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Essential Drugs Monitor

The Essential Drugs Monitor is produced and distributed by the WHO Department of Essential Drugs and Medicines Policy (EDM). It is published in 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 Essential Drugs and Medicines Policy 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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EDITORIAL

25 years of essential medicines progress

This special edition of the Essential Drugs Monitor celebrates twenty-five years of the essential medicines concept. The historic first meeting of the WHO Expert Committee on the Selection of Essential Drugs took place in Geneva from the 17–21st October 1977. Today, more than 150 countries have adopted the concept and developed their own national lists of essential medicines.

This issue includes a keynote address given by the Director-General of WHO, Gro Harlem Brundtland, at the 25th anniversary celebrations in Geneva, affirming the Organization’s commitment to the essential medicines concept. Stressing the concept’s relevance for all countries, developed and developing, she spoke of WHO’s two crucial functions for essential medicines – global normative guidance and technical support for Member States. Promoting equity and sustainability would be the focus of medicines work. Dr Brundtland went on to emphasise the Organization’s need to remain evidence-based and totally independent from commercial interests and from individual donor decisions. (See p 12 for the full speech). Margaretha Helling-Borda, who attended the first Expert Committee meeting (and later became Director of the EDM programme), shares some of her memories of that important occasion in 1977. Both these articles stress the point that selection is only one component of assuring access and ensuring rational use.

Other articles in our special issue focus on some of these different aspects. Francis Burnett from St. Lucia writes of a long-term, successful system in the Caribbean in which a group of small island countries have banded together to pool their drug procurement activities to reduce prices and guarantee a reliable supply. Sri Suryawati describes a community level programme in Indonesia to ensure that mothers understand about the medicines they purchase. This innovative approach has been carefully evaluated and has been shown to be very effective in changing knowledge and behaviour. On the other side of the world, Birna Trap and Ebba Holme Hansen report on a study of dispensing doctors in Zimbabwe, showing that if prescribers dispense medicines themselves there are significant differences in their practices!

Articles from India and Latin America

“Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.”


Of essential medicines de médicaments essentiels

No 32 (2003)
Improving drug regulation

In spite of all the efforts made, less than 20% of WHO Member States are thought to have a well developed drug regulation system, and those that do are mostly industrialised countries. Of the remaining Member States, about 50% implement drug regulation at varying levels of development and operational capacity. The other 30% either have no drug regulatory authority (DRA) in place, or have a very limited capacity that barely functions. Studies in some countries show that about 20% of tested drug products fail to meet quality standards and that the prevalence of substandard and counterfeit drugs is higher in countries where drug regulation is ineffective. WHO’s recent assessment of regulatory performances in selected countries and its publication of the results are timely contributions to efforts to improve this situation. The publication, Effective Drug Regulation: A Multicountry Study, gives an overview of the development of drug regulation in 10 countries, as well as the resources available and the strategies used when the studies were conducted in 1998–1999. An analysis of systems’ strengths and weaknesses in the countries – Australia, Cuba, Cyprus, Estonia, Malaysia, the Netherlands, Tunisia, Uganda, Venezuela and Zimbabwe – is also provided. Data collection was based on archival studies and key informant interviews, using a standardised tool developed by WHO, and refined by the participating investigators and research advisers. The tool, which is included as Annex 1 of the publication, is useful for countries and organizations wanting to assess drug regulation performance. The report includes a brief profile of each country, and compares a number of background features relevant to drug regulation. It then presents conceptual frameworks to be used in the analysis and synthesis of overall drug regulation in the subsequent chapters, and discusses the authority, capacity and organization of drug regulatory agencies. Chapters 6–10 address the main drug regulatory functions: licensing of manufacturing, distribution and retail sale; inspection and surveillance; product assessment and registration; control of drug promotion and advertising; and drug quality control laboratories. Each of these chapters contains parallel sections covering powers, process, personnel, financing, regulatory functions, and planning and performance. Chapter 11 sets out concepts, methods and indicators for assessing regulatory performance, and discusses country performance in relation to various aspects of regulation. The book concludes with key lessons and strategies for improving drug regulation, focusing on building regulatory structures and processes. It is the latter that we highlight here.

BUILDING REGULATORY STRUCTURES

In some countries studied legislation omits or exempts certain areas of pharmaceutical activity from the scope of control. Since legal structures form the foundation of drug regulation, regulatory gaps and new challenges should be addressed by modifying or extending existing legislation, or introducing new legislation. Drug regulation should cover all products for which medicinal claims are made, and all activities in the public and private sectors associated with drug manufacture, importation, distribution, dispensing and promotion.

Overall accountability

In some countries drug regulatory functions are assigned to two or more agencies, at the same or different levels of government. The study showed that such fragmentation was a potential impediment to regulatory effectiveness, with an increased risk of lapses in implementation, duplication of effort, wastage of resources and even confrontation.

Ideally, drug regulatory structures should be designed so that a central coordinating body has overall responsibility and is accountable for all aspects of drug regulation for the whole country. However, restructuring the entire DRA will require a substantial amount of time and effort, and there may be a need for intermediate options that allow improvements in an existing divided structure. Another solution is to establish official structures for coordination and information systems within existing organizations. A system with formal channels of coordination and information flow should be created to support drug regulatory decision-making at national level.

Multiple functions and conflicts of interest

The study showed that some drug regulatory authorities have been assigned multiple functions and so cannot focus solely on drug regulation. If the authority responsible for drug regulation is assigned non-regulatory functions, such as manufacturing, procurement, and/or planning and performance. Staff shortages appear to be a serious problem in all 10 countries studied. Difficulty in recruiting staff was cited in six countries, while there was difficulty retaining staff in four.

and resource allocation. Distribution of human and other resources to cover all these functions has a significant impact on the adequacy of support for regulatory activities.

Regulatory double standards

Not all drug regulatory requirements are applied equally. Exemptions are sometimes made, depending on where the drug comes from, who manufactured or imported it, where the drug is distributed or whether it is sold on domestic or overseas markets. For example, drugs manufactured or imported by state agencies may not have to be registered, whereas those from private businesses do. Such systems mean that products may not conform to the standards set by the DRA. Also, therapeutic goods manufactured for export may not be subject to the same standards as those consumed locally. Use of double standards is the case in the case of exported products raises questions of fairness in international public health.

Regulatory tools

The study revealed that not all drug regulatory authorities make available documented standard operating procedures for registration, and that even fewer countries have documented guidelines and checklists for inspection. When such tools are lacking, application of the legislation may become erratic and even lead to non-compliance with laws. The study required adhering to the standards of law enforcement.

Standards and guidelines should be established in written form for all drug regulatory functions. These tools should be used to guide practice, and be made publicly available in order to ensure the transparency of the drug regulatory process.

Resources

One of the study’s main findings is that shortage of qualified personnel is the greatest problem faced by drug regulatory authorities, partly due to the salaries offered to employees. Another factor may be the limited pool of pharmaceutical professionals in some countries because of a lack of places in pharmaceutical education.

Human and financial resources are critical for successful drug regulation, and governments should employ people with the required specialist knowledge and skills. Employees must have integrity

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Resource
and should be well remunerated. This is particularly important because regulation involves various stakeholders with commercial interests who may try to exert pressure on the authority in order to secure decisions favourable to themselves. Adequate and sustainable financing mechanisms are clearly crucial.

Government budget is the main mechanism of funding DRA; all 10 DRAs in the countries identified are sufficient in capacity and resources to perform the regulatory function. Fees collected by government-financed DRAs are transferred to the government treasury. Countries vary both in the type of services for which fees are charged and in the level of fees. Only two of the 10 DRAs are entirely self-financed from their charges; they cover all services provided, including licensing, inspection, quality control and control of promotion and advertising. But the fees that are charged should not be dependent upon the fees charged for its services. Governments should be fully committed to ensuring the sustainability of drug regulation. Financing for the authority should therefore be structured so that a balance is struck between a sufficiently high fee to cover the cost of services and provision of government support. Also, the collaboration of DRAs in the region and the remuneration of expert committee members performing reviews should not be directly linked to specific fees or to the agency’s overall earnings. This will help to ensure that regulatory decisions are not influenced by payment of fees.

The report recommends a number of other possible ways of overcoming human resources problems, including multi-skilling approaches and greater coordination between the DRA and educational institutions to increase the number of people with the requisite skills. Module-based educational packages could also be developed through collaboration between countries.

Pooling of information resources may help to reduce the regulatory workload. Networks of information sources and users could be built up to facilitate the transfer of information and technologies, particularly between developed and developing countries. Quality control laboratories with the same standards and which adhere strictly to good laboratory practice could be accredited, and countries could cooperate in certifying laboratories in providing services.

In addition to testing for pre-marketing quality control, the DRA laboratories in six of the countries also collect drug samples for testing as part of post-marketing quality surveillance.

### Building regulatory processes

#### Formal and informal sectors

The study showed that drugs distributed through the informal sector receive little attention compared with those distributed through the formal sector. Counterfeit products, products of dubious quality and faulty information – especially exaggerated claims of efficacy – are widespread in the sector. It is very important that monitoring of pharmaceutical activities covers both sectors.

#### Balance of priorities

Regulatory functions should be carried out in such a way that each receives sufficient attention and resources, but experiences in the countries indicate that different functions receive varying degrees of emphasis. Disparities are found in three key areas:

- **Pre-marketing versus post-marketing product assessment:** Drug legislation in all the countries assigns two types of power to DRAs – the authority to assess pharmaceutical products and determine whether they should be registered, and the authority to monitor and change the information and registration status of a drug after it has been marketed. However, much more time is assigned to pre-marketing assessment than to post-marketing review. Yet even if pre-marketing assessment is rigorously and soundly conducted, it may be insufficient to guarantee the efficacy and, especially, the safety of drugs. Emphasis should also be placed on post-marketing surveillance.

- **Product registration versus regulation of distribution:** The study showed that product registration is considered a major responsibility by all the DRAs. In contrast, regulation of drug distribution and information does not seem to enjoy the same level of attention. This is particularly so in those countries where the drug distribution system has several intermediate levels and the climate may be unfavourable.

- **GMP versus distribution-channel inspection:** In many countries, Good Manufacturing Practices (GMP) inspection receives more attention and resources than inspection of distribution channels. But it is not in the interests of the consumer if a product that has been produced according to GMP is later stored and distributed under adverse conditions. Inspection of distribution channels should be given equal emphasis, particularly in countries where the drug distribution system has several intermediate levels and the climate may be unfavourable.

### Recommendations for effective drug regulation

- **A clear sense of the mission of the regulatory authority is important in motivating DRA staff to pursue regulatory objectives in order to promote public health.** Clear communication of the regulatory function should be evidenced in the climate of the authority.
- **Drug laws should be sufficiently comprehensive, covering all activities involving drug products and information, and they should be updated regularly.** Government should state clearly the mission and objectives of drug regulation so that it is easy to assess the attainment of intended objectives.
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- **One central agency should be accountable for the overall effectiveness of drug regulation.** The same standard of regulation should be applied to all stakeholders, including the public, in order to increase the transparency of the DRAs’ operations. The same standard of regulation should be applied to all stakeholders, including the public, in order to increase the transparency of the DRAs’ operations. The same standard of regulation should be applied to all stakeholders, including the public, in order to increase the transparency of the DRAs’ operations.
- **Sustainable financing is essential to promote effective drug regulation.** Drug regulatory authority financing should strike a balance between fees covering the full cost of services and government support. Fees should provide increased revenue to the authority, so that it can perform effectively, and serve to discourage clienteles from “fleecing” the system with applications that do not meet official requirements.
- **Every regulatory function contributes to ensuring the safety quality and efficacy of drugs.** The action taken by the authority should cover all drug regulatory functions in a balanced fashion. Support for drug regulation should not be compromised by other non-regulatory tasks with which the DRA may also be charged.
- **The regulatory process should be systematically monitored in order to identify problems and determine whether actual activities match the intended actions.** Moreover, the DRA should become a learning organization, which routinely conducts self-assessment and continuous quality improvement. There should be administrative and legislative supervision in order to guarantee accountability. Peer review by drug regulatory authorities in other countries can serve as a means of external auditing, whereby the performance of one agency can be compared with that of its peers.
- **Any inefficiency in the regulatory process delays decision-making and may lead to shortages of critically needed drugs, thus endangering lives.** Drug regulatory authorities should employ various strategies to increase efficiency of resource use. Examples include: prioritisation and streamlining of the approval process; job enlargement and job enrichment for regulatory staff; pooling of international information resources; and sharing and pooling of international quality control resources.
- **Drug regulatory authorities should communicate regularly with their clients.** They should also acknowledge the right of citizens to be provided with accurate and appropriate information on drugs marketed in their country. Educating citizens about the efficacy, safety, quality and rational use of drugs will ultimately enhance the achievement of regulatory objectives.

### Assessment of DRA performance

Several approaches can be employed to assess the performance of drug regulatory authorities.

#### Self-assessment

Self-assessment can help an organization to learn about its own strengths and weaknesses. A DRA that routinely conducts self-assessment and continuous quality improvement can greatly enhance drug regulatory performance.

#### Performance by supervisory body

Drug regulatory legislation normally specifies the official chain of command and the supervisory body to which the DRA must report.

### Box 2

#### Sustainable financing

Several approaches can be employed to ensure sustainability of drug regulation systems. It serves as a means of external auditing, whereby the performance of one agency can be compared with that of its peers.

### cont’d on page 4

### Nineteen of the 10 countries studied have a system for monitoring adverse drug reactions, each based on a voluntary reporting system by health professionals.

### Perspectives of DRA staff

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### Implementation

Besides structural constraints, such as human and financial resources, the way in which DRA employees perceive their jobs and how they perform are key factors in drug regulation performance. Staff needs and clear sense of mission of regulatory processes are to be pursued consistently.

### Regulatory processes should be systematically monitored in order to identify problems and determine whether actual activities match those planned.

