Managing drug supply

Most leading causes of death and disability in developing countries can be prevented, treated or at least alleviated with cost-effective essential drugs. Despite this fact hundreds of millions of people do not have access to essential drugs.

Although the relative frequencies of specific illnesses vary among countries, health services throughout the world are presented with a fairly common set of health problems for which essential drugs have an important role. Mortality figures across developing regions reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used. And even in industrialised countries escalating costs of health care have placed evidence-based and efficient drug supply management high on the agenda. Good drug supply management is an essential component of effective and affordable health care services globally.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid 1950s to the mid 1970s basic drug management concepts began to evolve in countries as diverse as Cuba, Norway, Papua New Guinea, Peru and Sri Lanka.

Over the last 20 years countries have acquired considerable experience in managing drug supply. Broad lessons that have emerged from this experience include: that national drug policy provides a sound foundation for managing drug supply; that wise drug selection underlies all other improvements; that rational drug use requires more than drug information; and that systematic assessment and monitoring are essential.

Over the years the Monitor has aimed to share both positive and negative experiences in this critical field. This issue reports on the strengths and constraints of some national, provincial and local initiatives to rationalise drug supply and use. It also draws on material published in the comprehensive second edition of Managing Drug Supply, issued in collaboration with the Action Programme on Essential Drugs. This publication, which has long been a fundamental tool in many countries, now compiles state of the art knowledge, experience and guidance on every aspect of the drug management cycle. Watch out in future issues of the Monitor for a new “how to” section drawn from Managing Drug Supply and from accompanying training materials currently being developed.

What works best in drug supply has no simple answer. As the article posing this question on p.7 concludes, it will never be possible to state that one particular system is “the best”. Each country brings unique political, economic and geographical factors to the equation. And to weigh the pros and cons of one drug supply system against another cannot be properly done from a global perspective without detailed study. The Action Programme is embarking on just such a multicountry study to examine in depth at the country level the outcomes of the drug supply systems in use. This study will look at the advantages and disadvantages of the systems and the factors which influence the level of success or failure.

However, what the experiences of countless countries and programmes do demonstrate is that substantive and sustainable improvements in the supply and use of drugs are possible. But an equal or greater number of negative experiences show that success is by no means assured. Clear goals, sound plans, effective implementation and monitoring of performance are essential ingredients in pharmaceutical sector development. And we can be sure that if changes in a drug supply system are not based on a careful analysis of the underlying causes for the weaknesses of the existing system then they are unlikely to produce the desired outcome. Systems chosen, for example, because they function in a “successful” market economy may not prove the solution to the drug supply problems faced in the context of a developing country.
Health reform and drug financing

Health sector reform is a process aimed at improving equity, quality and efficiency in the health sector through changes in the organization and financing of health services. In this context, the role of WHO today is to explore and promote ways of organizing health services which respond better to the objectives of equity, quality and efficiency.

Nearly every aspect of national drug policy and pharmaceutical sector development is directly or indirectly affected by health reform initiatives. An addition to DAP's Health Economics and Drugs Series, which is summarised here, focuses primarily on certain financial aspects of health reform.

Drug financing reforms

Governments have the responsibility to ensure that drug financing mechanisms are managed in such a way as to achieve equity of access to essential drugs. Financing mechanisms include public financing, health insurance, user fees, donor financing and development loans.

Public financing

Some public spending will always be needed to ensure access to drugs by the poorest in society; to ensure provision of drugs for tuberculosis, sexually transmitted diseases and other communicable diseases; and to ensure care for target groups, such as mothers and children. As a share of national economic output (GDP), public spending on health in developing countries is one-quarter to one-half that of industrialised countries. Health financing reform should improve the use of public resources, but it should not be aimed to further reduce public spending on health.

The level of public commitment for financing health care and drugs should be a matter of explicit public policy, based on an analysis of health care needs and financing options. Policy makers, managers responsible for health care financing, and essential drugs managers should be familiar with the methods for analysing public financing for drugs and for planning public expenditures for drugs.

Health insurance

Formal health insurance and various informal community insurance programmes represent a growing source of health and drug financing in transitional and developing countries. The experience of many countries has shown that compulsory social insurance can be the critical step to a more equitable health care system. It must be recognised, however, that some developing countries will have difficulties in implementing widespread insurance coverage in the short-term for a number of reasons, including limited formal employment and weak state mechanisms.

There are benefits in providing pharmaceutical coverage together with health care coverage although challenges, such as difficulties in tracking prescriptions, exist. Policy makers and managers need to be fully informed about the value of insurance coverage, alternative mechanisms for providing pharmaceutical benefits, and methods to ensure quality of care, while controlling costs.

User charges

User charges are increasingly being implemented by governments and local communities in countries at all levels of development, both to supplement general government revenues or insurance premiums, and to help control use (see Box 1). Often, however, such programmes have not learned from past experiences, are not well managed, and, as a result, access shows no improvement, revenue replaces rather than supplements government funding, and drugs are overprescribed.

User fees can complement government allocations for pharmaceuticals, but should not replace them. Future efforts need to ensure that the lessons from existing research and actual experience are applied to the design, implementation and monitoring of user fee programmes to ensure that access to drugs does improve, and that rational use does not suffer. When fee mechanisms are instituted at a national level, a top-down approach, starting with major national incentives. Changes may include incorporation of competitive mechanisms within the public sector, decentralization of health service provision, and a greater role for NGOs and other non commercial “third sector” entities.

Affordability and efficiency

The appropriate choice and use of drugs is the key to the achievement of pharmaceutical policy objectives and should lead to greater economic efficiency in the health sector. A variety of cost-control measures have been applied at different levels within public and private drug supply systems. The appropriateness of different measures varies with the particular health system.

Affordability of drugs for consumers is a public health concern. Private expenditures for pharmaceuticals in developing countries typically account for 50 to 90% of all spending on drugs. Even for rural populations and the urban poor, the most common source of drugs is direct out-of-pocket purchase from the private market.

Use of generic drugs and price controls are the two most commonly pursued mechanisms to promote affordability. Generic competition with price information is effective in this regard. But generic drug markets have grown very slowly in most countries. The strength of public policy commitment to generic drugs is a major determinant of the growth of generic markets. Four essential factors for success appear to be supportive legislation and regulation, reliable quality assurance, professional and public acceptance, and economic incentives (see Box 2).

Various mechanisms exist to control producer prices and distribution margins. Wholesale and dispensing margins based on cost plus a fixed professional fee provide a better incentive for rational dispensing than margins based only on a percentage. The effects of pharmaceutical price controls have been mixed. Paradoxically, a number of developing countries are relaxing price controls on drugs, while governments in industrialised countries are becoming increasingly concerned with pharmaceutical prices. With or without price controls, price transparency should be a central objective.

Organizational reforms

Reforms to financing systems cannot be made without organizational reforms that should match the structure of the public and private sectors to their responsibilities in fulfilling policy objectives. Changes may include incorporation of competitive mechanisms within the public sector, decentralization of health service provision, and a greater role for NGOs and other non commercial “third sector” entities.
Box 1

Observations from user fee experiences in Africa

Revenue generation
In 34 countries with user charges (out of 51 surveyed), the revenue generated by these fees was generally a very small share of public recurrent health expenditures (almost always less than 10%). However, for some of the systems which have remained in place over several years, modest improvements in this percentage have been observed.

Recovery of funds
Of the community drug funds operating in 17 Sub-Saharan African countries (Benin, Chad, Niger, Sierra Leone, and Zaire are some examples), the success rate for the recovery of funds was about 50% with positive margins ranging from 49–83% (depending on the margin type).

Experiences of the Central African Republic indicate that public health centres which were self-managed, controlled their own drug sales, and had fees for all services, had higher cost-recovery rates than centres which did not exert as much control over drug sales and offered a range of free services.

Utilisation of facilities and quality of care
Demand for community health services which have user fees does seem to increase if quality, as measured by the availability of drugs, also increases. This is particularly true if accessing the next best care alternative involves significant time and travel costs.

However, because user fees do not always succeed in making drugs more available, and other factors are also involved in utilisation, decreases in use of health facilities are also frequently observed. Utilisation of community health centres, after the adoption of revolving drug funds, was noted to have increased in seven countries, and to have decreased in four.

Equity and affordability
Studies of health care use following the charging of fees show that the poor are more likely than other segments of the population to treat price increases as deterrents to accessing services.

