care in this sector.***

The final thesis, by Stephen Nsimba, looked at the effect of changing policies on malaria treatment in the United Republic of Tanzania.[8] The thesis combined qualitative studies of mothers' knowledge and practices, household and facility surveys, analysis of different chloroquine formulations in the market and examining capillary bloods of children coming for treatment. Two interesting findings from the facility surveys were that while 71% of children were diagnosed with malaria, only 38% had detectable malaria parasites. Ninety-seven percent of all the children had detectable chloroquine blood levels prior to the consultation. ***The key conclusion of the thesis was that when policy changes are planned in malaria treatment both households and facilities need to be targeted with information to support the policy change.*** This conclusion becomes particularly important with the shift towards artemisinin-containing antimalarials.

These different theses represent an impressive body of work, encouraged by the Division of International Health at the Karolinska Institute. They are important because they represent major advances in knowledge that occurred in countries where improving drug use whether for tuberculosis, malaria or other conditions is critically important. We can only hope that the next few years produces similar such excellent theses.

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PUBLISHED LATELY

WHO's update on the world medicines situation

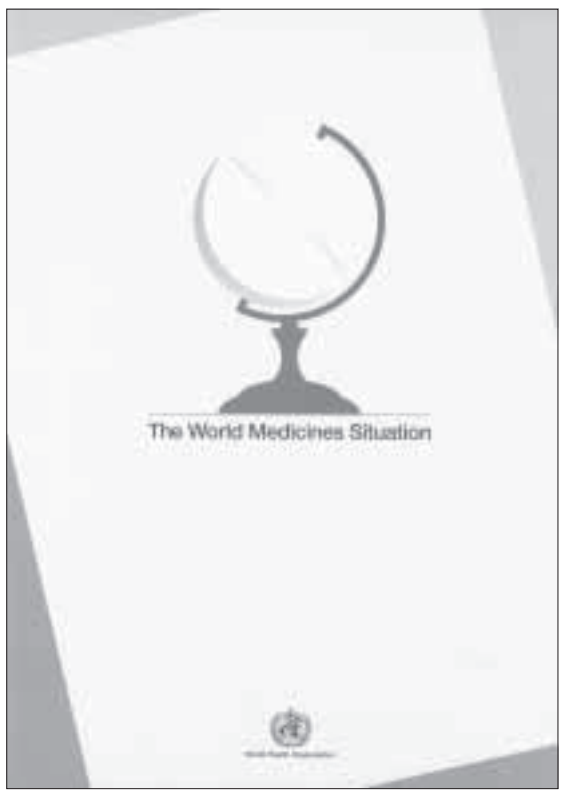
➢ Andrew Creese

A recent WHO publication provides the Organization's first overview of the world medicines situation since 1988 when *The World Drug Situation* appeared. *The World Medicines Situation* aims to provide an accessible source of information on the pharmaceutical situation at global and national levels. The target readers are researchers, academics and analysts concerned with medicines and public health.

The book assembles the available evidence regarding the production and consumption of medicines, and a range of issues in national medicines policies, including the level of people's access, patterns of utilization and the challenges of medicines regulation. Numerous different sources of data are used. A 32-page annex of statistics is included.

The main messages of the report are well illustrated with the growth of the HIV/AIDS pandemic in the last two decades. They include:

- The continuing huge imbalance in resources for, and access to, medicines between the better off and the poorer people of the world. An estimated 2 billion people – a third of the world's population – still lack access to the medicines they need. High income countries spend on average 100 times more on medicines per capita than low income countries, about US$400 compared to about US$4.
- The widespread underused potential of generic medicines of good quality.
- The growing public awareness of the need for action to improve access and utilization patterns, yet this is against a background of a growing role for private spending on medicines.
- As the HIV/AIDS epidemic, and the existence of emerging as well as continuing neglected diseases illustrates, the following are important:
  - Innovation
  - Prices
  - Medicines financing, particularly through prepayment or insurance
  - The capacity of health systems to ensure timely and widespread availability of the right medicines at the right time to people in need.