### Box 2

#### Sustainable financing

Several approaches can be employed to ensure sustainability of drug regulation systems. It serves as a means of external auditing, whereby the performance of one agency can be compared with that of its peers.
and its operations must be transparent to both clients (for example, drug manufacturers) and to consumers. Communication with clients should be a routine activity throughout the regulatory process. Information on its functions and the results of decisions should also be communicated regularly to the public.

Consumer empowerment

Traditionally, drug regulation has been considered as a process involving two actors, the DRA and the regulated firms. But policies that foster such arrangements run the risk of encouraging corruption. Since consumers are the end-users of drugs, all drug regulatory efforts should lead, ultimately, to protection of the consumer. Consumer groups or public interest groups can contribute to these efforts by participating both in the development of regulatory policies and in regulatory activities. They can act as independent “attorneys generals” and protect the public from undue pressure from industry or politicians. Support from the DRA and other organizations is needed to empower consumers so that they can make an appropriate contribution.

Educating consumers about the efficacy, safety, quality and rational use of drugs can also enhance the achievement of regulatory objectives.

Effective Drug Regulation: A Multicountry Study does not intend to prescribe ready-made strategies for drug regulation. Rather it sheds new light on the regulatory environment, providing new perspectives on constraints and options for improving the way systems work.

WHO’s study reinforces the message that if public health is to be protected governments must establish strong national drug regulatory authorities with a sound organizational structure and the legal power and resources to carry out their duties.

Effective Drug Regulation: A Multicountry Study, by S. Ratanaowijitrin and E. Wondemageneghe is available from World Health Organization, Marketing and Dissemination, CH 1211 Geneva 27, Switzerland. Tel: + 41 22 791 2476, fax: 41 22 791 4857, e-mail: publications@who.int Price: Sw.fr.20/$US18, and in developing countries Sw.fr.14.
A total of 43 private sector facilities were sampled. Data were collected from 29. The numbers in brackets indicate the number of facilities, from those sampled, that actually provided data. All the facility managers were asked for permission to carry out the survey. Time constraint was the reason most often given by those facilities that did not want to participate in the survey. The data were collected by four data collectors, all based in the selected geographical area.

Data collection, in the field, was undertaken in a week. Doctors (1) doctors (1) doctors (3) doctors (5) hospital (1) hospital hospital (1) hospital pharmacies (5) pharmacies (2) pharmacies (5) pharmacies (5) public health 5 public health 5 public health 5 public health

### Table 1

<table>
<thead>
<tr>
<th>Area 1</th>
<th>Area 2</th>
<th>Area 3</th>
<th>Area 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 public health facilities (1)</td>
<td>5 public health facilities (1)</td>
<td>5 public health facilities (1)</td>
<td>5 public health facilities (1)</td>
</tr>
<tr>
<td>5 retail pharmacies (5)</td>
<td>5 retail pharmacies (5)</td>
<td>5 retail pharmacies (5)</td>
<td>5 retail pharmacies (5)</td>
</tr>
<tr>
<td>1 private hospital (1)</td>
<td>1 private hospital (1)</td>
<td>1 private hospital (1)</td>
<td>1 private hospital (1)</td>
</tr>
<tr>
<td>5 dispensing doctors (1)</td>
<td>5 dispensing doctors (1)</td>
<td>5 dispensing doctors (1)</td>
<td>5 dispensing doctors (1)</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Sector</th>
<th>Brand</th>
<th>Most sold generic</th>
<th>Cheapest generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>24.26 (0.31–119)</td>
<td>14.05 (1.8–56.19)</td>
<td>13.86 (1.0–56.19)</td>
</tr>
<tr>
<td>Public</td>
<td>1.64 (0.05–16.91)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The figures in brackets indicate the range of ratios that exist from the lowest to the highest. The private sector procures just one product.

### Table 3

<table>
<thead>
<tr>
<th>Tariff</th>
<th>Size as a percentage</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value added tax (VAT)</td>
<td>14%</td>
<td>R60.72 (ex-manufacturer)</td>
</tr>
<tr>
<td>Distribution levy</td>
<td>6%</td>
<td>R75.11 (price charged to institutions by depot)</td>
</tr>
</tbody>
</table>

### Table 4

<table>
<thead>
<tr>
<th>Tariff</th>
<th>Size as a percentage</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale mark-up</td>
<td>34.43% (recommended maximum is 21.22%)</td>
<td>R61.19 (ex-manufacturer to wholesaler, excluding VAT)</td>
</tr>
<tr>
<td>Retail mark-up</td>
<td>41.52% (recommended maximum is 50%). Discounts varying from 0-30% can be offered to cash patients or medical insurance</td>
<td>R93.33 (wholesale selling price to retailer, excluding VAT)</td>
</tr>
<tr>
<td>VAT</td>
<td>14%</td>
<td>R159.60</td>
</tr>
<tr>
<td>Dispensing fee, broken bulk etc</td>
<td>0.5%–1%</td>
<td>R161.08 (price paid by patient)</td>
</tr>
</tbody>
</table>

The ex-manufacturer’s price was collected from the wholesaler. The prices quoted above in the cost column, apart from the last row, do not include VAT. However, each supplier, from manufacturer to wholesaler to retailer, charges 14% VAT on their mark-ups. These are then claimed back from the receiver of revenue. (8 Rand = US$1.00 approximately.)

results are given in Tables 2–5. From Table 2 it is clear that the branded products, in the private sector are the most expensive, with one product 119 times more expensive than the reference price. In the public sector, prices are approximately 1.64 times higher than the reference price, which is to be expected as public sector prices are much cheaper than those in the private sector.

### Table 5

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Cost in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Original</td>
<td>1.37</td>
</tr>
<tr>
<td>Most sold</td>
<td>0.66</td>
</tr>
<tr>
<td>Cheapest</td>
<td>0.54</td>
</tr>
</tbody>
</table>
Drug pricing survey... cont’d from pg. 5

The table shows price variation across regions within Sri Lanka. These are all the targeted drug products that were found at several facilities in each of the four survey regions. Median MPRs within regions are presented. Several drug products are precisely consistent in terms of price across regions. However, for other drugs, such as cotrimoxazole, ibuprofen and nifedipine, price differences between regions as high as 32% were found for the same product.


Some results from Armenia

The pilot study took place in Armenia in October and November 2001, with 40 private for-profit pharmacies sampled, 65% of them in the capital, Yerevan, and the rest in three regions (known as Marzes). Table 1 gives a regional level analysis of drug prices.

Relating drug prices to people’s earnings, the study found that the highest price for an average length course of a branded version of aciclovir was US$154 (see Table 2), meaning that the lowest paid Government worker in the country would have to work for 148 days to pay for the course. The same money would buy 318 kg of rice or 344 kg of sugar, enough for 10 years.

In the case of the cheapest generic drug the price of a course of treatment comes down 60% – not enough to solve the problem for most Armenians.

M. Aristakesyan.

Armenia Table 1

A regional analysis of drug price ratios in the Armenian pricing survey

<table>
<thead>
<tr>
<th>Marzes</th>
<th>Mean of all Pharmacies</th>
<th>Maximum of all pharmacies</th>
<th>Minimum of all pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yerevan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand drugs</td>
<td>4.6</td>
<td>14.1</td>
<td>0.3</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>3.2</td>
<td>19.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>2.8</td>
<td>19.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Kotayk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand drugs</td>
<td>3.9</td>
<td>9.6</td>
<td>0.2</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>2.8</td>
<td>16.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>2.6</td>
<td>16.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Shirak</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand drugs</td>
<td>4.2</td>
<td>12.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>3.4</td>
<td>16.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>3.1</td>
<td>16.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Syunik</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand drugs</td>
<td>5.9</td>
<td>11.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>3.2</td>
<td>11.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>3.1</td>
<td>11.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand drugs</td>
<td>4.6</td>
<td>14.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>3.2</td>
<td>19.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>2.8</td>
<td>19.3</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Some of the 49 drugs were 500–700% higher. (43%) were 200–499% higher; and 10 of the 49 (29%) were 100–199% higher than the international median; 21 out of 49 drugs (43%) were 200–499% higher; and 10 of the 49 drugs were 500–700% higher.

T. Nurghozian.

Affordability of monitored drugs in Armenia

<table>
<thead>
<tr>
<th>Monitored Drugs</th>
<th>Cost of course therapy</th>
<th>Lowest paid government worker</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARD</td>
<td>US$</td>
<td>Necessary to work/day</td>
</tr>
<tr>
<td>Aciclovir</td>
<td></td>
<td>154</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>44687</td>
<td>80</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>34536</td>
<td>62</td>
</tr>
<tr>
<td>Cefuroxone</td>
<td></td>
<td>62426</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>39530</td>
<td>71</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>34180</td>
<td>61</td>
</tr>
<tr>
<td>Simvastatin</td>
<td></td>
<td>34509</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>34262</td>
<td>59</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>34262</td>
<td>59</td>
</tr>
<tr>
<td>Diclofenac</td>
<td></td>
<td>28635</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>54722</td>
<td>10</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>4121</td>
<td>7</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td></td>
<td>28707</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>18941</td>
<td>34</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>16573</td>
<td>30</td>
</tr>
<tr>
<td>Beclomethasone</td>
<td></td>
<td>21173</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>14868</td>
<td>27</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>14868</td>
<td>27</td>
</tr>
<tr>
<td>Ranitidine</td>
<td></td>
<td>11234</td>
</tr>
<tr>
<td>Most sold generic</td>
<td>1987</td>
<td>3.5</td>
</tr>
<tr>
<td>Lowest priced generic</td>
<td>1865</td>
<td>3</td>
</tr>
</tbody>
</table>

The cheapest drug

| Furosemide      |                        | 227                          | 0.4                           |
| Most sold generic | 143                 | 0.3                         | 0.4                           |
| Lowest priced generic | 128             | 0.2                         | 0.5                           |
| Mean of republic level | 20728         | 37.0                        | 35.8                          |
| Most sold generic | 9779                 | 17.4                        | 16.8                          |
| Lowest priced generic | 8779            | 13.7                        | 15.1                          |

ARD = Armenian dram (national currency).

The survey in Kazakhstan

In Kazakhstan the monitoring survey of prices and availability of 85 medicines in 21 pharmacies in Karaganda City was conducted from December 2000 to May 2001. A cost calculation per unit was made, with a unit defined as a tablet/capsule, an ampule, a vial, or gram of ointment.

The Table on the following page shows that there were only four drugs with prices lower than the international median; all of which are available generically and have been used in Kazakhstan for some time. Fourteen out of 49 drugs (29%) were 100–199% higher than the international median; 21 out of 49 drugs (43%) were 200–499% higher; and 10 of the 49 drugs were 500–700% higher.

T. Nurghozian.
Reducing costs through regional pooled procurement

> Francis Burnett

Financial constraints have made it increasingly difficult for developing countries to adequately finance the supply of health facilities. The countries comprising the Organisation of Eastern Caribbean States (OECS) have recognised that improving the use of existing resources could be achieved by efficient procurement practices. Of the four areas of their annual drug supply management cycle (selection, procurement, distribution, and use) efficient procurement provides the greatest opportunity for cost-savings. The OECS/Pharmaceutical Procurement Service (OECS/PPS) is a self-financing public sector monopoly or buyers’ cartel that covers its operating cost from a 15% surcharge. This article considers the success of the OECS/PPS, formerly the Eastern Caribbean Drug Service in implementing improved pharmaceutical procurement as a cost containment strategy, and outlines essential elements for successful pooled procurement for other resource-constrained countries.

Political will and financial commitment

Political will was an essential ingredient for success, with the Prime Ministers of the Eastern Caribbean States agreeing to establish the OECS/PPS in 1986. The countries deposited one-third of their annual pharmaceutical budget to individual country drug accounts at the Eastern Caribbean Central Bank (ECCB) in order to assure prompt payment to suppliers and to maintain a revolving drug fund. This was a concrete sign of political will and financial commitment.

Establishing OECS/PPS

The OECS/PPS is an agency of the OECS, a formal grouping of nine Eastern Caribbean countries: Anguilla, Antigua and Barbuda, British Virgin Islands, Dominica, Grenada, Montserrat, St. Kitts and Nevis, St. Lucia and St. Vincent and the Grenadines. Their combined population is approximately 550,000. The OECS/PPS was established under a project funded by USAID, and by 1989 the scheme was financially self-sufficient.

The core function of the OECS/PPS is the pooled procurement of pharmaceuticals and medical supplies for the nine Ministries of Health (MOHs) of the OECS countries. During the 2001/02 tender cycle, the annual survey of a market basket of 20 popular drugs showed that the regional prices were 44% lower than individual country prices (Figure 1). The continuous annual cost-savings accrued after 16 years of the joint purchasing arrangement have reinforced the Procurement Service as an excellent cost-benefit model of economic and functional cooperation among OECS member countries.

Centralised tender

The OECS/PPS present suppliers with a public sector monopoly or a purchasing cartel so that products tendered by the Service are purchased exclusively through annual contracts. Prior to the establishment of OECS/PPS, the OECS countries purchased drugs individually from suppliers by direct negotiation. The cost of pharmaceuticals in any country depended on the following factors: the professional attitude and negotiating skills of the supplies officer, the governments’ payment track record and the source of supply. Consequently, drug prices for similar products used to vary widely among OECS countries.

The Pharmaceutical Procurement Service operates a centralised, restricted tendering system in which all approved suppliers are pre-qualified by a vendor registration questionnaire. Pre-qualification is necessary to assess the quality standards, technical competence and financial viability of competing suppliers. After soliciting bids from over 75 international suppliers, the Service awards annual contracts, places orders directly with suppliers, and monitors delivery and supplier performance. OECS/PPS does not warehouse supplies, but instructs suppliers to ship consignments directly to participating governments.