Of 25 Sub-Saharan countries with cost-recovery programmes, it appears that only one (Zimbabwe) had an official policy specifying national income ceiling criteria which would allow exemptions for the poor. Fourteen other countries indicated that exemptions for the indigent are permitted but did not provide criteria. The remaining 10 countries relied primarily on local and ad hoc measures for providing exemptions.

Exemptions based on income are difficult to formulate and implement where formal employment is limited. In some countries, the fairness of certain exemption policies remains questionable. Therefore, equity remains a critical issue. Easy-to-use, reliable methods for determining exemptions in mechanisms charging user-fees are not readily available.

Competitive mechanisms in public drug supply

Alternative drug supply strategies for public drug supply include the traditional central medical stores system, autonomous supply agencies, the direct delivery system, the prime vendor system and fully private supply. Several of these systems involve different public-private roles and rely on greater competition to improve efficiency.

The practical results of different mechanisms for public drug supply have yet to be clearly documented. Governments seeking to improve efficiency in public drug supply should do so with the knowledge that a number of options exist and that success depends not only on choosing an appropriate option, but also on the way in which the option is implemented.

Decentralisation and integration in drug supply systems

Control and decision making in health systems is increasingly being decentralised. For drugs, decentralisation may improve quantification of drug requirements, inventory control, prescribing and dispensing. But some degree of centralisation may still be required for functions such as drug registration, development of essential drugs lists and standard treatments, quality assurance and bulk tendering.

Efforts are also being made in some countries to integrate supply systems for family planning, tuberculosis control, and other “vertical” programmes into essential drugs programmes. Resource-intensive functions such as procurement, quality assurance, storage and physical distribution may be integrated under the essential drugs programme, while financing, quantification of needs and monitoring may remain under the management of the national control programme.

Role of the “third sector”

Discussions of public and private roles in the pharmaceutical sector should not ignore the vital role of the “third sector”. This includes NGOs’ health services, not-for-profit essential drugs supply agencies, professional associations, consumer groups, and specialised NGOs such as some national pharmacopoeial organizations.

Recently some governments have explored ways of carrying out “public” functions such as standard-setting or quality control testing through innovative arrangements with third sector institutions. The various roles played by the third sector should be clearly acknowledged by policy makers, and ways to best support and involve the sector should be explored.

Health Reform and Drug Financing: Selected Topics is available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

References

Table 1

Public health and drug expenditures for selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Total public health expenditures</th>
<th>Total public drug expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>as % GNP per capita (US$)</td>
<td>as % health budget per capita (US$)</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>3.8% 44.76</td>
<td>18.4% 8.24</td>
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<tr>
<td>Chad</td>
<td>0.6% 1.06</td>
<td>4.5% 0.05</td>
</tr>
<tr>
<td>Colombia</td>
<td>1.6% 20.03</td>
<td>18.0% 3.61</td>
</tr>
<tr>
<td>Guinea</td>
<td>0.4% 1.73</td>
<td>15.8% 0.27</td>
</tr>
<tr>
<td>India (Andhra Pradesh)</td>
<td>3.2% 1.93</td>
<td>6.8% 0.13</td>
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<tr>
<td>Mali</td>
<td>0.4% 0.74</td>
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</tr>
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<td>Sri Lanka</td>
<td>1.5% 8.58</td>
<td>15.6% 1.34</td>
</tr>
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<td>Thailand</td>
<td>2.0% 13.65</td>
<td>5.6% 1.89</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>1.1% 2.32</td>
<td>20.0% 0.46</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>2.8% 12.43</td>
<td>36.1% 4.49</td>
</tr>
</tbody>
</table>

Source: WHO/DAP. Public–private roles in the pharmaceutical sector. Geneva: World Health Organization, 1997. Data are from the most recent year available, generally in the early 1990s. Figures from Chad, Colombia, Sri Lanka and Viet Nam are still considered preliminary.

Box 2

Mechanisms for promoting generic drug use

- required use of generic names in all education and training of health professionals
- brand generic and generic-brand names indicated as available to health professionals
- required use of generic names in clinical manuals, drug bulletins, and other publications
- widespread promotional campaigns targeting consumers and professionals

Reliable quality assurance capacity
- development of substitution, non substitution lists
- procedures to demonstrate bioequivalence
- national quality assurance capability
- national drug manufacturer and drug outlet inspection capacity
- requirement that labels and drug information contain generic names

Economic incentives
- public and professional price information
- reference pricing for reimbursement programmes
- retail price controls that favour generic dispensing
- support by social and private health insurance organizations
- incentives for generic drug industry
- trade-offs with industry (reduced price regulation, increased patent protection)

Managing Drug Supply

How “topping-up” improved drug management at a small clinic in Ghana

Daniel Sekyere Marfo*

The adoption of the top-up system of drug supply has led to an improvement in drug supply management at the Bank of Ghana Clinic in Accra. As a result a small project that started with injectables has now been extended to other items with equal success.

The Bank of Ghana Clinic is a fairly small quasi-Government outpatient health facility. It was established in June 1988, mainly to provide quality health care (in terms of economy, efficiency, effectiveness and equity) for the Bank’s staff and their dependants. It is also open to a small group of non entitled but authorised paying patients – mostly expatriates and tourists. The clinic’s professional staff is made up of two doctors, one pharmacist, three pharmacy technicians, 10 nurses, one medical laboratory technologist, three medical laboratory technicians and a part-time physiotherapist.

The clinic is organized on a “functional unit” basis with medical consulting, nursing, pharmacy, medical laboratory and support units. It is funded entirely by annual budgetary allocations from the Bank of Ghana. Treatment, including drugs, is free for all members of staff and their dependants. Patients receive drugs of proven efficacy, purchased from reliable sources. They are counselled against abuse and misuse, and possible or expected adverse effects of drug therapy. They are also encouraged to complete the full course of treatment, to follow instructions correctly and to refrain from sharing drugs with colleagues, relations or friends. Additional written instructions and labels are provided to ensure adherence to treatment, successful outcome and patient safety. The pharmacy unit, which dispenses about 17,000 prescriptions per annum, is also responsible for managing medical stocks at the health facility, including selection, sourcing, procurement, storage and distribution through the system.

With the exception of injectables, all other dosage forms are supplied to patients directly on prescription from the pharmacy, as described earlier. Injectables are first supplied to the injection room where he or she assists in up-dating records of stock levels and send the forms to the pharmacy. A pharmacy technician sends the week’s supply of drugs, is free for all members of staff and their dependants. Patients receive drugs of proven efficacy, purchased from reliable sources. They are counselled against abuse and misuse, and possible or expected adverse effects of drug therapy. They are also encouraged to complete the full course of treatment, to follow instructions correctly and to refrain from sharing drugs with colleagues, relations or friends. Additional written instructions and labels are provided to ensure adherence to treatment, successful outcome and patient safety. The pharmacy unit, which dispenses about 17,000 prescriptions per annum, is also responsible for managing medical stocks at the health facility, including selection, sourcing, procurement, storage and distribution through the system.

With the exception of injectables, all other dosage forms are supplied to patients directly on prescription from the pharmacy, as described earlier. Injectables are first supplied to the injection room where they are managed by the nursing staff.

Problems of rational supply and use

The rational use of drugs is a prerequisite for good health delivery. The impact of drug use on the health of a population does not only depend on availability, affordability or accessibility, but even more importantly on the rational use of drugs at clinic level. This is particularly true in situations of relative plenty, in other words where pharmaceuticals are generally available, affordable (at no cost at all to users) and accessible. Sometimes health workers in such situations are overwhelmed by the variety and quantity of drugs available, and the result is excessive and unnecessary expenditure on drug supply.

Implementing a top-up system of injectables

Essentially a top-up system is based on real need and involves the replenishment of a running stock with items that are equal to those used (see Box). Meetings are held between the pharmacy unit and the nursing unit to discuss the issues involved in the supply of injectables.

> Initially a survey was carried out to determine the actual weekly consumption pattern of all injectable items supplied to the nursing unit. Recordings in the nursing books were extracted and analysed, with a safety margin of 10%.

> This information was used to agree on maximum weekly stockholdings. Review meetings were also planned.

> New weekly injection supply forms were designed to provide data on quantity used, top-up quantity and expiry dates.

> Since September 1996, at the beginning of each working week, the difference between the current stock and the maximum agreed stocks has been provided as replenishment. The nursing staff fill in the current stock levels and send the forms to the pharmacy. A pharmacy technician sends the week’s supply to the injection room where he or she assists in updating records of stock levels and expiry dates.