Over 15% of global health spending is for medicines.

The report has nine main chapters. Some of the main points are that:

- Medicines production grew faster than the global economy overall from 1985 to 1999, and became more concentrated in this period. Just five countries account for two thirds of total production in value terms, 10 companies account for half of the total, and 10 best selling products account for 13% of the value of the global market. Almost all production (by value) occurs in the high income countries.
- Estimated private sector research and development spending on medicines accounts for over 40% of all global health-related R&D. The private share of health R&D appears to have grown in major spending countries recently.
- Though international trade in medicines is dominated by a small group of high income countries, India and China have recently joined the top 10 global net exporters (exports minus imports). The USA remains the biggest net importing country.
- The share of originator brands versus other (mainly generic) medicines in total sales was large and growing in high income countries between 1990 and 2000. Private spending on medicines grew faster than public spending in the same period.
- Access to medicines generally follows a gradient similar to that of countries' income levels: the higher the income, the better the access.
- There has been substantial growth in the number of countries developing national medicines policies, from only eight in 1985 to 159 in 1999. Similar growth rates in the development of treatment guidelines and formularies are found. However, a majority of countries (60%) report having not yet developed implementation plans to support these policies.


A. Creese

- Major challenges persist in using medicines rationally.
  - Half of all medicines are estimated to be inappropriately prescribed, dispensed or sold, and half of all patients fail to take their medicine properly.
  - Two thirds of antibiotic sales occur without prescription.
  - Adverse drug events rank among the top 10 causes of death in the USA and cost $130 billion each year.
  - Growing resistance to antimicrobial medicines results largely from inappropriate prescribing and use.
- The challenge of medicines regulation remains pervasive: fewer than one in six WHO Member States have well-developed drug regulation. The informal sector, which many people rely on in poor countries, is commonly neglected by regulatory bodies.

Mr Andrew Creese is a health economist and an author of the publication.
Copies of the World Medicines Situation are available, free of charge, from: World Health Organization, Department of Medicines Policy and Standards, 1211 Geneva 27, Switzerland.

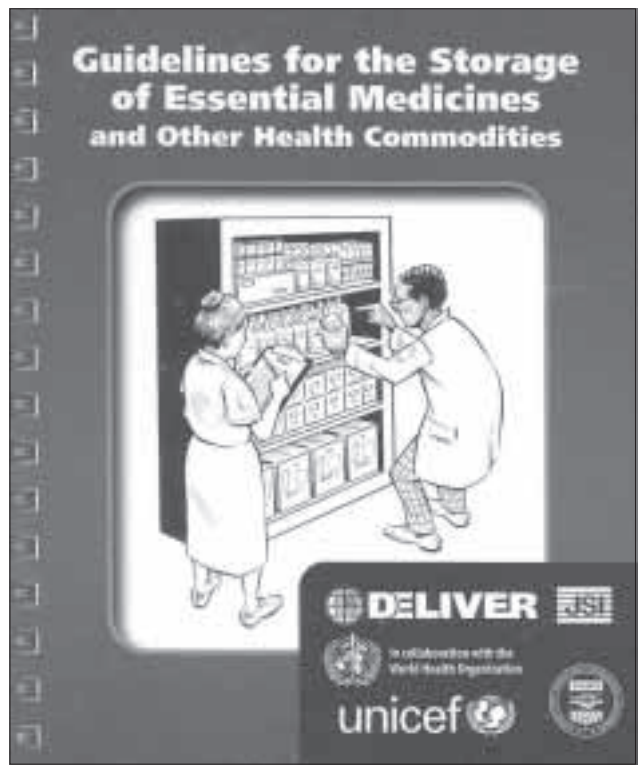
Guidelines for the storage of essential medicines and other health commodities. Deliver, in collaboration with WHO and UNICEF, 2004

➢ Charles Allotey

A number of essential drug supply organizations, health facilities and health commodities distribution centres, particularly in Africa, fail to recognize the vital link between proper storage and maintenance of products' quality. More often than not, these facilities do not have planned storage facilities and basic procedures which ensure the security, safety, and maintenance of quality. One reason for this is the lack of concise, easy to read and self explanatory materials which could serve as practical references for those managing or involved in setting up storage rooms or warehouses for essential medicines.