Kazakhstan drug pricing survey continued

Kazakhstan Table

Median drug prices in Karaganda, compared to the international median – Average of December 2000 and May 2001

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Median price Karaganda US$</th>
<th>Median price international US$</th>
<th>% difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic acid</td>
<td>1.57</td>
<td>11.70</td>
<td>100–199%</td>
</tr>
<tr>
<td>Tetracycline ointment</td>
<td>1.28</td>
<td>7.70</td>
<td>100–199%</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>1.31</td>
<td>4.70</td>
<td>300–499%</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1.27</td>
<td>2.50</td>
<td>500–700%</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>1.42</td>
<td>6.70</td>
<td>500–700%</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>1.53</td>
<td>6.20</td>
<td>500–700%</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>1.60</td>
<td>9.50</td>
<td>500–700%</td>
</tr>
<tr>
<td>Furosemide</td>
<td>1.78</td>
<td>14.50</td>
<td>500–700%</td>
</tr>
<tr>
<td>Verapamil</td>
<td>1.80</td>
<td>9.30</td>
<td>500–700%</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>1.86</td>
<td>9.80</td>
<td>500–700%</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>1.89</td>
<td>9.90</td>
<td>500–700%</td>
</tr>
<tr>
<td>Dihydroxyimidehidine</td>
<td>1.92</td>
<td>13.50</td>
<td>500–700%</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>1.94</td>
<td>12.30</td>
<td>500–700%</td>
</tr>
<tr>
<td>Nystatin</td>
<td>2.04</td>
<td>20.40</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Ergocalciferol</td>
<td>2.14</td>
<td>21.40</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Cephalozolin</td>
<td>2.37</td>
<td>23.70</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>2.69</td>
<td>26.90</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>2.71</td>
<td>27.10</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Captopril</td>
<td>2.29</td>
<td>22.90</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Theophylline</td>
<td>2.47</td>
<td>24.70</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Sulindac</td>
<td>2.49</td>
<td>24.90</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Heparin</td>
<td>2.53</td>
<td>25.30</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Spirotolactone</td>
<td>2.54</td>
<td>25.40</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Naldixic acid</td>
<td>2.76</td>
<td>27.60</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>3.22</td>
<td>32.20</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Dicyclline</td>
<td>3.33</td>
<td>33.30</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>3.43</td>
<td>34.30</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>3.46</td>
<td>34.60</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Folic acid</td>
<td>3.54</td>
<td>35.40</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Glutamic acid</td>
<td>3.56</td>
<td>35.60</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Atanol</td>
<td>4.06</td>
<td>40.60</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>4.20</td>
<td>42.00</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Digoxin</td>
<td>4.28</td>
<td>42.80</td>
<td>More than 500–700%</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>4.89</td>
<td>48.90</td>
<td>More than 500–700%</td>
</tr>
</tbody>
</table>

* Of 60 main list drugs, only 49 were in the International Drug Price Indicator Guide.

Figure 1

Average % unit cost reduction for a market basket of 20 popular drugs 2001/2002 compared with individual country prices

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Financial constraint: A decreasing gap in international and national prices of medicines in Kazakhstan. This is due to the government's effort to negotiate prices with suppliers, as well as the introduction of a fixed internal price list. The government also plans to increase import duties and excise taxes on medicines to enhance their financial autonomy.

Political will: The Kazakh government has demonstrated a strong commitment to improving its public health system through various initiatives. These include the establishment of a national pharmaceutical purchasing agency, the introduction of a National Drug Policy, and the implementation of a national health insurance program.

Financial commitment: The government has allocated significant resources to the health sector, including the purchase of medicines. However, there is a need for greater transparency in the procurement process to ensure that the government is getting the best value for its money.

Establishing OECS/PPS

The OECS/PPS is a good example of international cooperation among countries in the Caribbean region. Members of the OECS have recognized the importance of pooling resources to achieve economies of scale in procurement. This has led to the establishment of the OECS/PPS, which has been successful in reducing the cost of pharmaceuticals and medical supplies.

Centralised tender

The OECS/PPS has been successful in centralizing the procurement of pharmaceuticals and medical supplies. This has led to a significant reduction in the cost of these products for member states. The OECS/PPS has also been able to negotiate better prices with suppliers, which has further reduced costs.

Kazakhstan drug pricing survey continued

The Kazakhstan drug pricing survey has shown that there is a significant variation in the prices of medicines in Kazakhstan compared to international prices. This indicates that there is room for improvement in the price setting process in the country. The survey also highlights the importance of international cooperation in procurement to achieve cost reductions.
Reducing costs...cont’d from pg. 7

Organizational development and implementation

The ECCB, the monetary authority for the stable Eastern Caribbean dollar, facilitated the prompt payment of the foreign exchange to suppliers at no additional cost to participating countries. The formal country-based committees of the OECS/PPS, ensure participatory decision-making and commitment by Ministries of Health (MOH) and OECS/PPS. Policy Board comprises Ministers of Health (assisted by their Permanent Secretaries), the OECS Director General, the ECCB representative and the OECS/PPS Managing Director; the Board exercises overall responsibility for the Unit’s Policy directives.

The OECS/PPS’ management is part of the sub-committees; the Policy Board and the Sub-Committees meet annually and are chaired on the principal by the OECS/PPS’ Unit. These formal relationships are central to the participation and ownership of OECS/PPS’ constituent countries. In addition, the collective decision-making of the Tenders Sub-Committee reduces the political and financial commitment of participating countries. A core list of essential drugs to common to the nine participating members includes phenytoin, digoxin, warfarin and other states.

Choice of currency, foreign exchange and terms of payment

The OECS/PPS solicits bids in US dollars to provide one standard monetary unit for easy price comparison. The Eastern Caribbean (E.C.) dollar is pegged to the US dollar at a rate of 2.7 and has remained stable at this rate for the last 25 years. The use of the US dollar prices through the OECS/PPS procurement system allows OECS countries to forecast drug costs in the E.C. dollar without concern about fluctuations between international currencies, or between the E.C. dollar and the US Dollar. The stability of the E.C. dollar and the availability of US dollars are two advantages that many developing countries, including some Caribbean countries, do not have.

Past performance of suppliers

The selection of suppliers has a profound impact on both the quality and cost of drugs. Inadequate quality assurance in the selection process may result in the purchase of drugs that are ineffective and unsafe. Hidden costs caused by late deliveries, default on confirmed orders, low quality packaging and labelling, and expensive emergency orders. OECS/PPS has convened seminars on appropriate drug use. The OECS/PPS/PPS has implemented a three-year action plan to pursue the pooled procurement of pharmaceuticals along the OECS/PPS model. Against the background of severe difficulties that are confronting the global economy and the subsequent negative impact on developing countries, other countries should explore all strategies to use their scarce health sector resources efficiently. Better procurement methods have been shown to produce significant cost-savings.

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References

Increasingly dispensing may involve payment for medicines, creating conflict of interest related to the profit motive for health workers who both prescribe and dispense medicines. Major problems exist for such payment schemes to be successful. The focus has been on willingness and ability to pay, but little is known of how prescribing and patient care is influenced by the financial and for-profit motive related to prescribing by dispensing prescribers. Research in Zimbabwe in 1997 provides new information on rational prescribing by dispensing (for-profit) prescribers. The research was done by the Zimbabwe Essential Drugs Programme, The Royal Danish School of Pharmacy and the University of Zimbabwe, with financial support by The Danish Agency for Development Assistance (DANIDA).

Assessing prescribing practices

The study was designed as an analytical, cross-sectional, comparative survey of 29 randomly selected private sector dispensing doctors (DDs) and 28 non-dispensing doctors (NDDs) all in Harare, Zimbabwe’s capital. By selecting practices in Harare with a pharmacy nearby, easy patient access to dispensing of medicines was ensured for both types of practices.

Data on prescribing were collected from patient records. The quality of prescribing was assessed, based on expert opinion, focusing on well-known prescribing problems and applying “gold standards” – standard treatment guidelines as clinical assessment criteria. The study compared the WHO/ International Network for Rational Use of Drugs (INRUD) rational drug use indicators for DDs and NDDs, and assessed how upper respiratory tract infections were treated by the two groups of prescribers. Moreover, by using a panel of experts (three private practitioners and one pharmacist) it was possible to assess prescribing by looking at the recorded diagnoses and assessing the appropriateness of the prescribed treatment. A score sheet was developed based on assessment by a panel of experts, and this served as a reference for the assessment of the appropriateness of prescribing of the antibiotic, cotrimoxazole.

Major differences

The study identified major differences between the prescribing of DDs and NDDs. DDs prescribed significantly higher amounts of medicines, injections, antibiotics, mixtures, cough preparations and analgesics per patient than NDDs\(^1\),\(^2\). The higher prevalence of prescriptions was strongly associated with “symptomatic treatment” (i.e. a drug was prescribed for every symptom), general over-prescribing of antibiotics and prescription of medicines with lower clinical value\(^1\). Injections, particularly procaine penicillin, were prescribed three times more frequently by DDs than by NDDs in the treatment of upper respiratory tract infection\(^1\). DDs’ choice of antibiotics in the treatment of these infections was in general appropriate. When compared to NDDs, the antibiotics most frequently prescribed by DDs were chloramphenicol and aminoglycoside\(^1\). However, sub-curtive doses of antibiotics were prescribed to almost one-fifth of DDs’ patients. Sub-curtive dosages of cotrimoxazole were prescribed two and a half times more frequently by DDs than NDDs in 23% of encounters versus 9%\(^2\). DDs prescribed analgesics and psychoanaleptics more frequently in treatment of upper respiratory tract infection than did NDDs\(^1\). Consultation time was shorter for DDs compared to NDDs – 8.7 minutes versus 13.0 minutes.

The study analysed some of the factors influencing prescribing practices, in particular characteristics of the practice (clinic), the physician, working style and attitude. Consultation time was related to the location of the practice, high or low urban density and race. Caucasian prescribers were found to have longer consultation times, which could also be related to seeing fewer patients per day. Prescription practice was influenced by race and the doctor’s place of education. The practice of polyparmacy and prescribing more “symptomatic treatment” seemed to be related to site of education. Prescribers educated in Harare in Zimbabwe had better prescribing practices compared to those educated elsewhere. This could perhaps be related to the inclusion of the essential drugs concept and standard treatment guidelines in the curriculum for medical students in Zimbabwe. Although the study did not fully investigate how confounding factors such as gender, race, location of the practice, place of education and patient load influence prescribing, it can still be concluded that prescribing doctor is associated with less clinically and economically appropriate prescribing.

Serious implications

These findings give cause for concern, especially in view of the current trend in many developing countries towards increased numbers of “for-profit dispensing prescribers”, with little or no monitoring or control of their practices. This may have serious implications for appropriateness of treatment and patient care. The study demonstrated that, regardless of how a society ensures that medicines are available and accessible, the authorities need to set standards and to regulate dispensing, medicine management and activities related to pharmacy practices. Moreover, the study showed that the regulation by the medical profession has failed. The profession has accepted a practice by some of its members that is against the ideology and ethics of that profession – a practice which puts the interest of DDs before the interest of the patient.

While this study was done in a developing country, differences in rational prescribing quality between DDs and NDDs have also been documented in studies in other developing and in developed countries\(^3\),\(^4\). The general practitioners included in this study were of multi-ethnic origin, with 30–50% having non-African race or education. The study findings might therefore be valid outside Zimbabwe. This could be an important pointer for DDs in relation to “for-profit prescribing” throughout the world.

References


Figure 1

<table>
<thead>
<tr>
<th>Prescribing indicators by DDs and NDDs in Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>P = 0.001</td>
</tr>
<tr>
<td>P = 0.002</td>
</tr>
<tr>
<td>P = 0.006</td>
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</tbody>
</table>

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Drug and therapeutics committees: vehicles for improving rational drug use

Since 1998 WHO/EDM has been working to promote Drug and Therapeutics Committees. A WHO manual on this important topic will be published in 2003 and will be featured in the next issue of the Monitor. The article below describes the process used to develop the manual and the training course which is being used worldwide to introduce the number and effectiveness of committees. We would welcome readers’ comments on their experiences with Drug and Therapeutics Committees, particularly successful strategies and lessons learned. Contact details are on page 1.

Who should be on a Committee?
A successful Committee needs to have the appropriate leadership and members, and to meet regularly. It must be dynamic, resourceful and use all members’ skills. It is crucial that all key stakeholders in the hospital are on the Committee, and that hospital managers give members the necessary time to contribute in a sustainable and effective way.

Membership structure varies in different countries. Ideally a Committee has a strong chairperson, who is an opinion leader and who commands the respect of hospital and health leaders. Members often include: specialists from medicine, surgery, obstetrics and gynaecology, psychiatry and infectious diseases, pharmacists, a clinical pharmacologist, a drug information specialist, and nurses (either clinical or administrative nurse representatives), an infection control nurse, and the administrative officer or other high level hospital administration official.

For a Committee to be effective there must be a structured drug selection system that is explicit in its methodology, and that is transparent and evidence-based. The Committee must have the ability to design and implement interventions to improve the use of drugs. The hospital administration must give the Committee authorisation and support to carry out its functions, and have made explicit a clear line of authority to top administration officials. There is a need for regular meetings with published minutes and close follow up on all activities.

When a functioning Committee has these key features, it can be expected that it will be effective and that the result will be improved patient outcomes.

A combination of interventions, initiated by the DTC, will have the most significant effect on drug use and AMR.5 These include the appropriate selection of formulary drugs, the development of formulary-based guidelines, monitoring and evaluating drug use, surveillance, detection and appropriate care of patients with resistant organisms, and promotion and monitoring of basic infection control practices.6

Are DTCs effective?
In developed countries, studies have shown that DTCs can have a significant impact in promoting rational drug use, monitoring drug use and controlling drug costs.7,8 In developing countries the evidence is less compelling, but there is sufficient evidence to show that the individual functions of a DTC provide effective interventions to improve drug use and control costs. Proven successful interventions include: establishing and implementing a formulary list and standard treatment guidelines;9 and using educational techniques, especially interactive problem-oriented methods in face-to-face settings, and repeat sessions with different prescribers.10 Success has also been achieved through establishing and implementing audit and feedback (including drug use evaluation) of provider prescribing;11 and supervising and monitoring prescribing habits using indicators or simple protocols.12 A well-organized DTC will provide the structure to facilitate management of all of these well proven activities, and so it is reasonable to assume that it can be effective.