Measuring success

A comparative study of the value of stock requests before and after the institution of the top-up system (changed in September 1996) was carried out. The 13 most commonly used drugs were selected for study. Stock requests for the 13 drugs over a period of four months before and after September 1996 were recorded and analysed. The results indicated a general trend of over-stocking before the top-up system was introduced illustrated by an average 46.8% reduction in nursing requests after it began. The other obvious advantage is a notable reduction in inventory value. The success of the initial trial led to the extension of the new system to the supply of dressings and other sundries, followed by drug procurement. Currently procurement is largely on a replenishment basis. Over-stocking is prevalent in most government funded medical stores. It is our belief that a main cause lies in structures and procedures; the success achieved with the top-up system has substantiated our conviction.

However, the outcome of the trial could have been different if the pharmacy unit had decided to “go it alone” in the effort to change the old style of supplying injections to the nursing unit. The involvement of the nursing unit, as the major in-house customers of pharmacy services, was crucial. The top-up system of drug supply has proved to be very useful if well managed. The pharmacy can have better control over running stock. Drug needs’ estimation can be more accurate and thus funds and needs can be better matched for greater efficiency.

Drug budgets and therefore real expenditure can be reduced by the adoption of the top-up system of drug supply on an even wider scale.

* Daniel Sekyere Marfo is Chief Pharmacist, Bank of Ghana Clinic, Accra, Ghana.

Sample weekly replenishment form

<table>
<thead>
<tr>
<th>Item description</th>
<th>Maximum allowed quantity</th>
<th>Stock level as at</th>
<th>Top-up quantity</th>
<th>Expiry date</th>
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Remarks:

Sign 1 Date

Sign 2

The top-up system

With the top-up system total responsibility for supply is given to the supplier. It is a kind of imprest system that has proved effective for drug distribution within hospitals. As with other imprest systems, the maximum (imprest) level of stocks is agreed with the ward/department in charge.

The content of the list of stocks to be held is based on the regularly used drugs, and the final list is an agreement between the “user” and the pharmacy (store). The stock level of each drug is based on the known average use of the drug and the interval between stock replacements. In the top-up system it is the pharmacy staff who visit the ward/department on agreed days and note how much of each drug is needed to make the stock up to the imprest level. The pharmacy staff then deliver the noted items to the ward/department.

In this system there is no need for ward or department staff to order, the stock is automatically renewed by the pharmacy. The system depends on good communication and trust between user and supplier.
Good drugs at low cost: Thailand’s provincial collective bargaining system for drug procurement

MONGKOL NA SONGKLA, SUWIT WIBULPOLPRAISERT, PHUSIT PRAKONGGAJ

Drug expenditure constitutes approximately 35% of total health expenses in Thailand. Attempts to procure good quality drugs at a lower price are therefore important to improve health service efficiency, particularly in the current economic crisis. This article describes one such attempt at increasing bargaining power through collective provincial bargaining by all district hospitals in one province. The system not only brings down drug prices but also improves the quality of drugs, the efficiency of the drug management system and the strength of the referral system. In 1994 the Ministry of Public Health finally took up the model, and applied it to all 75 provinces. Success was limited to only three provinces during the first three years (1995–1997). However, after the economic crisis, with the reduced drug budget and increase in drug prices, the mechanism was implemented more vigorously and successfully on a wider scale. Currently 67 (out of 75) provinces implement the system and they have achieved a 25% reduction in drug expenditure.

Thailand is a lower middle income country in South-East Asia with a population of 60 million in 1997. It consists of 75 provinces, 774 districts, 81 sub-districts, 7,235 Tambons (communes) and 66,974 villages. The health care delivery system is composed of both public and private facilities. The public facilities have a 75% share of resources while private facilities have 25%. Approximately 80% of all public health resources are located within the Ministry of Public Health, with its extensive network of provincial general hospitals, district hospitals and commune health centres. In 1997 there were 89 general hospitals, 703 district hospitals and 9,135 commune health centres. Administratively all public hospitals and health centres, under the Public Health Ministry in each province, report to the Provincial Chief Medical Officer.

Drug expenditure in 1993 was US$334 per capita (retail value) and constituted roughly 35% of total health expenditure. Drugs are distributed through all public and private facilities, including more than 10,000 private pharmacies.

Services in public facilities are not free of charge. Unless patients are covered by some kind of insurance, they have to pay a subsidised level of user fees. The public hospitals thus receive financial support through government budget (tax revenues), insurance premiums and user fees. Each hospital is authorised to use these funds to purchase drugs. According to government regulations, public hospitals have to purchase 60%–80% of their drug budget based on items in the essential drugs list. Drugs are produced locally by 176 private factories and a few public enterprises, the biggest one being the Government Pharmaceutical Organization. Locally produced drugs have a 50%–60% market share. There are also 490 drug importers. Most public hospitals purchase drugs from both the Government Pharmaceutical Organization and private companies. Only those private drug factories with Good Manufacturing Practice (GMP) certificates from the Thai Food and Drug Administration are allowed to sell drugs to public hospitals.

The prices of drugs from the Government Pharmaceutical Organization are fixed, and quality control is carried out by the Organization itself. On the other hand, prices of drugs from private companies depend on direct bargaining without a good quality control system on the buyer’s side. Thus drugs are purchased, based on different hospital drug lists, at varying prices and quality levels in different hospitals. Bigger provincial hospitals usually have more bargaining power and more access to better quality drugs. Under this system, different drugs are used by different health facilities in the same provinces.

The Provincial Bargaining System

In 1990, in order to solve the problems of inefficient drug procurement – high prices and questionable quality – a collective provincial bargaining system was developed in one of the biggest provinces in Thailand, Nakorn Ratchasima. The system aims at procuring good quality drugs at lower prices, and ensuring an adequate supply of the same essential drugs to all district hospitals and health centres. The rationale of the system is summarised in Figure 1. This system consists of six sub-systems:

1. Establishment of a common hospital drug list

Representatives of doctors and pharmacists in all 23 district hospitals collectively developed the common drug list of Nakorn Ratchasima district hospitals, under the Provincial Pharmaceutical and Therapeutic Committee. Since the first list was drawn up in 1990 it has been reviewed annually, and in 1997 contained 356 drugs. This is the essential initial step to reduce unnecessary drug items and establish a common list for collective bargaining. This common drug list is also used in the procurement of drugs for the commune health centres.

2. Drug procurement system

A drug procurement committee, comprising pharmacists from all district hospitals, invited private drug companies to join the provincial bargaining system. A short-list of companies was prepared through an extensive survey of drug factories by the committee members, relying on their previous experiences as a further determinant. In 1994, 78 companies (45 local, 27 imported) declared their intention to join the system. The companies with the lowest price for each item are selected to provide drugs to the system. The prices offered stand for a year.

Each hospital then places orders during the year, according to need, directly with the winning drug companies. After receiving the orders, the companies send their drugs and the bills directly to the hospitals. There is no central provincial stock, no need for provincial financial

...cont’d on pg. 6
was designated by the committee to procure and stock these drugs to supply to all district hospitals. This sub-system not only reduces the drug price and improves quality, but also guarantees the availability of good quality low temperature drugs. In 1991, 22 such drugs were included in the sub-system.

5. Drug supply system to commune health centres

There are 287 commune health centres in the Province. Previously their drugs were supplied through the Provincial Health Office. There were problems of expired stock, overstock and shortages of some drugs due to unresponsiveness of the Provincial Health Office to meet the demand of various health centres.

Under this new system, the district hospitals maintain the district stock of drugs to be supplied to the lower level commune health centres according to their demand and allocated budget. This system gives more flexibility and reduces unnecessary expired stock. Most important of all it allows the same type of drugs to be used in the district health systems, which strengthens the referral system in the districts.

6. Monitoring the district’s drug management system

The ordering and sampling of drugs by district hospitals is monitored closely by the Provincial Health Office’s pharmacists.

The district level drug management system is monitored through indicators covering the development and implementation of the drug management plan, continuous supply of drugs, drug utilisation, overstock and the expired stock. Forty-one specific indicators in 10 sub-groups under three main groups were developed. The scores of all 41 indicators amounted to 200. The districts were classified by grades A to F according to their level of management achievement.

There was much improvement after the implementation of the system (see Table 2). Satisfaction levels of the district hospitals and commune health centres were thoroughly checked. Only approved factories were allowed to join the collective bargaining system. After the drugs were received at the district hospitals, samples were systematically collected according to the sampling plans, and sent to the Regional Medical Science Centre for analysis. The sampling plans usually focus on antibiotic, commonly used drugs, drugs for specific diseases and life saving drugs.