It is therefore timely that this useful and attractive pocket-size practical reference book has been published. The book outlines most of the important issues to consider in the storage of essential medicines and other health commodities. It contains written directions and clear illustrations on the following:

- The design and construction of the storage facility or medical store
- Receiving, arranging and tracking commodities
- Special storage conditions
- Maintenance of product qualities



- Waste management and disposal methods.


C. Allotey

It gives essential resources and contacts of organizations offering general warehouse equipment such as cold chain, fire fighting, forklifts, pallets and pallet racks. It also provides sample forms for basic record keeping which could be adapted to any storage facility in any type of environment.

The clarity and simplicity of the guideline make them ideal for use by all categories of staff involved in commodity storage and supply. This guideline should as far as possible be made available to all facilities in sub-Saharan Africa involved in the storage of essential medicines and other health commodities.

Mr Charles Allotey, pharmacist, Catholic Pharmaceutical Service, Accra, Ghana.

Available in English and French, free of charge from: Department of Medicines Policy and Standards, WHO, 1211 Geneva 27, Switzerland.

RATIONAL USE

Experiences with insurance coverage of medicines in the Philippines


M. Valera

➢ MADELEINE R. VALERA

THE Philippine Health Insurance Corporation (PhilHealth/PHIC) aims to provide all 80 million Filipinos access to health services in 15 years. Its vision is to ensure sustainable, affordable, and progressive social health insurance which ensures the delivery of accessible quality health care for all Filipinos. PhilHealth as a financial intermediary should continuously evolve a sustainable National Health Insurance Programme (NHIP) that shall:

- lead towards universal coverage;
- ensure better benefits for its members at affordable premiums;
- establish close coordination with its clients through a strong partnership with all stakeholders;
- provide effective internal information and management systems to influence the delivery of quality health care services.

At the heart of the NHIP is the spirit of social solidarity – where the rich will subsidise the poor, the healthy will assist the sick and the employed help the unemployed. The state policy is to adopt an integrated and comprehensive approach to health development that would make essential goods, health and other social services available to all citizens at an affordable cost.

Accreditation of service providers

The majority of health care providers operating in the country are accredited by PhilHealth, and to date, PhilHealth has over 1,500 accredited health care facilities and more than 20,000 health care professionals nationwide. The accreditation of rural health units (RHUs), TB DOTS centres, maternity care clinics and free-standing dialysis clinics are some of PhilHealth's initiatives to expand its provider base and realise its goal of improving access to health services.

Quality assurance programme: improving access to health care

PhilHealth aims to improve access and health through the development of benefit packages. Two such packages are the TB DOTS outpatient package and low-risk maternity care package. The TB DOTS package ensures full coverage of anti-TB drugs, uses incentives for physicians to refer or adhere to the treatment protocol and promotes a public – private mix. The maternity care package emphasises quality prenatal, birthing, and postnatal care, and opens accreditation to midwives.

PHIC is mandated to ensure that drugs for reimbursement are of good quality. With this mandate in mind, PHIC collaborated with the University of the Philippines College of Pharmacy and the Zuellig Foundation to promote Good Manufacturing Practices (GMP) and assisted in providing training to drug manufacturers. The goal is to nurture a culture of GMP among pharmaceutical companies.

PhilHealth leads in instituting reforms in the pharmaceutical sector and in the health sector generally, with emphasis on participatory and evidence-based medicine. It has embarked on policies to improve health care such as:

- promotion of rational drug use;
- introduction of the PHIC positive list (a list of additional drugs from the existing clinical practice guidelines that were reviewed using the evidence-based matrix for reimbursement);
- upholding the Philippine National Drug Formulary as the main reference for drug reimbursements.