Promoting DTCs in developing countries
WHO/EDM in cooperation with Management Sciences for Health (MSH) is developing a manual on how to establish and maintain a DTC at hospital level, to help developing countries instigate basic DTC activities and so improve drug management in hospitals. The manual will be published in 2003.

At the same time MSH’s Rational Pharmaceutical Management Plus (RPM Plus) programme in cooperation with WHO, has developed an 8–10 day DTC training course. The course promotes the creation of DTCs, trains potential and actual Committee members and promotes the effective functioning of DTCs on formulary management and drug use. It is designed for physicians and pharmacists who are interested in improving the rational use of drugs through DTCs, or who will be able to provide training and technical assistance to other DTCs.

For effective formulary management, DTC members need to make their decisions on inclusions or exclusions using evidence-based drug management principles. Participants need information on the principles, concepts, approaches and tools of clinical pharmacology (drug efficacy), pharmacoeconomics (drug safety), pharmacoeconomics (drug costs) and pharmacoeconomics (drug cost product quality). The course also covers effective methods of improving drug use, aggregate and indicator methods for assessing drug use, and successful methods of implementing and monitoring change.

The exchange of experiences and ideas among participants adds depth to the learning process in this highly participatory course. The methodology is based on brief interactive presentations, with group and plenary discussions followed by exercises and field visits.

As far as possible sessions are integrated, so, for example, during the STG
exercise participants are given all the data to develop evidence-based STGs for pneumonia and surgical prophylaxis for Caesarean section. Then these STGs are used when making drug utilization review (DUR) criteria. On the field visits to local hospitals the STG/DUR protocols are used to look at practice and costs. These practical exercises during field trips can improve results. For example, when looking at drugs and doses in surgical prophylaxis for Caesarean section at one hospital, it was found that by not following the STG and using unnecessary antimicrobials, the cost paid per patient was US$6.47–13.6 times more than necessary.

Follow-up

Training courses on their own rarely result in sustainable behaviour change, so participants are asked to develop a one-year work plan for their institution, which is followed up to assess progress and give advice when needed. Follow-up is done in different ways. For local courses someone visits or telephones the participants, but the challenge is greater with international courses, and e-mail and a course web site are used. The site stimulates interactive learning for those who have been on a course. Each team’s work plan and updates on its progress are posted, along with personal profiles and photos of participants. Successes and failures are shared on the discussion board, so that people learn from each other. The site also provides links to important DTC resources. In addition, the RPM Plus web site (www.msh.org/projects/rpmplus) has valuable information on DTCs, including a fact sheet, links to training course sessions, and DTC-related work activities in the future.

Great potential

In hospitals and developing and developed countries a DTC can be a key instrument in improving drug selection and drug use. Yet in many cases DTCs are not functioning optimally. This is often because the chairperson is not committed, the membership is not representative of all stakeholders, or lacks adequate training, or the administration is not supportive in terms of recognition and remuneration for the time needed for Committee work.

The DTC training course is proving a major step towards promoting effective DTCs internationally, and we now need to develop a longer-term, sustainable, framework for presenting and follow ing up this course. Our focus will be on determining the main factors that make DTCs as effective as possible in developing country settings.

DTCs offer the opportunity and environment to improve drug management within hospitals and primary care settings. Overall these important Committee can provide the link to control and manage drug use, improve patient outcomes, and contain AMR.

All of these activities facilitate identification of potential problems. Given that most of the courses took place very recently it is expected that many more participants will provide us with information about achievements in their DTC-related work activities in the future.

Progress

To date, the training course has been presented in 10 countries to 295 participants from 42 different countries. Locations have included: International courses in Indonesia (June 2001), Kenya (October 2001) and India (September 2002): Regional courses in Bolivia (December 2001), Guatemala (February 2002), Moldova (June 2002) and Jordan in December 2002: and National courses in the Philippines (February 2001), Turkey (July 2001), Nepal (December 2001) and South Africa (March 2002).

While a significant number of participants have been lost to follow-up, we know that many are involved in post-course DTC activities, including:

- Further courses – so far there have been 14 courses and nine more are planned in eight countries.
- DTCs are being created or restructured in 11 countries.
- Three countries have introduced new processes for drug selection, improving formulary management.
- STGs have been developed in at least three countries.
- DURs have been conducted in four countries. ABC and VEN analysis of pharmaceutical purchases completed in two countries andADR and medication error reporting programmes are underway in two countries.

References


Announcing ICIM 2004

The first International Conference on Improving Use of Medicines (ICIM) was held in 1997, and brought together a wide range of participants and a wealth of interesting and important materials on how to improve medicines use (see Monitor No. 23, available at: http://www.who.int/medicines/information/informaton.shtml). Following this success, ICIM 2004 will be held in Chiang Mai, Thailand, from 30 March to 2 April 2004. Once again the main organizer is the International Network for Rational Use of Drugs (INRUD), with the local involvement of the Thai INRUD group and the Institute of Health Research at Chulalongkorn University, Bangkok. WHO/EDM, in collaboration with Management Sciences for Health, Boston University School of Public Health and Harvard Medical School, are also supporting the event.

ICIM 2004 aims to build an international consensus on effective and innovative interventions for improving drug use, particularly in developing countries. It will also seek to define a new global research agenda relevant to current conditions and unfolding developments in international health. A range of options and challenges will be explored across six main areas: international policies and systems; national policies, systems and programs; hospitals, inpatient and specialty care; primary care, focusing on health providers; primary care, focusing on the community; and special topics.

This stimulating, interactive event will be of great interest to policymakers, health ministry officials, programme managers, clinicians, researchers, advocates and donors. Individuals are encouraged to submit abstracts for presentation at the Conference. A limited number of scholarships, covering registration fees, travel and accommodation will be available to participants from poorer countries who have abstracts accepted or who are key policy-makers.

Further information is available on the Conference web site: www.icim.org or enquiries can be e-mailed to: icicum@msh.org
Access to essential medicines: a global necessity

It is a great pleasure for me to join you in the celebration of the 25th anniversary of the first WHO Model List of Essential Medicines. To understand the revolutionary nature of the idea behind the Model List, and the tremendous importance of this List over the past quarter century, we must take a minute to look back. The twentieth century opened with only one widely available modern medicine: aspirin. In the 1940’s, the first antibiotic, the first mass produced antimalarial, and the first antitubercular were introduced. The 1950s and 1960s saw the rapid introduction of oral contraceptives, diabetes medicines, and then medicines for mental illness, many infectious diseases, cardiovascular diseases and cancer.

By the 1970s, effective medicines – though not always ideal – existed for nearly every major illness we know. Yet, for half the world’s population, it was as if they were still living in the 1880s. For them, modern medicines were unavailable, unaffordable, of poor quality or ineffectively used. The World Health Assembly of 1975 was a watershed. This Assembly introduced the concepts of “essential drugs” and “national drug policy”. Seeing how central and everyday these concepts have become to public health, it is impressive to think that they are not much more than 25 years old.

The Assembly hoped to begin closing the huge gap between those who were benefiting from the pharmaceutical harvest of the mid-1900s and those who could not access these medicines. It began developing this bridge by building on precedents set in Scandinavia, on the North America formulary literature, and on pioneering efforts by countries as diverse as Papua New Guinea, Peru, Sri Lanka, and Tanzania.

In October 1977, WHO produced the first Model List of Essential Drugs and, in 1978, the Declaration of Alma Ata identified “provision of essential drugs” as one of the eight elements of primary health care. The Model List has clearly filled a need. By the end of 1999, 156 countries had a national list of essential medicines; three-quarters of these lists had been revised in the five preceding years. Over the past few years, the Model List has developed rapidly on several fronts in response to a growing global demand for wider access to essential medicines.

The last decade has seen inequities in health care increase, with reduced public budgets and increased reliance on the private sector. “For many the reality is stark: no cash, no cure.”

The new procedures for updating and disseminating the WHO Model List were approved in 2002; a process that was strongly supported by the Executive Board and the Assembly.

In April 2002, WHO included 12 antiretroviral medicines and the first artemether-based anti-malarial medicine on the Model List. Our new Essential Medicines Library now brings together all WHO’s core evidence and normative information on all essential medicines.

The new WHO Model List was issued for the first time two months ago, based on the Model List of Essential Medicines. It presents all relevant medicine information and summaries of most WHO’s clinical guidelines. It is available in hard copy and as a searchable web version. This has led to a complete renovation and re-actualisation of the whole essential medicines concept.

The new WHO Model Quality Assurance System has, for the first time, led to the pre-qualification of manufacturers and products for HIV and malaria on behalf of all UN agencies.

The last decade has seen inequities in health care increase, with reduced public budgets and increased reliance on the private sector. “Access to essential medicines depends on a nucleus of key factors: rational selection, affordable prices, sustainable financing and reliable supply systems.”

New international agreements, including the WTO TRIPS Agreement and the WTO Agreement on Technical Barriers to Trade (TBT), will undoubtedly affect access to medicines in developing countries. The recent UK Commission on Intellectual Property Rights provides a very comprehensive analysis of the potential impact. WHO is closely involved in the negotiations – and the wider debate – on intellectual property, where it is relevant for public health. The basis for our position is very clear: no clause in any trade agreement should work in a way that denies – to those who need them – access to life-saving medicines for common diseases. This applies wherever they live and whatever their ability to pay. In accordance with this position, WHO has formulated global guidance and is giving practical advice to Member States on the consequences and possibilities that lie in the rules on intellectual property being negotiated within the World Trade Organization.

“For many the reality is stark: no cash, no cure.”

Dr Brundtland, WHO’s Director-General, gave a keynote speech, quoted here, at anniversary celebrations in Geneva.

“The last decade has seen inequities in health care increase, with reduced public budgets and increased reliance on the private sector.”
We have come a long way since 1977. But the challenges ahead are great. For too many of the world’s poor people – those with an income of one or two dollars a day – nothing very much has changed at all. The onset of serious illness in the family too often leads inexorably to death, disability and impoverishment. Thirty-eight countries spend less than two dollars per person per year on medicines, while many of these countries have large numbers of people living with AIDS. Overall health expenditure may be as little as 10–12 dollars per person. Inevitably, in such circumstances, the cost of care falls to the individual and the family. Few poor people have access to health insurance. They have to pay for drugs when they get sick. Out-of-pocket payments – a large proportion of which go on medicines – constitute up to 90 per cent of total health spending in some poor countries. For many the reality is stark: no cash, no cure. Drug prices are only part of this challenge. Access to essential medicines depends on a nucleus of key factors: rational selection, affordable prices, sustainable financing and reliable supply systems. These four components of the strategy are interdependent. Lower prices attract more donor and government financing; radically increasing drug availability boosts health systems development; more effective supply systems mean greater coverage; and more coverage increases sales revenues.

WHO needs to remain evidence-based and totally independent from commercial interests so that we can ensure an independent development of normative work. Member States should always feel confident about the independence of our policy advice.”

“WHO's future work in essential medicines

“For our future work, this means continued support to countries, with a focus on results.

- Within country support, more focus will be put on capacity building through normative information, practical policy guidance and training.
- More focus will be put on supporting Member States in aspects of good governance and formulation of essential government functions, such as promoting the right mix between public and private functions and regulating the private sector.
- We will continue development of the evidence base for drug selection, based in part on WHO’s independence as a source of scientific information. Scientific and normative work benefits all Member States and needs to remain independent from individual donor decisions. It is certainly part of WHO’s core functions and will remain so.

- More focus will be put on strengthening the functions of district hospitals in ensuring equitable access to primary care.
- Access to essential medicines is part of the progressive fulfilment of the fundamental right to health. The rights-based approach will be further developed and supported as a means of empowering NGOs and the general public in making their governments accountable.
- More focus will be put on further developing and supporting health insurance as an important approach in making health care more affordable for all, and in promoting access to cost-effective health care. WHO will follow a pragmatic approach to critical issues, such as affordability and the use of TRIPS safeguards to ensure access, building on good governance by countries.
- The promotion of the essential medicines concept will be further intensified through close collaboration with other clusters, other UN agencies, the World Bank and NGOs.

“The Model List of Essential Medicines is a key tool.”

“Access to essential medicines is part of the progressive fulfilment of the fundamental right to health.”

argued that the old dogma which says development assistance is only cost-effective if it focuses on prevention – not treatment – is outdated. The recent developments within a number of diseases, such as HIV/AIDS, TB and malaria – and now with cardiovascular diseases – show that prevention and treatment are integrally linked. Spending money on essential medicines – and on the systems needed to deliver them effectively, equitably and safely – is a good health investment. We need to find ways to respond to these great challenges. Essential drugs are not an ordinary commodity. Access to health care is a human right. Governments and international agencies have an obligation to see that this right is progressively realised. Access to essential drugs is part of this obligation. The concept of essential medicines has global relevance and is a global necessity. The Millennium Development Goals include access to essential medicines as one of 17 health indicators. The world is committed to expanding access to essential medicines and WHO is committed to supporting this goal. WHO has two critical functions for essential medicines: to develop and promote global normative guidance, and to give technical support to Member States. Some of the normative work and all technical support puts emphasis on promoting equity and sustainability, with a focus on fulfilling the needs of poor and marginalised populations. WHO works with all stakeholders – both at the global level and in the countries. Besides the ministry of health, this includes especially the nongovernmental sector and academia.

WHO needs to remain evidence-based and totally independent from commercial interests so that we can ensure an independent development of normative work. Member States should always feel confident about the independence of our policy advice.

We are in the middle of a great struggle to increase investments in health as part of the fight to reduce poverty and achieve the Millennium Goals. We have to show that we have effective means to achieve measurable improvements in health. We need to find effective ways of delivering basic health care to all – also to the world’s one billion poorest people. A key part of this challenge will be to ensure a widening access to essential medicines. The Model List of Essential Medicines is a key tool in this work. Let us all work to make the next 25 years even more successful than the quarter century we celebrate today.”

“Access to essential medicines is part of the progressive fulfilment of the fundamental right to health.”