With this system, the proportion of substandard drugs was reduced from 36% before, to under 15% after implementation of the system (see Table 1).

4. Low temperature drug management system

Supplying low temperature drugs to rural health facilities requires a good cold chain system. Private drug companies usually hesitate to send low temperature drugs to individual district hospitals because of the difficulty with the cold chain system. Thus the provincial health office

### Table 1

**Quality of drugs before and after implementation of the system in 1990.**

<table>
<thead>
<tr>
<th>Year</th>
<th>Samples analysed</th>
<th>Number of substandard drugs</th>
<th>Percent of substandard</th>
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<tbody>
<tr>
<td>1990</td>
<td>207</td>
<td>62</td>
<td>29.95</td>
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<td>1991</td>
<td>32</td>
<td>4</td>
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<td>1993</td>
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<tr>
<td>1997</td>
<td>57</td>
<td>3</td>
<td>4.69</td>
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Source: Provincial Health Office, Nakorn Ratchasima Province.

### Table 2

**Improvement in the district drug management system**

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<th>Year</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
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<td>1992</td>
<td>28.29</td>
<td>27.51</td>
<td>27.90</td>
<td>12.40</td>
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<td>1993</td>
<td>59.77</td>
<td>23.31</td>
<td>11.28</td>
<td>3.01</td>
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<td>1994</td>
<td>58.33</td>
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<td>15.25</td>
<td>2.26</td>
<td>1.12</td>
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*Scoring for each level of drug management: A = 181–200, B = 161–180, C = 141–160, D = 121–140, F = < 120*

Source: Provincial Health Office, Nakorn Ratchasima Province.

The success in Nakorn Ratchasima Province prompted others to follow. In 1992 Ayuthaya Province started the system, to cover not only the district hospitals and health centres but also the main provincial hospital. The number of drugs for common bargaining increased from five together with information on corruption in drug procurement, also prompted the Anticorruption Committee of the Prime Minister’s Office to demand the Ministry of Public Health to implement the system on a nationwide basis.

### The way forward: Opportunities for change

The success in Nakorn Ratchasima Province prompted others to follow. In 1992 Ayuthaya Province started the system, to cover not only the district hospitals and health centres but also the main provincial hospital. The number of drugs for common bargaining increased from five together with information on corruption in drug procurement, also prompted the Anticorruption Committee of the Prime Minister’s Office to demand the Ministry of Public Health to implement the system on a nationwide basis.

### Factors behind the success

Several factors contributed to the success of this system:

**Strong leadership**

Drug procurement often involves many vested interests and much inefficiency. In many cases 20%–30% commission is requested or paid to the hospital authority. Thus some hospitals did not want to participate in the system, and some were hesitant. Strong leadership from the Provincial Chief Medical Officer and peer influence among district hospital directors was essential to the initiation and the success of the preliminary phase of development.

In the case of Nakorn Ratchasima, the Provincial Chief Medical Officer, who initiated this system in 1990, used his strong leadership and perseverance to overcome the vested interests. He was strongly supported by a few leading district hospital directors and pharmacists who dedicated their time and wisdom to design, develop and manage this system.

### Sound justification

The system was able to show the expected outcomes – better quality drugs at lower prices, a better drug management system, and better support to the district referral systems. Only such evidence can satisfy all partners and guarantee continuity of the system.

### Partnership

Active involvement of all district hospitals created an environment to support accountability, transparency and acceptance of the system, without increasing any bureaucratic steps or any vested interests, at the provincial level. This backed by strong leadership and sound justification, was essential to the sustainability of the system. The system in Nakorn Ratchasima Province has been on-going up to present (eight years) despite the change of four Provincial Chief Medical Officers.

### Publicity and strong civil society

Publicising the results created public awareness, strengthened civic movements and supported the sustainability of the system. It was also a strong advocacy tool to get policy support for wider implementation. The Thailand Health Research Institute evaluated the system in 1991. Its report was widely publicised and finally, in 1994, discussed in the National Drug Committee chaired by the Minister of Public Health. The Minister then brought the issue into further discussion in the ministerial committee, and a Ministry policy was developed. The report, in 1992 to 23 in 1995. They were able to save from 0.33 million Baht in 1992 to 4.7 million Baht in 1995. Other provinces, such as Buriram, Surin and Lumphoon, started to follow. In November 1994, three years after the system was launched and the success story was publicised, the Ministry of Public Health put forward a policy to establish such a system in all provinces. However, during an era of high economic growth with a high drug budget (1995–1997), the response was rather weak. Evaluation of the implementation in 1996, by the National Health Foundation, found that only three provinces implemented the system as intensively as Nakorn Ratchasima. Another 30 provinces did it weakly to moderately and the rest did not implement it at all.

The current severe economic crisis, which began in July 1997, is a good opportunity for further development. The system was promptly included in a comprehensive “Good Health at Low Cost” policy package. Inspector Generals of the...
Drug supply choices: what works best?

PERSPECTIVES on the role of government in health vary from a social welfare approach (the state should provide all health and other social services except where it is unable to do so) to a market economy approach (the private market should provide most health services). In the past many governments (in both developing and developed countries) have subscribed to the social welfare approach, particularly when health technology was limited in scope and cost and was therefore affordable. Increasing complexity and technology has taken the cost of health care provision beyond the reach of most developing country governments, and there is a growing emphasis on the responsibility of the individual to provide for their own health care.

In fulfilling the goals of a national drug policy government has a central role in ensuring that drugs distributed through the public and private sectors are of acceptable quality, safe and effective. Also government has a responsibility to promote the rational use of drugs. In addition, it is necessary to actively promote drug availability (geographic access) and affordability (economic access) if a large share of low income and remote populations depend on private sector drug supply.

Among the decisions which governments have to face in the pharmaceutical sector the most complex and the most costly often concern the financing and supply of drugs for government health services. In some countries public sector drug supply is well financed and administratively efficient. In other countries the drug supply system is unreliable and shortfalls and shortages are common. Such systems suffer from inadequate funding, outdated procedures, inefficiency or a mixture of these and other problems.

In a situation of diminishing resources one response is to maximise them by increasing efficiency. Can private sector mechanisms be used to improve public sector efficiency and, thereby, improve access to essential drugs through government health services? It is important to remember that one element which stimulates efficiency in the private sector is the existence of competition.

Various strategies have been tried in order to provide access to pharmaceuticals and, in particular, to essential drugs. At least five alternatives exist for supplying drugs to governmental and nongovernmental health services.

ALTERNATIVE SYSTEMS OF DRUG SUPPLY

- Central medical stores (CMS): conventional drug supply system, in which drugs are procured and distributed by a centralised government unit;
- Autonomous supply agency: a centralised supply system in which the management responsibility is devolved to an autonomous or semi-autonomous Board;
- Direct delivery system: a decentralised, non CMS approach in which drugs are delivered directly by suppliers to districts and major facilities. The government drug procurement office tenders to establish the supplier and price for each item, but the government does not store and distribute drugs from a central location;
- Primary distributor system: another non CMS system, in which the government drug procurement office establishes a contract with a single primary distributor, as well as separate contracts with drug suppliers. The primary distributor is contracted to manage drug distribution by receiving from the suppliers, storing, and distributing all drugs to districts and major facilities;
- Fully private supply: in some countries, drugs are provided by private pharmacies in or near government health facilities.

It is possible to identify some advantages and disadvantages for each of the above systems and to make some theoretical comparisons, but true comparisons of cost-effectiveness have not been made. In part this is because other issues have made such comparisons very complex. The introduction of policies on user charges, decentralisation, contracting-out and privatisation all have an impact on the drug supply system.

The Central Medical Stores system

The historical approach to public sector drug supply is the Central Medical Stores (CMS) approach, in which drugs are procured and distributed by the government, which is the owner, funder and manager of the entire supply system. Selection, procurement and distribution are all handled by the central government, often by a unit within the ministry of health. Financing is usually from central treasury allocations and/or donors, though a CMS can function as a revolving drug fund.

This is a demanding approach in terms of human resources, physical infrastructure, management systems and communication systems, requiring the state to manage and fund every aspect of the system. It has been a logical approach in situations where the vast majority of items were imported through one channel; the demand was predictable; finance and administration were highly centralised; and a developed and professional private sector did not exist. Traditional CMS structures continue to be used in a number of countries including Ghana, Gabon and Zimbabwe. However the distribution and financing mechanisms in use vary.