Influencing provider practice

PhilHealth has established the National Health Technology Assessment Committee (HTAC) to evaluate the effectiveness and safety of medical and surgical procedures, devices and drugs. The HTAC conducts drug assessments to determine which drugs should be reimbursed by PHIC, and ensures nationwide and effective dissemination of clinical practice guidelines developed by local medical societies.

As the country's prime accreditor of health institutions and professionals, PhilHealth has the power to influence behaviour. By 2006 all of these professionals will have to take an exam on rational drug use or undergo a training course on rational use to be accredited. A performance monitoring system through the use of clinical vignettes, financial incentives for good performance and feedback mechanisms are now being tested. We have been conducting research studies to develop policy on evidence-based medicine and rational use of drugs.

PhilHealth has established the National Peer Review in collaboration with the specialty societies to evaluate appropriate care. As a staunch supporter of the Generic Law, PHIC requires strict generic prescribing. We have been conducting continuous research studies on rational drug use since 2002, identifying patterns of utilization of drugs, behavioural analysis of Filipino doctors and what influences their prescribing habits.

In 2002, the Medical Informatics Division was instituted to assist the Department of Health in training hospitals and doctors on the use of ICD-10. We have imposed strict implementation of ICD-10 in order to standardize diagnosis.

Leveraging industry

To date the Government has no programmes designed to actively manage and develop the local pharmaceutical industry.

In 1998, a study noted that the Philippines ranked second to Singapore in terms of per capita drug consumption in the ASEAN region. Ironically, less than 30% of the population has access to drugs. Nonetheless, drug prices in the Philippines are, on average, about 600% more expensive compared with other South-East Asian countries. The Drug Price Reference Index (DPRI) has been developed to address issues such as irrational drug pricing, lack of price transparency in the market and hopefully for PHIC to leverage its purchasing power with industry. As one of the largest third-party purchasers of health care in the country, PhilHealth has both the power and mandate to push for the use of high quality drugs at the most reasonable and affordable prices.

The immediate goal of DPRI is to help expand and improve PhilHealth's benefit package by creating a more uniform and comprehensive basis for drug reimbursement. In the long term, the project seeks to promote:

- more rational and fair pricing of drugs while balancing the needs of the key stakeholders and PhilHealth and its members;
- more rational use of drugs.

PhilHealth has resolved to embark on a social marketing campaign to help assure acceptance of the DPRI among key stakeholder groups in a cost-effective way.

Pharmaceutical manufacturers are now seeking to meet with us to discuss prices and have expressed willingness to negotiate. A coalition of NGOs has prepared a bill ("An act to ensure the affordability and accessibility of essential drugs being made available to the public") to institutionalize DPRI.

A future full of challenges

PhilHealth is facing numerous challenges, some of which are outlined below.

- In general, doctors' conduct is marked by a laissez-faire attitude. They remain largely influenced by the Medical Act of 1959, which assigns doctors full power and discretion over the choice and prescription of drugs.
- "Breaking the Bank" – PhilHealth has to manage existing funds so that there are enough for the moment universal coverage is achieved.
- PhilHealth needs to sustain the membership of the informal and indigent sectors.
- The majority of consumer groups focusing on drug and health policy issues are small, but could be strong strategic allies.
- Conflict of interest in the way providers practice, especially hospital owners – as they are both attending physicians and the owners of pharmacies. There is a high financial incentive to over-use drugs.
- PhilHealth has no regulatory powers to control charges of professional fees, room charges, and mark-ups for medicine and laboratory services.
- Implementation of DPRI would be difficult because it is a cost issue that affects various stakeholders.

We have learned that the only way forward is to develop innovations that we truly believe will deliver results. It has required us to be extremely careful and confident about the evidence that guides us. It has also required us to be bold, uncompromising and take a leadership position that is so often questioned by sectors that fear change. ❑

Dr Madeleine R. Valera, is Vice President for the Quality Assurance Research and Policy Development Group, Philippine Health Insurance Corporation. This article is based on a paper presented at ICIUM 2004.