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Memories of the First Expert Committee Meeting and celebrating 25 years later

In 1968 when I joined the WHO Research Project for Adverse Drug Reaction (ADR) Monitoring after the thalidomide disaster, I started to develop a Drug Dictionary for drugs in the ADR reports received from the 10 developed countries participating at that time. I remember being amazed that so many brand names existed, and that the generic or nonproprietary names were so little used. The chemical name was often used to describe the active substance of a medicine in the then frequently objective and commercial drug information sources. In this plethora of names and substances and lacunae of good objective information how could prescribing physicians and others be expected to practice rational drug use? For developing countries with their enormous needs and cost-constraints, the problem was even more serious and their situation became acute in the 1970s. In 1974 a Chief Medical Officer wrote to WHO “our latest indent is 105% more expensive than last year’s. I need hardly say that this makes complete nonsense of our financial estimates, and my Government cannot, in the near future, double the money allocated for medicines”. That Chief Medical Officer was Dr Ebrahim Samba of the Ministry of Health of The Gambia, now Regional Director for WHO’s Regional Office for Africa.

Need for selection of essential drugs

With the focus on developing country needs, health priorities and primary health care, Dr Hiroshi Nakajima, chief of a small three staff unit (Drug Policies and Management) at WHO Headquarters, in 1974 began preparations for the First Expert Committee on Essential Drugs to be held in October 1977. The work had strong backing from World Health Assembly resolutions and WHO senior management, notably Dr Mahler, WHO’s Director-General and Dr Fattorusso, Director of the Division of Prophylactic, Diagnostic and Therapeutic Substances.

Dr Nakajima often spoke about the need to have a limited list of about 150 drugs that would cover the majority of health needs and achieve the widest possible coverage of the population. In the first Consultation on the Selection of Essential Drugs that took place in October 1976, the annotated list of essential drugs (active substances) came to around 200.

The 1977 Expert Committee on the Selection of Essential Drugs

Preparing a WHO Expert Committee is a complex task with strict rules and regulations. One major criterion is that any person considered for an Expert Committee has to be on a WHO Expert Panel. To place someone on a Panel took a very long time so one had to choose from people on existing Panels. In 1977 there were two Panels related to drugs: one for Drug Evaluation and another for Pharmaceutical Specifications.

The Drug Evaluation Panel included mostly pharmacologists and clinical pharmacologists, as safety of medicines had been of major concern at WHO since the 1960s. But very few members were from developing countries where this discipline was rare. Dr Darmansjah from Indonesia and Dr Lionel from Sri Lanka, among the eight members of the 1977 Expert Committee, were exceptions. The other Panel members consisted mainly of pharmaceutical technologists, and even fewer were from developing countries. Mr Yeap Boon Chye from Malaysia was selected because of his considerable experience of collaborating with WHO.

Geographical distribution was another criterion for Expert Committee membership selection. Four pharmacologists/clinical pharmacologists from teaching, research and clinical institutions in Brazil, France, Italy and the USA respectively (Professors Zanini, Lechat, Garattini and Azarnoff) were chosen from the Drug Evaluation Panel. Professor Babajan from the USSR was also selected but could not attend. But there was no one from Africa on either of the two Panels (nor on many others either). The Committee needed to have an expert from Africa – someone who would know about the problematic situation of medicines in Africa. I remember going to the WHO Library searching all the Panels for a subject that would come close to or touch that of medicines. Dr Beausoleil, Director of Medical Services at the Ministry of Health, Ghana, was thus invited. Dr Probst and Mr Richman of UNICEF were the only representatives from other organizations. The pharmaceutical industry was only invited to the second expert committee in 1979, when dosage forms were added to the Essential Drugs List. The criterion of having a woman on an Expert Committee came years later. Women were very rare on any Expert Panel 25 years ago – it was truly a man’s world in which we somehow survived.

Why such details on the composition of members? Because I am convinced that the eight competent committee members, backed by a secretariat of four temporary advisers – all Drug Evaluation Panel members (Drs Borda, Lunde, Tognoni and Ulianova) – and WHO staff (Drs Fattorusso, Nakajima and me, together with our excellent secretaries, Ms Burford) – had a fine catalytic effect on each other. We represented a good balance between sound scientific knowledge, common sense, vision and experience, coupled with political awareness and astuteness.

The Model List and Technical Report Series No. 615

Of course there were some heated exchanges in the Committee, in an otherwise quite sophisticated and scientific atmosphere. One major issue was whether or not explanatory text and justification should be included for each selected or rejected drug. Luckily wisdom prevailed. The text of the Expert Committee only gives some examples and lists scientific criteria and other guidelines that need to be applied in the selection of essential drugs. In its report it did not provide details of why each drug was selected or not. It was felt that this would have led to endless discussions after the report’s publication, particularly with the pharmaceutical industry. The three well-prepared and widely circulated working papers, including a draft Model List, were excellent reference sources on which the Committee could base its final decisions and from which large parts of text could be used. The clinical comments – the ones not included in the final Expert Committee text but so important in the decision-making process – were in the major working paper (DPM/WP/77.3 I. Borda). These later became very useful when WHO undertook country support in drug selection.

Approving every word before closing

There is no such thing as a draft report from an Expert Committee. Every word in the text and content of a Committee has to have final approval before the Committee disperses on the last day of the five-day meeting. But in 1977 we were not of the computer generation. Most professionals wrote their material by hand and gave it to a secretary for typing, and I think that this favourably reduced our “word output”. Moreover, none of the Committee members or the temporary advisers were people of many words. These may be the reasons why a very concise and clear main text of only 12, A5 pages resulted from our work – a text that still stands the test of time. In total, the small blue booklet of 36 pages included, apart from the text, the first Model Essential Drugs List with 220 main and complementary drugs, an alphabetical index, recommendations for the development of the WHO programme on essential drugs, a glossary and a bibliography. When published, Technical Report Series No. 615 became an instant WHO bestseller, which sold out in three months and had to be reprinted several times.
meeting, my own strong recollection from the historic days 17–21 October 1977 are my visits to the WHO medical services, preparing for the country visits right after the Committee. Two vaccinations were mandatory then – against cholera and against smallpox. I had both during that week. They put me in a state of febrile euphoria and malaise. Perhaps this was a premonition of what was to come with the bouts of malaria and diarrhoeal diseases that I experienced during my first trip to developing countries – a real “eye opener”.

Only a few days after the committee meeting closed, Dr H. Nakajima, Dr F.S. Antezana and I took off for our six countries, six-week country situation analysis trip to Asia – to Sri Lanka, Indonesia, then Burma, Nepal, Thailand and India. And to be consistent with the “sixes” I also lost six kilos in weight during those weeks. But I learnt a lot about the conditions in a developing country. I started to understand why a national essential drugs list and programme were needed. I realised that WHO had produced a great tool to get the process started and tried in my then very inexperienced way to assess the situation and write a prototype report of the pharmaceutical situation in “my three countries”. These were Sri Lanka where Dr Lionel helped me, Indonesia where Dr Darmansjah guided me and Burma (Myanmar) where I met with Dr Nakajima. When the three WHO “assessors” met again during a final three-day period in Delhi, India, to try to get a grasp of the problems in that huge country, I remember retreating to my hotel in a state of exhaustion, overwhelmed by all my impressions. But that was 25 years ago. Hundreds of country visits, assessments and evaluations later on all continents, I am very happy to see the great progress countries have made. Nepal provides just one example. In 1977 pharmaceuticals were handled by the Ministry of Forestry and there was only one pharmacist, Dr Siwal. He was later responsible for building up and modernising that country’s pharmaceutical supply system.

25 years later – celebrating the anniversary

For 21 October 2002 I was invited to Cambodia by WHO’s Regional Office for the Western Pacific to participate in an inter-country workshop to evaluate National Drug Policy implementation. Twenty-seven participants from 14 countries in the Region attended, from places as diverse as Australia, Brunei, China, Fiji, Laos, Malaysia, Solomon Island, the Philippines and Viet Nam. It was good to see that at least half of the workshop participants were women – a great change from 25 years ago when, as mentioned earlier, it was very much a man’s world in this professional area.

The workshop coincided with the 25th Anniversary of the WHO Model List of Essential Drugs and a half-day seminar on this topic started the workshop. I was very pleased to be given the opportunity to speak about the “WHO Model List of Essential Drugs/Programme – start and evolution: global perspective and reflections”. For me it was a great opportunity to hear about progress – but also new, challenging and difficult problems in Western Pacific countries. For example, I recalled my first visit in 1985 to Viet Nam and the many subsequent visits, to Mongolia in 1991 and 1992, Malaysia for the first time in 1977, to China in the early 90s, the Philippines, and to Australia where an important WHO-sponsored meeting on national drug policy took place in 1995. I learnt about the host country, Cambodia, and its fine essential drugs programme, developed in such a short time and after all the difficulties the country had endured. It was gratifying to report to the workshop that the essential drugs concept has become nearly universal over a 25-year period. More than 150 countries have a national list of essential medicines, major international agencies now base their catalogues on the WHO Model List, 101 countries had a national drug policy in 1999 (only five in 1985), and access to essential drugs has almost doubled between 1977 to 1997. But one-third of the world’s population still does not have regular access to essential medicines. This preoccupying fact means that there still is very much to do, and the essential medicines concept is therefore more valid than ever for the challenges of today, such as the emergence of new epidemics of HIV/AIDS, resistant malaria and tuberculosis. Another challenge is to expand and introduce the concept’s use in the private sector.

I am indeed very grateful to have had – and to continue to have – the opportunity and privilege to work with so many committed, knowledgeable and fine people in and outside WHO, and in countries. We work together towards the worthwhile cause of increased access to the most needed medicines, through the essential medicines concept and its core, an essential medicines list, modelled on WHO’s List – born at that first Expert Committee in 1977.

* Margaretha Helling-Borda worked for WHO for over 25 years and was Director of the Action Programme on Essential Medicines from 1994 until 1996. She is now a consultant on public health issues.

25 years of essential medicines: events around the world

I n Geneva on the 21st October 2002, the 25th anniversary of WHO’s Model List of Essential Medicines was marked by a day of debate led by international experts. Discussions focused on many aspects of what the List and the essential medicines concept mean to improving public health. One highlight was the keynote speech by WHO’s Director-General, re-inforcing the message of the concept’s continuing relevance (see p 12). But celebrations in Switzerland were being mirrored around the world, and here we mention just some of these memorable events.

The Christian Medical Association of India organized a press conference on the 25th October 2002, in New Delhi, to celebrate the anniversary. The Community Health Medicinal Unit of Patna “joined hands with WHO” by holding a two-day media orientation and awareness seminar on essential drugs and rational use of drugs. In Calcutta, West Bengal, the Community Development Medicinal Unit hosted a Commemorative Panel Discussion, which attracted an enthusiastic audience of doctors and pharmacists. And at the Mumbai International Training Course on Drug and Therapeutics Committees, an evening was devoted to a talk on 25 years of essential medicines.

“Twenty-five years is a long time for successful implementation of a programme. Yet, the problem of providing equitable and affordable access to safe, effective and quality-assured drugs to people around the world is so vast and so complex that the journey remains far from finished.”

Community Development Medicinal Unit, West Bengal, India.

In Rio de Janeiro, Brazil, the first day of the 3rd International Seminar on Access to Medicines – Fundamental Role of the State, a special session was held to commemorate the anniversary. Eighty participants from 18 countries were unanimous in recognising the universality and increased relevance of the essential medicines concept today.

Russia’s Pharmaceutical Newsletter featured a special article, “The purpose – ensuring access to medicines, to celebrate the jubilee, and the 12th WHO Model List of Essential Medicines”, See above for more about events in Cambodia.

Further information is available at: http://www.who.int/medicines/organization/par/anniversary.shtml
Personal reflections on 25 years of the WHO Model List of Essential Medicines

➢ RICHARD LAING

In late 2002, I was asked to join a group to write a review article on 25 years of the WHO Model List of Essential Medicines, which will be published in the Lancet in early 2003. As is normal with such articles, there are sections on history, data tables analysing the List over time and between countries, a discussion of the issues related to the List, and a conclusion about future perspectives. As I wrote the paper, I reflected on how my personal and professional life has been intertwined with the List and the essential medicines concept that the List generated.

First exposure

I was first exposed to the WHO Model List in 1979. I was working in a rural hospital in pre-Independence Zimbabwe, struggling with issues around drug selection and procurement. A visiting professor with a few students from the local university came out to visit the hospital and showed me a much photocopied 1977 List – the first ever compiled. I remember clearly being struck by what a great idea this was, and I started to use the List to guide our selections for procurement.

Soon after Independence, a small booklet called PEDLIZ (Proposed Essential Drugs List for Zimbabwe) was published and circulated widely. It was meant to be in circulation for 18 months but it took longer than that to produce the first EDLIZ (Essential Drug List for Zimbabwe). It was a fairly revolutionary document, as it combined treatment guidelines for common conditions with the List, and also it was a “levelled List”. This meant that drugs could be designated for use only at certain levels of the health system. The book was small enough to fit in your pocket and doctors in hospitals began to use it.

ZEDAP experiences

In 1986, I was involved in establishing ZEDAP (Zimbabwe Essential Drugs Action Programme). This programme revolved around implementing the various elements of the essential drugs concept, focusing on selection, management training and the promotion of rational drug use. One of our first activities was a nationwide survey, which revealed that while the EDLIZ was universally available, it was not being used. We discovered that this was because nurses working at primary health care facilities thought that the book was for “experts” and not for them. To dispel this perception we changed the way that the treatment guidelines and the List were developed. We involved end users in the process and found this to be very successful. This ZEDAP approach has now been duplicated in other countries.1

But we also involved the industry in the process of selecting the Essential Drug List! Naturally industry representatives had commercial incentives for advocating selection of specific drugs, and they were successful in including many “me-too” drugs. Our List ballooned to be one of the longest in the world. This experience convinced me of the need to have a “levelled List” to describe the dangers of involving pharmaceutical industry members in actual selection decisions. One other lesson we learned was the need to involve procurement staff in the process. For example, at one time we changed the regimen for treating gonorrhoea from penicillin to kanamycin and neglected to inform the supply staff. Very soon we were out of stock of kanamycin and the penicillin that had been procured was likely to expire.