Using the traditional CMS system the availability of drugs in the public sector has deteriorated in many (but not all) countries as the nature of medical practice has changed and real financial resources have diminished. At the same time the demand for, and cost of, health service provision has increased.

The causes are many. The drug supply environment has changed drastically from a range of chemicals and galenicals to a multiplicity of manufactured finished products. CMSs have experienced problems with financial management, quantification of requirements, management of tenders, warehouse management, transport and security of drugs. These problems have been exacerbated by political or administrative influences and... cont’d on pg. 8

References

6. Rural Hospital Division, MPhP. Progress report on the drug management under the Good Health at Low Cost Policy Package. Report to the Permanent Secretary.
Drug supply choices... cont'd from pg. 7

underpinning in Benin, Haiti, Sudan, Tanzania, Uganda and Zambia.

A commonly seen Ministry of Health organogram is as follows:

where the board is autonomous in running the agency but reports to the minister of health, who may be involved in the appointment of the chairman of the board and/or the executive officer.

The goals of establishing an autonomous supply agency are to achieve the efficiency and flexibility associated with private management and private sector employment conditions. At the same time sufficient public sector supervision is maintained to ensure that the services provide a range of essential drugs, at reasonable prices, with adequate control of quality.

The basic concept is that, under the right conditions, a well constituted management board or board of directors will have the freedom to appoint qualified senior managers, who will in turn ensure an efficient, accountable supply agency.

Supply agencies may be established in the context of a public sector revolving drug fund, where fees are used to purchase drugs on a cash-and-carry basis as in Benin, or in a system where government institutions purchase drugs with centrally allocated treasury funds as in Uganda, or where budgets are still centrally controlled as in Tanzania. Whatever the financing mechanism, autonomous agencies can only function if there is a market for their products and if the client(s) has funds to purchase the products.

Autonomous agencies are likely to improve drug supply only if structured to overcome the constraints of the CMS approach. Experience to date, though limited, suggests that features which should be sought in establishing autonomous supply agencies, include:

- supervision by an independent management board;
- professional pharmaceutical supply managers;
- good personnel management;
- adequate financing;
- public accountability and sound financial management;
- focus on essential drugs (rather than "profitable" alternatives);
- focus on quality assurance, both in terms of products and of services provided.

The intention is that an autonomous supply agency will achieve greater value for money and improved drug availability through more efficient management. Three important characteristics that are needed to promote efficiency are flexibility, incentive and competition. The existence of competition will encourage efficiency, but in the majority of situations the monopoly of the CMS continues to apply to the autonomous agency, with no pressure to improve the quality of services and products or aim for the lowest prices.

A whole series of difficulties may occur, for example, if senior managers are political appointees rather than professional managers appointed by an independent management board. Similarly, if the government retains the authority to require distribution of drugs without charge or on a credit basis (without ensuring payment), again, if special interests outside the agency influence drug procurement, or if the agency is required to retain staff members regardless of their ability or performance, these factors will be counter-productive.

Countries considering an autonomous supply agency should recognise that this approach will not solve problems related to lack of funding for drugs.

Direct delivery system

In general, CMS and autonomous supply services involve bulk procurement into, and distribution from, a central warehouse. The costs and logistical problems associated with central storage and distribution are substantial. An alternative is the direct delivery system.

In this non-CMS model, a government procurement office tenders to establish prices and suppliers for each essential drug, but drugs are then delivered directly to the suppliers to individual regional stores, district stores or major health facilities. Variations of direct delivery contracts have been implemented in many countries, including Chile, Colombia, the Eastern Caribbean, Indonesia, Mexico, South Africa, Thailand, UK and Peru. In Indonesia annual allocations for drugs are made on a per capita basis to each district. Using their budget and the Ministry's current price list for essential drugs, each district determines its own drug order.

Contracts for direct delivery may specify fixed quantities with scheduled deliveries (generally the approach in Indonesia) or estimated quantity tenders with orders placed by the local store or health facilities as needed. Financing arrangements can be a sensitive issue. Debts can quickly accumulate if drug supplies are not balanced against available funds. This means maintaining separate accounts for each supply point (if funding is from central allocations) or ensuring that all supplies are paid for at the time of delivery.

Like most procurement systems, direct delivery contracts require a sole-source commitment, that is, for the tender drugs the local warehouse and facilities will contract from the supplier who holds the tender contract. The local purchasers are free to order drugs that were not won on the tender from any supplier.

Direct delivery supply agreements depend on and encourage further development of an effective private sector distribution system. In principle, they reduce storage and transport requirements and risks for the government by specifying in the procurement contracts that drugs are to be delivered directly to district stores and major health facilities. The government then has only to store drugs at the regional or district level and deliver them to health centres and peripheral health units.

Direct delivery, however, district level and facility level drug management responsibilities are much greater, since the quantities and quality of drugs may need to be confirmed. Success will depend on the ability and willingness of staff to manage the increased responsibilities. Finally, direct delivery in itself cannot solve problems of inadequate financing.

Primary distributor system

The primary distributor system is a variation of direct delivery in which the public procurement agency contracts and establishes two types of contracts. The public procurement agency contracts with any number of suppliers to establish the source and price for each drug. But the drugs are not delivered directly to health facilities; instead, a separate contract is negotiated (through tender if feasible) with a single private sector distributor, the primary distributor.

Two provinces in South Africa use the primary distributor system for delivery of drugs and medical supplies to hospitals (see p.10). Contracts for the procurement of drugs are negotiated nationally using competitive tenders.

The suppliers deliver tender drugs to the primary distributor, who is responsible for maintaining sufficient stocks to fill orders from regional warehouses, district stores and/or health facilities. Primary distributors may maintain their own vehicle...
fleets or subcontract transportation.

Like other direct delivery contracts, this system depends on sole-source commitment for the essential drugs list, though districts and health facilities may be allowed to purchase non-tender drugs from any source. The system also requires the same level of good information and monitoring.

The primary distributor is paid a fee or commission for storage and delivery services. The primary distributor may appear to add an extra middleman and extra costs, but the expectation is that the cost of the primary distributor will be less than the cost to the government of running the warehouse and distribution system itself. Competitive bidding for the primary distributor contract is important to achieve this efficiency.

**Fully private supply system**

Finally, national policy, insufficient financing or management problems have led some countries to avoid responsibility for providing hospitals and health centres with even essential drugs. Where this is the case, retail pharmacies become the source of supply, especially in urban environments. Often the pharmacies are located very close to the hospital, and may be located inside the hospital. Such pharmacies may be part of a parastatal or other special interest to profit personally gain is common in drug supply systems. While decentralisation is meant to improve accountability, it makes it easier for local officials or other special interests to profit fraudulently.

Increased cost: decentralisation of procurement usually means smaller order quantities. It can result in higher drug costs, which if you can find someone else to do a specific task then pay them to do it rather than committing the capital resources to do it yourself; for example, distribution is usually contracted out by large supermarket firms.

Primary distributor systems, transport contracts, port-clearing services and related approaches to private sector involvement require contracting for services in contrast to contracting for products (drugs, for example). However to contract out activities requires the skills of writing, negotiating and monitoring contracts. Contracting functions most effectively where there is competition with any tendering process. Contracting-out also demands a commitment to pay the contractors according to the terms of the contract.

Privatisation in health is properly defined as the transfer of ownership from the public to the private sector. But the term is also applied, less precisely, to contracting out government services to the private sector (as with direct delivery contracts) or introducing private sector features into the public sector (as with government owned but semi-autonomous supply agencies). The full privatisation of drug supply would have implications for equitable access to drugs in an environment where profit will become the motive for supply.

**Conclusions**

If a different drug supply system is not chosen as a result of a careful analysis of the underlying causes for the weaknesses of the existing system in a particular country, the change may not produce the desired outcome. Systems chosen because they function in the climate of a “successful” market economy may not prove to be the solution to the problems faced in the supply of drugs in the context of a developing country.

To weigh the pros and cons of one supply system against another, it is not necessary to be done from a global perspective without detailed study. Each country brings unique political, economic and geographical factors into the equation. It will never be possible to state that one particular system is “the best”. However some basic factors will point in the direction of certain systems, for example, the existence of an effective private sector is necessary for either direct delivery or prime distributor systems to function.

The Action Programme on Essential Drugs has initiated a multicountry study to examine in depth at country level the outcomes of the drug supply systems in use. This study will look at the advantages and disadvantages of the systems, and the factors which influence the level of success in correcting problems and meeting needs.