INRUD and Managing Drug Supply 2

In 1990, I moved to the USA and began to coordinate the International Network for Rational Use of Drugs (INRUD) and work on the revision of the first edition of the standard text, Managing Drug Supply.2

One of my early activities at this time was to work with a young Brown University undergraduate on a revision of the first 15 years of the WHO Model List, which was published in the Lancet.3

One of the key insights from this review was that while the List was primarily used for public health purposes the selection of the List was done by clinical pharmacologists. We suggested that the membership of the WHO Expert Committee on the Use of Essential Drugs be broadened.

I was also working on revising the text of Managing Drug Supply. The section of the book on selection is fewer than 40 pages out of a total of over 800, and yet the key concepts that came to be implemented in the next decade are described in this section. The diagram of the “bull’s-eye with ears” to describe the levelled List and the diagram to show the many uses of an essential drugs list occurred here for the first time.

Eritrean experience

My first opportunity to put these new ideas into practice occurred when I was asked to assist the Eritrean Ministry of Health in the third revision of their national Essential Medicines List. A great deal of preparation went into this. All the members searching text books and price lists to synthesize the information. What became clear to me in this process is the need for standard comparisons are only valid within a therapeutic group of drugs, and that documented evidence will always triumph over undocumented experience. What also struck me was the need to make systematic reviews available in an accessible format to people making these difficult decisions.

Change from experience to evidence

In 2000 and 2001 I attended a series of meetings held in Geneva to address perceived problems in the process by which the WHO Model List was revised. The key concerns identified by WHO and the Expert Committee in November 1999 revolved around the need to base decisions on evidence rather than just experience, and to improve the transparency of the process and the speed at which the List would be published and translated. MSF had expressed concern that cost was being used as an absolute barrier to inclusion of expensive though effective drugs.

A meeting was organized by the Médecins Sans Frontières Access to Medicines Campaign and gave an additional opportunity for the NGO and academic community to make their case that changes were needed. Senior members of EDM attended the meeting, taking the many criticisms with a good grace, and agreeing that some changes in the process would be necessary.

The next meeting was an informal consultation organized by EDM and attended by Committee members, health economists, academics and field staff; there was also an open session with Member States. This was a very practical meeting at which the problems which existed in the process were examined and suggestions made for how they could be addressed. For many issues there was a
compromise between what was ideal and what was practical. The meeting resulted in a draft document which was circulated to Member States. Their comments were posted on the Web and a second round of comments was invited. Reading and responding to these was a very useful activity for me, as it forced me to reassess all of my assumptions about the Model List.

Finally, after all of these reviews, a document was submitted to the WHO Executive Board that finalised the process. The document, Procedure to update and disseminate the WHO Model List of Essential Medicines, is available at URL: http://www.who.int/medicines/organization/par/edl/procedures.shtml

Having been involved in this process, my faith in the value of having a global body to provide technical leadership was reaffirmed. The final document was a model process for any country.

2002-3 EML meetings

In 2002, I attended the meeting of the WHO Expert Committee on the Use of Essential Medicines, and it was a high point of my professional life. Here was a group of very experienced people from all over the world coming together to share their expertise for the good of the world. Many tough issues were debated, but in every discussion there was an emphasis on evidence and reaching the best possible decision for those who are sick, wherever they may be. There was an open session at which different proponents stated their points of view and these were carefully considered. At the meeting the process approved by WHO’s Executive Board was formalised into specific activities. The inclusion of antiretroviral drugs was presented using an evidence-based format. I left the meeting confident that the new processes could be implemented both at global and national levels.

Within hours of completion of the meeting the List was published on WHO’s medicines web site, and translations were made very quickly.

What lies ahead?

There are many challenges for both WHO and countries in translating the ideal of an essential medicines list produced from evidence-based treatment guidelines into reality. Who will do the work? Where is the evidence? Will countries have the capacity to revise the WHO Model List to meet their specific country needs?

But I remain confident that this grand idea of identifying a few essential medicines that should be made universally available will continue to energise people to work to ensure that sick people do not die or suffer from lack of access to medicines.

Finally, I wonder when the original essential medicines concept was proposed whether those involved could have realised how they were changing the world. I know that is has made a huge difference to my own and many other people’s lives. Long may it continue to do so.

Richard Laing is Associate Professor in the Department of International Health, Boston University School of Public Health, USA, and guest editor of this issue of the Essential Drugs Monitor.

References

Drug utilization in Latin America – the example of DURG-LA

In 2002, I attended the meeting of the WHO Expert Committee on the Use of Essential Medicines, and it was a high point of my professional life. Here was a group of very experienced people from all over the world coming together to share their expertise for the good of the world. Many tough issues were debated, but in every discussion there was an emphasis on evidence and reaching the best possible decision for those who are sick, wherever they may be. There was an open session at which different proponents stated their points of view and these were carefully considered. At the meeting the process approved by WHO’s Executive Board was formalised into specific activities. The inclusion of antiretroviral drugs was presented using an evidence-based format. I left the meeting confident that the new processes could be implemented both at global and national levels.

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Promoting drug utilization studies

Part of the initial core group participated in the first multicentre collaborative DU study, which was on self-medication and self-prescription, carried out in a sample of more than 240 pharmacies in 11 regions in six countries.

Since then the different participant groups have made presentations on a number of local and multicentre DU studies, involving nearly all DU methods. Methodologies include quantitative and qualitative analysis of drug prescription and consumption, and time trends of general patterns of drug use, together with analysis of specific areas of therapeutics. Some of these studies have been published in local or international journals, presenting DURG-LA’s message to a wider audience. Cuba provides one outstanding example of success, with more than 160 municipal centres for pharmacoepidemiology set up during the 1990s, run by general practitioners trained in the discipline. The Cuban network is involved in problem-oriented continued medical education and therapeutic information, drug utilization research and pharmacovigilance, with over 20,000 adverse drug reactions reported each year.

The third DURG-LA meeting in 1997 called for the creation of a permanent observatory on the quantitative and qualitative time trends of drug use in Latin America. By the end of the meeting the drafting of the data collection form to be used in this work was ready. A first evaluation was done, including qualitative and quantitative analyses of the 50 most consumed products (both by number and by value) in 11 countries (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, Nicaragua, Peru and Uruguay). Data were presented and discussed at the 1999 meeting (see Table 1), and will soon be published. It is hoped that funding will be found to set up a permanent observatory for the region.

Selecting essential information

In parallel with the exchange of information about participants’ research and support activities, DURG-LA groups have been discussing another area of concern – the new challenges of the information and telematics revolution in relation to clinical pharmacology. Teaching, drug information, drug selection at different levels of the health system, drug regulation, pharmacovigilance and research have all been debated. While scientific information grows and is more accessible, this does not necessarily mean that knowledge – the ability to appropriately interpret and use information for decision-making – increases accordingly; rather, an excess of information may contribute to confusion regarding therapeutic priorities. In addition, access to scientific literature is more difficult for many of the 400 million Spanish-speaking community because of language barriers.

To address these concerns SIETES (Sistema de Información Esencial en Terapéutica y Salud; System of essential information on therapeutics and health)
was created, and the system was presented at the Fourth DURG-LA meeting in 1998. It is a database of selected bibliographic references, more than 30% of them with an abstract and/or a comment in Spanish. SIETES contains manually selected articles, short communications, letters, editorials, review articles and news published in over 80 journals, including both the major general and specialty medical journals, and leading clinical pharmacology, therapeutics and pharmacoepidemiology journals. Between 5,000 and 6,000 new references are added each year. By March 2003, the SIETES database contained more than 60,000 references, which are retrievable by various means including use of key words (there are over 8,000), name of author, or name of journal. The abstract, the title, or both abstract and the text, etc.

SIETES, which receives support from WHO/EMD, covers all areas of therapeutics, with special focus on new drug evaluations, comparative drug evaluations, translation of evidence into clinical practice, natural history and epidemiology of diseases, research in drug utilization and pharmacoepidemiology, and methodology in all areas of clinical pharmacology. Also covered are international health, with a focus on global inequalities, pharmacoeconomics and cost-effectiveness, pharmacology teaching, training, continuing education in drug prescribing, drug regulation, drug policy, and news of interest, focusing on Spain and Latin America.

In 1999 a CD-ROM version was launched, and since 2001 SIETES can be accessed at: http://www.sietes.es. Participants in DURG-LA use it regularly, and promote its use among health professionals and students in their respective countries. Another successful initiative to promote information exchange was launched in 2000, when at EMD’s suggestion, the electronic discussion list e-farmacos was set up. This is the Spanish equivalent of the electronic list “E-Drug” (http://www.esentialdrugs.org) e-farmacos generates more than 400 messages per year and has nearly 300 subscribers.

Knowledge production and sharing
DURG-LA was born and has grown in response to changes in the pharmaceutical sector. The past 10 years has seen extraordinary growth in the world medicines market, but globally inequalities in access to medicines have deepened. The WTO TRIPS Agreements, the International Conference on Harmonisation, and consensus between the global pharmaceutical industry and the regulatory authorities of the main pharmaceutical markets may be seen to have contributed to accelerate market innovation and pharmaceutical company mergers. These companies may exert strong influence on health regulatory authorities and may have an increasing, sometimes overwhelming, presence in continuing education of physicians and other health professionals.

On the other hand, poor public investment in health, privatization of health systems and deregulation impose additional barriers to access to good quality essential medicines. Rational selection, prescribing and use are critical in improving access to drugs, but they involve not only providing the right drug at the correct dosage and duration of use, but also providing information and patient education on its use. DURG-LA works to ensure the updating of continuing education and training programmes both in universities and health care organizations using independent problem-oriented information. The group sees one of the most exciting challenges for clinical pharmacology as selecting those information materials which are essential, i.e., which help to build up knowledge oriented to satisfying health needs in a cost-effective, equitable and responsible way. Problem-oriented learning, as described in the very widely used Guide to Good Prescribing, is a basic methodological component of this strategy, and one which has been discussed at numerous DURG-LA meetings.

The group is going from strength to strength. To date more than 80 health professionals from 26 university departments, drug regulatory authorities, and hospital and primary care centres from 18 countries (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Panama, Peru, Spain, Uruguay, the US, and Venezuela) have attended DURG-LA meetings on a regular basis. And the group has attracted funding from a wide range of sources. In the global society, networking and knowledge sharing are essential in order to meet the research, teaching and service goals of clinical pharmacology. We believe that the most original contribution of the DURG-LA is its specific focus on sharing and transferring knowledge.

References
Global TB Drug Facility: improving access to TB drugs

Ian Smith, Jacob Kumaresan, Virginia Arnold

Despite the availability of effective treatment for over 50 years, tuberculosis (TB) continues to pose a serious threat to global health, with nearly 9 million new cases and 2 million deaths every year. In the early 1990s, WHO promoted DOTS (Directly observed treatment short-course) as an effective and multi-faceted TB control strategy. However, progress in expanding DOTS over the last decade has been inadequate, and WHO estimates that only 27% of people with infectious TB were diagnosed and treated in DOTS programmes in 2000. Without a rapid acceleration of DOTS expansion, the global targets of detecting 70% of people with infectious TB and curing 85% of those infected will not be met until 2013. Drug shortages are a significant barrier to rapid DOTS expansion, and these are frequent and serious in many parts of the world. They are often caused by financial constraints, inefficient drug procurement systems, poor quality drugs and lack of product standardisation.

The five components of DOTS:
- political commitment;
- diagnosis of infectious cases by smear microscopy;
- short course chemotherapy (directly observed for at least the first two months);
- uninterrupted drug supplies;
- monitoring of treatment outcome.

The Global TB Drug Facility (GDF) has been developed by the Global Partnership to Stop TB to address these issues, with the aim of increasing and securing access to high quality TB drugs. With initial funding from the Government of Canada, the GDF was formally launched on 24 March 2001, and is housed in WHO’s Stop TB Department. Further details of the GDF are available on the web site at: http://www.stoptb.org/GDF/

With its budget of US$250 million, the Fund aims to provide treatment for 10 million patients by 2005, averting deaths and reducing the risk of drug resistant TB. The GDF’s primary support mechanism is in the form of ‘grants in kind’ of first-line TB drugs. The Fund has established an independent mechanism for reviewing applications for support. The quantity of drugs provided is calculated on the basis of the number of additional patients to be treated, in accordance with a national DOTS expansion plan to reach the global targets by 2005.

In addition to grants in kind, the GDF direct procurement mechanism can support countries which have adequate funds for drugs, but lack efficient mechanisms for procurement and quality assurance. With the establishment of the Global Fund to Fight AIDS TB and Malaria (GFATM) as a major funding source for programmes to tackle these three diseases, it is likely that the direct procurement mechanism will gradually become the primary means of GDF support to countries.

Since its launch in 2001 the GDF has reviewed nearly 60 applications from countries, NGOs and states. Most of the 37 countries approved for support so far are in sub-Saharan Africa, and South East and Central Asia, with over 1.8 million patient treatments to be supplied. Drugs have been ordered for 30 countries, and delivered to 19. Four countries are also using the direct procurement mechanism.

The development and progress of this initiative has attracted much interest. Several of the lessons learnt through the GDF could be extended to help increase access to medicines for diseases other than TB, specifically HIV/AIDS and malaria. The lessons include the need to:

1. Link demand, supply and monitoring, to facilitate increased access while ensuring rational use.

By linking supply of drugs to objective assessments of technical soundness and operational feasibility, and by monitoring drug use, treatment outcomes and drug resistance, the GDF has greater confidence that drugs are being used appropriately.

2. Establish a ‘virtual organisation’ through a partnership of agencies.

The GDF has created a ‘virtual network’ of agencies around the world, each providing specific services to the GDF on a contractual or collaborative (no fee) basis. This network is coordinated by the GDF secretariat in Geneva. These include procurement, manufacturing, quality control, freight/shipping, monitoring and quality assurance. Through a competitive bidding process, GDF identifies organisations that provide efficient, quality and low cost services, and creates an effective partnership chain. The GDF currently has three funding agencies, five contractual partners and over 10 collaborative partners, in addition to the support provided by WHO regional and country offices.

3. Use product packaging as a means to simplify logistics, promote rational use by health workers, and enhance patient acceptability and compliance.

For many years TB treatment has been characterised by extraordinary diversity. There are currently 19 TB products for six drugs on the WHO Model Essential Medicines List (and many other products in use by national programmes). WHO guidelines include 11 treatment regimens in three treatment categories, with two recommended dosages (daily and intermittent), and three weight categories (not always consistent). Added to this complexity, there is a wide variety of packaging available: blisters, foil wrapped tablets, and containers of loose tablets. Not surprisingly, this results in confusion for managers, clinicians, nurses and patients.

The GDF aims to address this by providing a standardised catalogue of TB drugs, and it promotes Fixed-Dose Combination (FDC) tablets supplied in individual patient treatment packages. Four and two drug FDCs are the core products provided by the GDF, which will be provided as individual patient packs containing a full course of treatment (six to eight months). Using complete patient packs simplifies ordering and stock management, ensures that health workers provide the correct combination of tablets to patients, and can assist in promoting patient acceptance and adherence to treatment.

4. Use grants of drugs to catalyse improvements in the quality of health service provision.

By linking grants of drugs to programme performance, and encouraging partners to provide additional technical and financial assistance, the GDF has demonstrated its ability to catalyse improvements in several key areas which are concerns of the GDF, but do not fall within its mandate. These include planning for DOTS expansion, monitoring, and drug management.

5. Establish a diverse funding base.

In addition to the grant making mechanism, the GDF has also established a direct procurement mechanism, whereby countries and NGOs can use their own resources to buy high quality low cost drugs through the GDF. This mechanism may also be used by other funding partners (eg GFATM) for support to countries.

The Facility demonstrates many key aspects of the essential medicines concept. The TB drugs supplied are carefully selected with a view to improving treatment success. Procurement of the drugs through international mechanisms has reduced the price and increased the reliability of supplies. Distribution of the drugs has been through international and national organizations and the provision of blister packs and the use of Fixed-Dose Combination products has facilitated the process. Improved use of the products is facilitated by the supply of these drugs through a DOTS programme.

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Demystifying antiretroviral therapy in resource-poor settings

➢ TROY KASPER, DAVID COETZEE, FRANCOISE LOUIS, ANDREW BOULLE, KATHERINE HELDERBRAND

Few areas of public health have generated as much debate, controversy and protest in recent years as the drive to expand access to antiretroviral therapy – the drugs that have transformed AIDS from a death sentence to a chronic condition – in developing countries. Several years ago, it was a fulsome discussion: with a yearly cost of US$10,000 per patient, there was little possibility of widespread access in developing countries. But, largely as a result of a potent combination of generic competition and activism, prices have plummeted, with triple therapy now being available for as little as US$209 a year¹, causing a huge shift in the debate about availability.

Today, the debate centres on if antiretroviral therapy is possible in severely resource-poor settings and, increasingly, on the best ways to deliver these drugs. In a poor township 30 kilometers outside Cape Town, South Africa, Médecins Sans Frontières set out to grapple with both of these issues. Khayelitsha has around 500,000 inhabitants – a figure swollen by a steady influx of economic migrants from rural areas – of whom 30% are unemployed and more than 70% live in shacks. HIV seroprevalence rates at antenatal clinics are above 24%, having risen with shocking rapidity over the past 10 years.

The provincial government of the Western Cape decided to launch South Africa’s first government-run programme to prevent mother-to-child transmission (MTCT) of HIV in Khayelitsha. Zidovudine (AZT), first became available in the township’s two maternity wards in early 1999, and the programme has subsequently become one of the continent’s biggest, with more than 20,000 women having accepted testing, and over 3,000 having received antiretroviral therapy. Médecins Sans Frontières began supporting this MTCT programme in 1999, before opening clinics to offer treatment to the mothers, their infected children, and others with HIV from the broader community at three government primary health care centres in April 2000. Despite catering solely to those with HIV, the centres were called “infectious disease clinics”, out of a fear that labelling them HIV clinics would generate stigma and deter people from accessing services. This concern turned out to be entirely misplaced, as the community quickly branded them AIDS clinics, and nonetheless the queues steadily lengthened.

Treatment was initially limited to opportunistic infections – the conditions that arise with increasing frequency as HIV erodes the immune system’s capacity to ward off infections. But in May 2001, this was broadened to include antiretroviral therapy, making the project the first to use antiretrovirals in government health facilities outside the context of clinical trials.

This step was motivated by both humanitarian and public health principles: despite receiving quality care and prophylaxis for opportunistic infections, patients were getting sick and dying at unacceptable rates and so needed access to the only drugs that have been proven to suppress HIV infection and thus extend life. Further, there was a clear need to develop models for the delivery of antiretroviral therapy in South Africa. Thus the project was intended to demonstrate that the use of antiretroviral therapy at primary health care level was feasible, affordable and replicable.

Impressive survival rates

Preliminary analyses recently presented at the XIV International AIDS Conference in Barcelona provide strong indications that poor black women and men can indeed derive considerable benefit from antiretroviral therapy without undue toxicity. To date, 180 patients have been placed on this therapy, selected from among the 3,000 patients who have attended the MSF clinics in Khayelitsha (Box 1 gives details of the selection process). These patients were extremely sick when they began therapy, having a median CD4+ T cell count of 43, with as many patients initiating therapy with under 20 CD4+ T cells as above 100. In contrast, a typical CD4+ T cell count in a seronegative person would be in the range of 800–1200, and it is well-established that the risk of death increases significantly as the count drops below 50. Thus if untreated, the prognosis of this group of patients would be extremely poor, with death within a year the sad reality for most.

However, on antiretroviral therapy, their survival was impressive. After nine months of treatment, 88% of the patients were alive. The reason for this dramatic improvement is simple: patients with immune systems weakened by HIV infection are prone to get sick with infections that people with healthy immune systems can normally fight off. On antiretroviral therapy, the rates of these opportunistic infections were significantly reduced (see Graph 1). The reduction was particularly striking for tuberculosis, which is one of the major killers of people with HIV/AIDS in South Africa.

Reduction in opportunistic infections is largely attributable to the considerable improvements seen in immunologic status. After six months on therapy, the median increase in CD4+ T cell count was 143. This meant that while 54% of patients had below 50 CD4+ T cells at the start of therapy, only 2% were still below this level after six months; in contrast, none were above 200 at baseline, while at six months 53% had climbed above this important threshold. Interestingly, even patients with severely compromised immune systems at initiation of therapy experienced large improvements after beginning antiretroviral therapy, as shown in Graph 2. These improvements were possible because antiretroviral therapy effectively suppressed viral replication in the large majority of patients, thus allowing the immune system to recover, instead of having to concentrate its energy on fighting off HIV infection. This success was evident whether measuring using the “gold standard” of undetectable levels of viremia (less than 125 copies in the test available) or using a higher level that some have suggested is more appropriate to developing country contexts, as shown in Graph 3.

Three key factors

In analysing the programme’s success to date and assessing the possibilities of using it as a model in other settings, three key factors stand out.

First and most fundamentally, the drugs must be affordable. In this case, it meant beginning with brand-name drugs which, although considerably cheaper than in developed countries (or, indeed, in South Africa a few years earlier), were still much more expensive than generic versions produced in countries such as Brazil, India and Thailand. These alternatives were not registered in South Africa, but after authorisation to use Brazilian generic antiretrovirals was received from the South African Medicines Control Council, a change to Brazilian drugs has allowed twice as many patients to be treated.

The second key to success was the involvement of the community. This was facilitated by giving all treatment at primary health care level, rather than at a large reference hospital. Additionally, the community was integrally involved in the process of selecting patients for therapy, which played a major role in guaranteeing local ownership over the project as a whole (see Box 1 for more on the selection process).

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Finally, the involvement of the patients themselves has been essential. They are genuine partners in the project at a number of levels:

- At the political level, when politicians have questioned the validity of using antiretroviral therapy in resource-poor settings, it was the patients who responded, writing letters to newspapers and speaking out in the media.
- At the community level, they play an important role in the support groups run for patients on antiretroviral therapy, with those who have been on therapy for longer periods helping mentor those beginning. Also, a number of patients work with a South African NGO, the Treatment Action Campaign, on a major community education initiative.
- At the individual level, patients have educated themselves on the importance of adherence, allowing them to take responsibility for their own therapy, making it unnecessary to use medical staff to observe them taking their pills (see also Box 2).

The lessons

The project has revealed a number of important lessons:

First and foremost, antiretroviral therapy can be safely and effectively used in resource-poor settings, and the time has come to scale up from pilot projects to widespread access.

Managing patients on antiretroviral therapy is often easier than managing patients not taking antiretrovirals. Patients in advanced HIV infection are frequently ill with a variety of opportunistic infections, many of which are difficult to diagnose and treat, particularly at a primary health care level. In contrast, patients on antiretroviral therapy typically experience rapid improvement in their health, and particularly after the first few months on antiretroviral therapy (when the bulk of side-effects occur), they can be followed by nurses. In Khayelitsha, this was facilitated by the development of standardised tools to assist in the assessment and management of adverse events.

The availability of antiretroviral therapy bolsters the entire health system. South Africa – and many other sub-Saharan African countries – is experiencing a major loss of medical staff, in part as a result of poor working conditions and low morale engendered by the enormous influx of patients with HIV, many of whom are difficult to control despite the best efforts of the staff. When antiretrovirals are available, the staff’s role shifts back from care of the dying to being able to help patients return to good health, with an obvious improvement in staff morale.

Additionally, access to antiretroviral therapy provides an important role for patients to stay in the medical system: in Khayelitsha, not a single patient on antiretroviral therapy has been lost, in marked contrast with the general experience in this highly mobile township. Finally, the significant decrease in opportunistic infections (and the resultant need for hospitalizations) suggest that those who argue that antiretroviral therapy is unattainable, based on crude calculations of the cost of drugs, are missing a fundamental aspect of the provision of antiretroviral therapy. That is that a considerable percentage of the costs incurred by drug purchases can be offset by drops in hospitalisations and opportunistic infections. This has been demonstrated in Brazil21, and is quite likely to be true in South Africa, a country that spends an estimated R4 billion (approximately US$400 million) on care and treatment for HIV/AIDS. Research is ongoing in Khayelitsha to quantify the magnitude of this offsetting effect.

Finally, in contrast to those who argue that treatment and prevention are inextricably opposed and competing for resources, in Khayelitsha the synergy between treatment and prevention has been striking, with the availability of treatment providing a powerful incentive to live one’s status. It was thus no surprise that a recent survey of nine sites around South Africa found that Khayelitsha had the highest rates of HIV testing, and desire to be tested among those who had yet to be tested, as well as the highest levels of condom use.1

- Patients on antiretroviral therapy in Khayelitsha, South Africa.

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5. Toby Kasper was Head of Mission for MSF South Africa at the time this paper was written, and now works for the Global Fund to Fight AIDS Tuberculosis and Malaria. Francoise Louis works for MSF South Africa, PO Box 27401 Rhine Road, 8050 Cape Town, and David Coetzee, Andrew Boule and Katherine Hilderbrand work in the Department of Public Health and Primary Health Care, University of Cape Town, South Africa.


The issue of how to ensure that antiretroviral therapy is taken regularly and appropriately has generated considerable discussion and controversy. Some even suggest that the use of antiretroviral therapy in poor countries will only lead to the widespread development of resistance. They advocate either that resources are not put into making the drugs available or that they are only administered under strictly controlled conditions, such as in the presence of medical staff (along the lines of the DOTS model for TB, although the comparison is complicated by the greater frequency of dosing of antiretroviral therapy and the fact that it is life-long rather than of a limited duration). However, in Khayelitsha, an approach centred on educating patients and empowering them to be actively involved in the treatment programme has yielded very positive results.

This begins with the careful selection of a regimen that is easy to take – for example a combination of nevirapine and co-formulated AZT/3TC, which amounts to two pills twice a day – and setting the health care facilities within easy reach of the patients (for example, at primary health care level). Once patients begin therapy (after an educational process), a tripartite programme supports adherence:

- Individual support is available in the form of trained counsellors available during clinic hours to answer questions, and, more formally, through “treatment assistants,” a household member or neighbour whom each candidate for therapy is requested to identify who can provide support on adherence.
- Peer support comes in the form of support groups run solely for patients on antiretroviral therapy, and which serve both as valuable spaces for patients to discuss barriers to adherence with others sharing similar experiences and as a forum for ongoing education.
- Educational materials are provided to help patients fully appreciate the risks and benefits of antiretroviral therapy, and understand the importance of adherence.

Research is ongoing to quantify the levels of adherence, but the dramatic improvements in the surrogate markers of changes in viral load and CD4+ T cell counts strongly suggest that adherence is good.
CBIA: improving the quality of self-medication through mothers’ active learning

SRI SURYAWATI*

ELF-MEDICATION is beneficial for the treatment of minor ailments only if there is sufficient knowledge about the correct use of the medicines. There are at least five pieces of information required for appropriate self-medication: information about the active compound; indication; dosage and administration; side-effects; and contraindications. However, a survey carried out in Yogyakarta, Indonesia, in 1993 showed that the level of knowledge mothers had about medicine was considered inadequate to support safe and effective self-medication (see Figure 1).

**Potential for disaster**

The most common lack of information concerns the active compound. Mothers only know the brand-name drugs marketed for a certain symptom, and therefore, they are sensitive to drug advertisements. The direct effect of this lack of knowledge can be seen in household drug consumption patterns, where several brand-names with the same active compound are used concurrently. This is a waste of money, yet ironically, many studies show that a key factor motivating self-medication is cost-efficiency. But of course the impact of self-medication cannot only be measured in financial terms. Figure 1 shows that there is ignorance of side-effects and contraindications, with the risk of using the drugs that they commonly use, and to increase drug procurement efficiency in households.