This article has been adapted from Drug Supply Strategies, Chapter 6 of Managing Drug Supply [see reference below].

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Some experiences with competitive mechanisms for public drug supply

**Autonomous supply agency in Tamil Nadu, India**

The Tamil Nadu Medical Services Corporation (TNMSC) was created in 1995 to contain drug costs and reduce shortages by purchasing and delivering drugs to government health care facilities. TNMSC is set up as a government company, with a Board chaired by the Secretary of Health, which is accountable to the Minister of Health. The TNMSC created a list of 267 essential drugs from the previous state drug list of 900 items.

Drugs are procured through tender and delivered directly to district level stores. Quality assurance procedures are in place, including sampling of products from manufacturers and district stores. Testing is contracted to reputable private laboratories through tenders. TNMSC adds a 5% charge to fund its operations. Each facility is given a budget target and issued a “pass book” in which to record the value of drugs it has received. Through prompt payment and other administrative efficiencies, TNMSC has considerably reduced drug costs, while maintaining reliable supply.

**Combined supply strategies in Zimbabwe**

The Zimbabwe Essential Drugs Action Programme (ZEDAP) uses different systems for different categories of drugs. High-value drugs on the essential drugs list are procured, stocked and distributed in bulk through the central medical stores. For high-cost, slow-moving specialist items, direct delivery contracts are used. For most specialist items an annual tender is contract to fix the price for the year. Drugs are then ordered as needed by the roughly two dozen national hospitals and NGO hospitals which require them. Orders are delivered directly to the hospitals. Finally, for cancer agents and some other highly specialised drugs, no contract exists.

Instead, drugs are purchased by the Ministry’s pharmacovisical division by individual order, with permission from the Secretary of Health.

Source: Bennett S, Muraleedharan VR. Personal communication on Tamil Nadu Medical Services Corporation. 1997.

“Contracting-out” drug procurement and distribution: experience with a primary distributor system in South Africa

R.S. Summers1, H. Moller2, D. Meyer4, R. Botha

Public sector relationships have been suggested as means of achieving some of the goals of national drug policies and essential drugs programmes. Because of work which showed that “contracting-out” the procurement and distribution of drugs can offer advantages and improve performance, two of the country’s nine provinces have opted for this approach. South African provinces have a considerable degree of autonomy. In this method, structure, process and outcome specifications are established by a public sector authority and offered to prospective providers on “tender”. The authority, usually through a bidding process administered by a tender board, will then select and establish a formal contract with a successful tender.

Experience and some critical lessons learned in using this approach in South Africa are described here, providing valuable insight into one of the few documented primary distributor systems outside the USA.

Background

South Africa, with a total population of just over 40 million1, had a pharmaceuticals’ expenditure of some 4.8 billion Rand in the private sector and 1.1 billion Rand in the public sector in 1996 (when R1 was approximately US$0.22). Annual per capita expenditure on drugs for the 85% of the population who rely on public sector health services was approximately R52 (US$11). For the remaining 15% served by the private sector the equivalent figure was around R792 (US$174).

To place this figure in context, the World Bank quotes an average drug expenditure of US$2.1 for nine African Countries in 1995 to contract out the procurement, warehousing and distribution of pharmaceutical supplies. These functions were contracted out to a private company at a commission of 8.05% of the value of the products. The contract also included a 2.25% commission for computerisation of hospital pharmacies and computer training of provincial pharmaceutical staff. From January 1996, medicinal supplies have been distributed from a single depot in the centrally situated provincial capital.

In Province B, an essentially rural area with less infrastructure than Province A, a similar contract was awarded early in 1997. A provincial warehouse was built on the western border of the province, in March 1997. A more central site would have facilitated distribution.

Contracting-out is one of the options described for public sector/private sector cooperation in drug supply2. In South Africa all of these factors needed to be tackled:

- The public sector does not insure stock against theft, fire or natural disasters, so all losses occur at government expense, if services are not contracted out. Theft is a major problem in pharmaceutical warehouses in South Africa.
- Strikes have become increasingly common since the 1994 elections as trade unions are trying to negotiate new equitable rules and remuneration in the labour sector.
- Vehicle maintenance, cost-effective staffing and management information are areas where the public sector has not always been efficient in the past. Government departments have been notoriously overstuffed, but employees were poorly paid and often underqualified. Many motivated workers found work more rewarding in the private sector. With limited financial and logistic resources, services in remote areas were not easy to manage.

The decision of two provinces to “contract-out” procurement and distribution to hospital level provided experience from which important lessons can be drawn.

Tender Specifications

Against this background, clear structure, process and performance specifications are essential elements for success. Tender specifications may need to vary according to the needs of different provinces. In Province A, seven years’ experience—one of the former homelands had already used contracting out service prior to 1998—have shown the following requirements to be necessary for a successful system:

- Procurement: The province must manage the procurement database and have the capacity to say on orders, including prices.
- Warehousing and inventory management: At least one senior pharmacy manager should be on the provincial payroll. The public sector should own the warehouse and equipment. This ensures independence so that if the contractor does not perform to specifications, the province has the facilities to continue operations. However, the contractor is responsible for the maintenance and insurance of the facilities and stocks.
- The Department, in negotiation with the contractor, determines stock levels. This precaution ensures that adequate levels of stocks are kept in a situation where the contractor pays insurance coverage.
- The contract should include the installation of adequate computer hardware and software for inventory management at hospital pharmacies, and for on-going staff training.
- Distribution: The contractor’s own transport is to be used, courier and similar services are not acceptable. When other transport is used, medicines are not always regarded as priority by the transport contractor and deliveries may not be according to a schedule.
- Management information: The contractor is required to supply comprehensive management information reports at agreed intervals.
- Billing: As the contractor is paid a commission on items delivered to hospitals the billing structure must separate these costs from the cost of purchasing stocks into the warehouse. In an earlier South African experience with limited contracting out the company received a commission on stock purchased into the warehouse and not on stock delivered to clients. This arrangement left many opportunities to purchase inappropriate medicines and quantities.
- Human resource development: The entire contract must be seen as a partnership between the Department and

Some advantages of “Contracting-Out”

1. All losses by fire, theft or natural disasters are the responsibility of the contractor.
2. The staff required to run a warehouse efficiently and effectively is expensive. Cost-effectiveness of this component will be monitored by the contractor, because of the effect of poor performance on profitability.
3. Strikes and industrial disputes can be a major threat to the health services in a situation where all medicines are distributed from one depot. The service provider will be responsible for ensuring continuity of services.
4. Transport is a major cost component in the distribution cycle. Adequate vehicle maintenance and efficient scheduling of deliveries become the responsibility of the contractor.
5. Management information on drug availability and use can be improved without major investment by the public sector.

See Chapter 17 of Managing Drug Supply for a more detailed description of issues involved in contracting out pharmaceutical services.

References

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See Chapter 17 of Managing Drug Supply for a more detailed description of issues involved in contracting out pharmaceutical services.
the contractor. The Department must also ensure that the contract is carried out according to the specifications. This necessitates the active involvement of provincial staff members in the entire process from database management, and procurement to receipt and distribution.

**Current Challenges**

Sufficient data are available to enable an evaluation of how the first two elements listed above have contributed to goal of improved drug supply.

**Procurement and financial control**

Procurement was initially effective in Province A. Toward the end of 1997, however, and for approximately the first quarter of 1998, the situation deteriorated. This situation arose because of financial difficulties within the Province which led to the transfer of funds from Health to Education to offset overexpenditure on the Education budget.

In Province B, the situation manifested major difficulties from the start. Initially, accurate demand data had not been given to the contractor. Hence, order quantities did not match requirements. Cash flow problems surfaced as a result of a backlog in payments during 1997/1998. More recently, the health budget was decentralised to district management, which caused major difficulties with cash flow at the depot. Suppliers who had not been paid suspended deliveries.

**Warehousing and inventory management**

As described earlier there were significant differences in the location and available space of the two depots. In addition to the poor sited and inadequate space at the depot of Province B, attracting (and retaining) professional staff to the area has been a major problem. These factors significantly influenced the performance of the depot which was, reflected in a relatively high number of out-of-stock items. Between March and June 1998, the percentage of 132 essential items listed as out of stock by Province B increased from 23% to 35%. Twelve critically important drugs were listed for virtually the entire period. We have rated procurement and stock control systems as ineffective when more than 15% of items are always out of stock. The situation at the depot of Province B is therefore very poor.

As the first six months of 1998, Province A, which operates a similar system but has a provincial chief pharmacist at its depot at all times, had a stock-out rate between 7% and 22%. This performance was also far from ideal but better than Province B. The reasons for the stockouts included poor selection of supplier, who may have overerved and therefore could not deliver; payment difficulties (see above) and poor depot management. Province A faced managing the first two problems, whereas all three applied to Province B from time to time.

**Relationships between the Players**

To obtain a perspective of the actual difficulties involved we examined the components of the procurement and distribution cycle in terms of the relationships between, and responsibilities of, the two role players (see Figures 1 and 2).

The provincial authority is involved in every element except receipt and counting of goods at the depot and distribution from the depot to facilities. It meets this responsibility by checking the performance of the contractor through the data in the management information system, without being involved in day-to-day procedures.

Here the contractor plays the main role but is supported by important inputs from the province. In both provinces, the contractor’s responsibility extends only to the hospital level. Thereafter, to the clinics, the responsibility for effective delivery and inventory control becomes that of the province. Transport and management information at this level have often been problematic.

**Lessons Learned**

Perhaps the core lesson learned is that what occurs in contracting-out is a partnership. If either partner does not deliver, and there are weak links in the chain, the process will fail!

There were differences in performance between the two provinces. These lay in the partnerships and inputs in each case. In the early stages of the process in Province A, there was extensive preparatory work by both parties. Facilities had adequate stock in place. Stock at different depots was checked and consolidated. This was not the case in Province B. The depot there had been newly set up and had encountered difficulties in establishing its own management information system. In addition the depot was too small for the Province B’s needs. It lacked adequate supervision, which is essential for proper control of public sector resources and funds. Too many items were listed at the various levels of pharmaceuticals distribution in this province.

Towards the end of the financial year, both provinces faced payment difficulties which inhibited procurement. In Province A, where the budget was centralised, budget over-runs in departments other than Health and Welfare led to the withdrawal of funds from Health. In Province B, decentralisation of budgets and responsibility for payment to district level management, continued to cause major cash flow difficulties with consequent difficulties in establishing its own management information system. In addition the depot was too small for the Province B’s needs. It lacked adequate supervision, which is essential for proper control of public sector resources and funds. Too many items were listed at the various levels of pharmaceuticals distribution in this province.

For a project like this to succeed both parties need to have insight into, and understanding of, the functioning of a depart-}

**Figure 1**

**Procurement cycle**

<table>
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<tr>
<td>Set format of reported information</td>
<td>Receive orders</td>
</tr>
<tr>
<td>(Contractor)</td>
<td>(Province)</td>
</tr>
<tr>
<td>Pay suppliers</td>
<td>Review four</td>
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<tr>
<td>(Province)</td>
<td>(Contractor)</td>
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<tr>
<td>Receive and check</td>
<td>Monitor contractor</td>
</tr>
<tr>
<td>(Contractor)</td>
<td>(Province)</td>
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<tr>
<td>Reorder needs and funds</td>
<td>(Province)</td>
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**Figure 2**

**Distribution cycle**

<table>
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<td>(Contractor)</td>
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<tr>
<td>Prepare receipt</td>
<td>Delivery and payment</td>
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**References**

Improving the supply, quality control and access to essential drugs in Guatemala

MANUEL ENRIQUE LEZANA

Over the past 15 years, Guatemala has followed through its commitment to the concept of essential drugs by developing a range of strategies and actions designed to improve the supply of drugs and ensure wider access to them. More recently, the Guatemalan Ministry of Health has drawn up a blueprint for overall health policies to the year 2000. The proposals include: the modernisation of state health services through decentralisation of finance and administration, the capacity of governing bodies; improving sectoral and intersectoral coordination; and making better use of existing resources.

During the period of generalised crisis, the Ministry of Health had committed to improving the quality of health services and ensuring wider access as well as improving the management of health services.

Within the Health Ministry’s budget, the largest items of expenditure are medicines (10%), surgical materials (5%) and medical equipment, including maintenance and replacement equipment purchases (6%–7%). However, over time, the administration of this budget has lacked transparency in the selection, purchase and distribution of these products. The quality of the product purchased was neither defined in advance nor checked on receipt. Meanwhile, suppliers had no guarantee of payment – resulting in price speculation of up to 400% of the original price.

One of the first steps taken was to form a group of national consultants to work with the WHO Regional Office for the Americas and the Pan American Health Organization. The group was to draw up a strategy to resolve existing problems and capitalise on the then current employment of an international company with expertise in drug purchasing systems.

Sweeping policy changes

A Multisectoral Commission for Policies on Medicines was formed within the Public Health Ministry with representation from both the private and public sector as well as international health organisations. The Commission’s remit was to advise the Ministry on new policies for the quality control and supply of drugs. Because of the seriousness of the problems encountered, it was decided to implement new policies across the board. These included:

- strengthening the drug regulatory authorities and the official quality control laboratory;
- setting up working groups to develop quality standards and new procedures for administration, purchasing and distribution;
- revision of the legal framework;
- new guidelines for the purchase of drugs;
- an improved system of logistics for the provision of supplies;
- establishment of a drug vigilance programme.

Reform of the drug regulatory authorities and the official quality control laboratory was achieved through strengthening the management structure, decentralisation of finance, staff training programmes and a review of salaries. Other measures included: the establishment of a Drug Registration Department; the creation of a standardised system for drug registration; better inspection of Good Manufacturing Practices; the purchase of laboratory equipment; and the development of a computerised data system for drugs.

Elsewhere, the Quality Standards Working Group studied the list of 1,400 drugs purchased by the Government – which contained many duplicate products – and recommended the use of the 13th edition of the US Pharmacopeia and the US Pharmacopoeia Dispensing Information, to define the specifications of products purchased by the Government. Other products on the list had to be ratified from alternative sources, such as the British, French and Japanese Pharmacopoeias.

The Working Group also estimated the supply needs on the basis of figures provided by different health units. The aim was to establish quantities that would be attractive to suppliers and ensure savings through bulk purchase orders. Medical surgical materials and medical equipment were handled in a similar way, using international standards such as those of the US Food and Drug Administration, as well as alternative standards. At every stage, both consumers and suppliers were involved in defining the quality of the product. A second working group was established to review the legal aspects of Government purchases of medicines and medical surgical materials.

As part of the modernisation process, the law was updated and a new Health Code issued. The regulation that this law implements facilitates Guatemala’s participation in the globalisation process, and establishes responsibilities for all personnel involved in the supply of medicines.

Meanwhile, overall control remains within the Ministry of Health. The legal framework provides for the development of a Programme of Ease of Access to Medicines through already established state and municipal pharmacies, and the establishment of a Sales of Medicines for Community Benefit scheme run by civil groups to ensure they are self-financing and sustainable.

The proposal for the Purchase of Medicine system, which came into operation in early 1997, adopted the open contract system already in force for Government purchases. This is an administrative tool with centralised negotiation and decentralised execution – designed to guarantee the quality of the product, purchased at prices previously determined at central level.

Ensuring transparency in supply

The new drug purchasing system was modified to include an open tendering system, with control over those who make the offers, and clear rules to ensure transparency and bring an end to corruption. A computerised system has been developed for this.

Resources must be used rationally to allow for extended coverage. Meanwhile, quality must be in conformity with the US Pharmacopoeia, and all medicines referred to by their International Non-proprietary Name. Norms have been established for the qualification and awarding of suppliers and products, together with a procedure and payment guarantee to ensure successful relationships. This agreement provides for payment within a maximum of 30 days after receiving the product, compensation in the event of fluctuations in the exchange rate and payment of interest on delayed invoices. Sanctions can now be imposed for the supply of poor quality products and for failure to deliver within the agreed timeframe (with a maximum penalty of five years’ suspension as a Government supplier).

The new system allows for a maximum of 3% deviation in the minimum price offered by a maximum of eight suppliers. Meanwhile, an inter-institutional commission has been established to oversee the operation of the open contract system and apply sanctions for non-performance. The private sector participates as an observer in this commission. The Process of Public Awarding provides for the participation of personnel from the administrative units and executing officers from the public health sector as well as observers from private sector organisations and professional colleagues (doctors and pharmacists).

Focus on quality

The establishment of administrative and technical norms was also necessary to guarantee that the item gets to the user in perfect condition, in the correct quantity and on time. These included a definition of the role of the professional pharmacist to ensure that drugs are used and administered correctly. Norms were
also established for selection, purchase, reception, storage and distribution in order to ensure the punctual delivery of the correct medicines. A system was put into place to deal with complaints about the efficacy or safety of products, and take appropriate action wherever needed.