**Conducting CBIA sessions**

The CBIA module uses small-group (6–8 people), interactive discussions. The process can be incorporated in regular meetings of women’s grass roots organizations, as well as in other arranged gatherings. Not only mothers but fathers and teenagers can all participate. Community gathering points, such as houses, mosques and village offices, are excellent for conducting CBIA. Students or others familiar with the contents of drug packages can be recruited as tutors, and it is also possible to invite tutors from the target groups. Before carrying out the activity, tutors familiarise themselves with the problems relating to each drug package being used in the session. A pharmacist or physician can be invited as a resource person. Each participant is requested to bring all the medicines they have at home, and in addition re-use several sets of medicines to be provided. Each group works with one set of around 30–40 preparations in original packages, with price labels, consisting of several classes of medicine, such as antipyretics/analgesics, vitamins/minerals and cough remedies.

The activity usually takes 2–3 hours. A tutor begins with an introduction on the advantages/disadvantages of self-medication, and then participants are requested to form small groups. Using the medicines, they observe where they can find information on active ingredients, group together over-the-counter drugs based on their main ingredients (not the indications), and then discuss the findings.

**Topics to cover**

Discussion should, as a minimum, cover the following points, (although experience shows that participants can identify others, and sometimes come up with surprising findings):

- Active ingredients are always stated on the package, and this information is hardly ever found in drug advertisements. Incomplete and unclear information in drug advertisements can be identified by consulting the drug package.
- Brand names may be sold in many different forms, e.g., syrup, tablet, etc., with exactly the same active compound. Participants should learn the difference between brand names with “Forte” or “Plus” included, and their conventional forms.
- Though the brand names for adults and children are often similar, the active ingredients are sometimes different. Participants should be aware of those differences.
- Prices vary between the drug forms, for example, syrup may be 10 times more expensive than tablets.
- Drug purchasing can be more efficient if people think about the prices in relation to the dose. Brand names with “Forte” may be several times more expensive than the conventional one, although there is only a slight difference in the amount of the active ingredient.
- For commercial purposes, the names of active ingredients are often hidden in other names, which are not commonly known by the public. For example, 1,3,7 trimethyl-xanthine is used for caffeine and paracetamido-phenol for paracetamol.

After completing the discussion, participants are requested to collect the information needed for appropriate self-medication: the active ingredient, indication, dosage and administration, side-effects and contraindications. At the same time, participants examine the clarity and completeness of information found on each package. The expected impact of this exercise is to encourage participants to read all information critically.

**Is CBIA effective?**

CBIA has been field-tested and evaluated in a controlled study, in comparison with a large seminar, which is a more common form of education. One hundred and twelve mothers of low to moderate levels of education were recruited for the study, and randomly assigned to three groups. Group A received CBIA, Group B attended a large seminar to train them in the same skills, and Group C served as the control. The results showed that the scores of the five main components of knowledge increased significantly in both Group A (4.9±0.3 to 8.3±0.2; P<.001) and Group B (4.5±0.6 to 6.4±0.3; P<.05), in comparison to controls, where there was no change (4.2±0.4 to 4.8±0.3; NS). In addition, the increase in knowledge in the CBIA group was significantly greater (P<.02) than among mothers attending

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**Figure 1** Percentage of mothers who know the components of information of the medicines most commonly used in their households

**Figure 2** Average score of knowledge on the medicines most commonly used in their households

**Figure 3** Average number of brandnames procured in household in one month

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*SRI SURYAWATI*

(For Cara Belajar Ibu Aktif ( Mothers’ Active Learning Method). It is an educational module developed by the Department of Clinical Pharmacology, Gadjah Mada University, Yogyakarta, in 1993, aimed at improving mothers’ knowledge and skills to select non-prescribed or over-the-counter medicines. CBIA uses a problem-based approach and self-learning process. Information printed on the pharmaceutical package is used as training material. The training is intended to empower mothers to seek and critically assess information on the drugs that they commonly use, and to increase drug procurement efficiency in households.

CBIA: taking up the challenge

CBIA is an abbreviation for Cara Belajar Ibu Aktif (Mothers’ Active Learning Method). It is an educational module developed by the Department of Clinical Pharmacology, Gadjah Mada University, Yogyakarta, in 1993, aimed at improving mothers’ knowledge and skills to select non-prescribed or over-the-counter medicines. CBIA uses a problem-based approach and self-learning process. Information printed on the pharmaceutical package is used as training material. The training is intended to empower mothers to seek and critically assess information on the drugs that they commonly use, and to increase drug procurement efficiency in households.

An innovative public education strategy

If more information is needed to improve the quality of self-medication, efforts must be made to equip users with knowledge about the five components listed above. Many types of public education have been tried, such as campaigns through the mass media, seminars and articles in magazines, but their impact has been limited. In a large country like Indonesia, with over 200 million people, it is impossible to rely on the limited drug information services available. The community should be empowered and equipped with skills to seek information rapidly and correctly, using any available source of information. In short, there is an urgent need for an innovative public education strategy that promotes active learning; facilitates self-learning; empowers the community with skills and a critical attitude in seeking information; and creates information-seeking behaviour. The learning process should also be transferable.

When the necessary information is already available on drug packaging, the question is: why is it being wasted? As this information is approved by the Drug Regulatory Authority, it is considered reliable, and if it is used optimally people will have the facts they need for appropriate self-medication.

The results showed that the scores of the five main components of knowledge increased significantly in both Group A (4.9±0.3 to 8.3±0.2; P<.001) and Group B (4.5±0.6 to 6.4±0.3; P<.05), in comparison to controls, where there was no change (4.2±0.4 to 4.8±0.3; NS). In addition, the increase in knowledge in the CBIA group was significantly greater (P<.02) than among mothers attending.
Indian hospital drug use study shows need to improve prescribing

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Taking action
An intervention programme to change doctors’ prescribing behaviour is underway at Osmania General Hospital, through educational activities such as lectures, seminars, group teaching and distribution of printed material to improve the use of corticosteroids and ranitidine. Already another Indian study has shown the benefits of such educational interventions to improve prescribing. In a drug utilization study done in Government Headquarter Hospitals, Ooty, 46% of patients admitted were prescribed ranitidine. After an educational programme reopening the study was noticed after one year.1

Reference

Table 1
Top 20 drugs used in Osmania General Hospital (Drug use is expressed as number of DDDs/1000 PD)

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1. dexamethasone</td>
<td>430.98</td>
<td>ranitidine</td>
<td>488.92</td>
</tr>
<tr>
<td>2. ranitidine</td>
<td>380.42</td>
<td>dexamethasone</td>
<td>442.22</td>
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<tr>
<td>3. diclofenac</td>
<td>330.42</td>
<td>deflazacor</td>
<td>370.12</td>
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<tr>
<td>4. normal saline</td>
<td>287.73</td>
<td>normal saline</td>
<td>296.34</td>
</tr>
<tr>
<td>5. ampicillin</td>
<td>254.58</td>
<td>ampicillin</td>
<td>243.88</td>
</tr>
<tr>
<td>6. ringer’s lactate</td>
<td>238.14</td>
<td>ringer’s lactate</td>
<td>227.17</td>
</tr>
<tr>
<td>7. dextrose 5%</td>
<td>196.25</td>
<td>dextrose 5%</td>
<td>190.38</td>
</tr>
<tr>
<td>8. dextrose saline</td>
<td>172.19</td>
<td>dextrose saline</td>
<td>186.20</td>
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<tr>
<td>9. furosemide</td>
<td>146.61</td>
<td>furosemide</td>
<td>141.50</td>
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<tr>
<td>10. atropine</td>
<td>145.71</td>
<td>furosemide</td>
<td>132.32</td>
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<tr>
<td>11. ciprofloxacin</td>
<td>140.10</td>
<td>metronidazole</td>
<td>102.6</td>
</tr>
<tr>
<td>12. ibuprofen</td>
<td>117.61</td>
<td>CPM</td>
<td>102.6</td>
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<tr>
<td>13. gentamycin</td>
<td>106.18</td>
<td>paracetamol</td>
<td>103.18</td>
</tr>
<tr>
<td>14. metronidazole</td>
<td>102.54</td>
<td>gentamycin</td>
<td>101.18</td>
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<tr>
<td>15. ibuprofen</td>
<td>95.43</td>
<td>vitamin C</td>
<td>99.96</td>
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<td>16. dextrose 25%</td>
<td>93.09</td>
<td>ibuprofen</td>
<td>72.71</td>
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<tr>
<td>17. paracetamol</td>
<td>90.13</td>
<td>hydrocortisone</td>
<td>67.71</td>
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<tr>
<td>18. ferrous sulfate</td>
<td>72.58</td>
<td>atropine</td>
<td>59.86</td>
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<td>19. vitamin C</td>
<td>61.60</td>
<td>phenytoin</td>
<td>54.48</td>
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<tr>
<td>20. hydrocortisone</td>
<td>58.44</td>
<td>ferrous sulfate</td>
<td>54.39</td>
</tr>
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</table>

TOTAL USE OF DRUGS
4426.66
4484.35

References

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Evidence-based selection

Rational drug use depends heavily on selecting essential medicines that reflect the best combination of efficacy, safety and comparative cost-effectiveness. Their selection should be evidence-based and free from commercial influence. In 2002, WHO introduced new procedures aimed at establishing a model selection process for updating its Model List of Essential Medicines. This new process now includes tying selection directly to treatment guidelines, preparing systematic reviews of the clinical evidence for proposed choices, and making this evidence publicly available in advance of decision-making meetings. This means that there is an opportunity for all stakeholders (including industry and patient advocacy groups) to comment on proposed changes in the List, before taking the final decisions in a closed meeting of independent experts, and publicly documenting the reasons for each decision.

Effective use of medicines also depends on the actions of health care providers, formal and informal distribution channels, the pharmaceutical industry and the public. Over the last decade, through the efforts of the International Network for Rational Use of Drugs (INRUD), and a host of operational research initiatives, much has been learned about improving the use of medicines. For example, it has been shown that interventions such as unfocused drug treatment, treatment guidelines without active follow-up, and non-interactive communication efforts have no measurable impact. On the other hand, standard treatment guidelines supported by effective training programmes have been shown to reduce mortality from acute respiratory infections in children. Targeted training of licensed drug sellers can increase dispensing of effective treatment and reduce dispensing of unsafe ones for diarrhoea and acute respiratory infections; and interactive group discussions involving prescribers and mothers can dramatically reduce the overuse of injections. The challenge for health policy-makers is to learn from these lessons and act accordingly.

It is estimated that only two-thirds of developing country populations have some form of access to essential medicines. For those countries, pharmaceuticals can represent as much as 40% of the health budget. Because of the considerable impact on the quality of care and the cost of treatment, the selection of essential medicines, and their appropriate use, constitute the most effective approach to improving equitable access to health care. This principle also applies to industrialised countries, where details of medical insurance coverage are always important concerns for the public, and central to policy debates. For example, in Europe and North America annual medicine expenditure increases of 10–18% in 1999–2001 are raising concerns among public reimbursement schemes and health insurers. Prepayment and insurance schemes have all found that application of the essential medicines concept is critical to the financial viability of such programmes — no insurance system can afford to reimburse all medicines available on the market.

The WHO Model Formulary of Essential Medicines, recently updated to include 12 essential antiretroviral medicines for the treatment of HIV/AIDS, focuses on pharmaceutical efforts on priority conditions and quality medicines that are the most cost-effective, safe and affordable possible. For instance, the vast majority of medicines contained in the Model List are well-known and well-established pharmaceuticals which are off patent and available from many sources.

Adapting to national needs

The new Formulary is primarily intended as a model for national governments and institutions, to be used as a basis for creating their own national formularies. It is particularly relevant for developing countries, where commercial and promotional materials are often the only available source of drug information for health workers, prescribers and patients. The WHO Formulary may also be useful for individual prescribers — and for this reason it is available at reduced cost for developing countries.

The Model List of Essential Medicines and the Model Formulary constitute the backbone of the new WHO Essential Medicines Library (www.who.int/mediacentre), which is being developed. Visitors to this site will find the reasons drugs were included on the Model List, the underlying evidence, price information and normative information, such as International Nonproprietary Names (INN), International Pharmacopoeia monographs, and the Anatomical, Therapeutic and Chemical (ATC) and Defined Daily Dose (DDD) classifications. To make access to information as wide as possible, the WHO Model Formulary is available both in PDF format and as a searchable database. A CD-ROM version is in preparation.

National and institutional committees can also decide to use the WHO Model Formulary as a starting point for their own formularies. Rather than starting from scratch they can use the existing WHO text and adapt this to their local conditions. They can do this by eliminating medicines which do not figure on their national list, entering other medicines from their national list, and adding specific information on national products, brand names, product specifications and prices. It should be stressed, however, that the availability of this WHO text should not be used to cut short the development process of a national or institutional formulary. An essential condition for the acceptability and use of a formulary is a development and review process which involves wide consultation among future users. Formulary committees interested in this approach should contact their national or regional WHO offices for advice.


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ESSENTIAL DRUGS MONITOR

ANNIVERSARY ISSUE

WHO’s new Model Formulary — promoting consumer rights and patient safety

In its efforts to promote safe and cost-effective use of medicines, WHO has recently released the first edition of the WHO Model Formulary. The Formulary is the first global publication to give comprehensive information on all 325 medicines contained in the WHO Model List of Essential Medicines. It presents information on the recommended use, dosage, adverse effects, contraindications and warnings of these medicines. Correct use of this tool will improve patient safety and limit substantial medical spending.

A look at some statistics shows why the need for a formulary is so great. Bad prescribing habits are very common in all countries of the world and overuse, under-use and misuse of medicines remain widespread. For example, 30–60% of patients in primary health care centres receive antibiotics (perhaps twice what is clinically needed); 25–75% of antibiotic prescriptions in teaching hospitals is clinically needed; 25–75% of antibiotic prescriptions in teaching hospitals are not sterile; and many of these are not even needed. Only one in two countries actively regulate drug promotion, and less than 50% of people with chronic illnesses, such as diabetes and hypertension, adhere to prescribed treatment. Ineffective and unsafe treatment leads to exacerbation or prolongation of illness and harm to the patient. In addition, inappropriate treatment increases the costs to the patient, the insurance system or the government.