In late 1997 doubts about the quality of medicines purchased through prescription prompted the launch of clinical studies of some products. The finding that some medicines were lacking in efficacy led to the establishment of the Drug Vigilance Programme – designed to assess complaints about therapeutic failure and advance the adoption of medicines purchased through the open contract system.

The new policies have met with opposition from some groups – including prescribers and suppliers who failed to win contracts – each preferring to maintain the status quo on drug supplies. Other problems have included inadequate supply forecasting – leading to drug shortages – and budgetary restrictions on efforts to ensure vigilance and control. However, failure by some suppliers to provide the correct amount and quality of drugs has led to the imposition of sanctions, including five-year exclusion from the Government supply system.

Among the major achievements of the new policies were the decentralised budgets and the extended coverage with low-cost, high-quality medicines. The Ministry of Health has saved 65% of its budget and the Guatemalan Institute of Social Security – the country’s other public health service provider – saved 23% of its drugs budget. Meanwhile, through the Access to Medicine Programme – which benefits from decentralised price negotiations – medicines are now being made available to underserved communities.

Elsewhere, quality standards have been established for the purchase of medicines and sanctions put in place to deter the supply of poor quality medicines or late deliveries.

Multidisciplinary teams now participate in negotiations for the purchase of drugs and other medical items, and the decentralisation of health budgets facilitates the prompt payment of suppliers.

* Ing. Manuel Enrique Lezana is Chief of the Drug Coordination Office, Ministry of Health, Guatemala


References
2. Governmental Agreement 472–96, dated 4 November 1996, related to the quality of medicines and medical surgical materials in which the purchasing standards are established.
4. This regulation is awaiting final Presidential approval.
5. Governmental Agreement 714–97 dated 8 July 1997.


NATIONAL DRUG POLICY

Belarus: progress in the pharmaceutical sector

The Ministry of Health in Belarus has set out its plans for health sector development, which include changes in the pharmaceutical sector. Among proposals are that a network of state and private pharmacies will develop in parallel, with their activities strictly regulated. At the same time, state control of drug pricing will continue. Drugs will be supplied to the population through both centralised and decentralised procurement, using the country’s list of essential drugs. Other important initiatives include a campaign to promote the rational use of drugs, and plans to hold a national conference to adopt a new approach for developing the pharmaceutical education system. It is hoped the Government will adopt the public health development package by the end of 1998.

The country plans two main approaches for the pharmaceutical industry: the production of generics included in the essential drugs list for centralised drug supply, in accordance with state directives; and the modernisation and upgrading of existing pharmaceutical manufacturing enterprises. Three new factories have already begun pharmaceutical production.

Over the next five years it is planned to develop and introduce up-to-date requirements for clinical trials and standards for drug quality and production, and to review other regulations covering pharmaceutical issues.

Increased role for regulators

The drug regulatory authority is expected to have a stronger role and independent status. Recently, the Ministry of Health established the Republican Centre of Expertise and Trials in Health Care. The aim is to help solve current problems in the drug supply system, and to improve the drug registration process, authorisation of products for medical use and industrial production, licensing of pharmaceutical activities, and control over drug imports to Belarus. The Ministry intends to implement national drug policy through the Centre, and through all these measures to exercise effective control over the pharmaceutical sector.

Ensuring access

Centralised procurement of certain important medicines will continue, among them those for treating diabetes, cancer, and tuberculosis. Such procurement is done on a large scale, in bulk and exclusively on a tender basis. This system allows the purchase of needed drugs to be more cost-effective, and ensures access to these vital drugs for the population. All pharmaceuticals supplied in this way are free of charge to patients.

In April 1991 the first version of the essential drugs list was adopted. It has been reviewed annually since then and is widely used. The list is the basis for procurement at all levels of the health care system and ensures guaranteed coverage of the population’s pharmaceutical requirements.

In September 1992 the Principal Department of Pharmacy, Medical Equipment and Regulation was established. Within this framework the process of developing a national drug policy started.

In December 1992 licensing of the pharmaceutical market was initiated. This allowed the Government to preserve its control of the pharmaceutical sector and to regulate newly established pharmacies, regardless of their ownership.

In November 1993 the Pharmacological Commission was reorganized and the Pharmacological and Pharmacopoeia Committees. Requirements for drug registration in Belarus were approved and legally approved.

In November 1993 the national programme for pharmaceutical industry development was adopted. The list of drugs produced in Belarus increased from 150 to 300 items.

In October 1997 the Republican Centre of Expertise and Trials in Health Care was established. This facilitated reorganization of drug registration and pharmaceutical licensing procedures to meet international standards.

Major changes ahead

Step by step over the next five years, Belarus will introduce international standards for good manufacturing practice. It will modernise and increase the capacity of existing production plants, build new plants, widen the list of drugs produced, and strengthen the State’s role in drug production to better satisfy national drug requirements.

The Ministry foresees the further development of the network of newly established private pharmacies and improved regulations that will ensure increased access to drugs for the rural population. There are plans to review existing pharmacy regulations and to introduce a list of compulsory medicines that should be available in every pharmacy at all times.

Plans are also underway to encourage the more rational use of drugs, especially within the drug reimbursement scheme; increase the role of the essential drugs list; introduce treatment guidelines; improve doctors’ access to drug information; encourage the procurement of drugs in the hospital package; and review the price regulation system.

Fruits of collaboration

International contacts, especially those established during 1993/1994, have played a significant role in allowing Belarus to make more rational decisions on how to organize its drug regulation and supply systems.

Agreements on collaboration in the pharmaceutical sector have been signed with the Health Ministries of Latvia and Ukraine, as well as with the French Medicines Agency, and the US Food and Drug Administration. This allows Belarus to receive much needed drug information more efficiently, and to organize training for its experts at these institutions. Contacts and cooperation with the Pharmaceuticals Programme at WHO’s Regional Office for Europe has also broadened knowledge on all aspects of the pharmaceutical sector.

Belarus has also benefited from an Interstate Commission for standardisation and quality control of pharmaceuticals and medical equipment established under the Commonwealth of Independent States Council for Cooperation in Health. It has allowed better harmonisation of pharmaceutical standards and requirements for products manufactured in these countries, and the simplification of their circulation within the Commonwealth’s internal markets.

This article is based on an interview with Gennady Godolavikav, Head, Pharmaceutical Department of the Ministry of Health of Belarus, which first appeared in: Pharmaceutical Reforms, WHO News for Newly Independent States, No.3, June 1998.
Involving African consumers in drug policy

While many countries in Africa have adopted national drug policies these policies do nothing for the public they are meant to serve if they remain only written plans. Consumer involvement in implementing such policies is crucial in order to address the public’s real needs regarding health and medicines. In many cases countries have done little to make sure national policies address consumer’s health needs in a participatory and attainable way. The reasons behind these successes and failures, and strategies for ensuring consumer involvement in various aspects of these policies were the focus of HAI’s second regional workshop for Africa. Entitled Networking for Rational Drug Use in Southern Africa Consumer Involvement in National Drug Policies, the meeting was held from 30 May to 5 June 1998. It brought 34 participants – including consumer activists, NGO representatives, drug information experts, journalists, pharmacists and clinical pharmacologists from 11 African countries – to Johannesburg, South Africa.

In his introductory remarks to the workshop, Dr Harm Pretorious, Deputy Director-General of South Africa’s Department of Health, spoke about this critical period for his country’s drug policy. After South Africa’s first democratic elections in 1994, the Department of Health had revised its policy in order to remove all of the health sector’s past inequalities. The new policy was developed through broad consultation and included many stakeholders because of its far-reaching impact on all groups in society. The policy’s main objective is to supply essential drugs to the majority of the people at an affordable price, ensuring safety, efficacy, good dispensing practices and patient education.

Obstacles to overcome

However, discussions revealed that the national drug policies adopted by other countries in the region are less clear. Other problems also emerged. In many Southern African countries there is an acute shortage of public sector health care providers, especially pharmacists. This has a serious impact on the success of national drug policies. Key positions remain vacant and trained workers often leave for better-paid jobs in the private sector. Inadequate budgets, major local currency devaluations, drug shortages and emergency procurement damage the national drug policy’s possible impact. Rising drug prices make drugs inaccessible to many consumers in the region. Due to economic liberalisation, drug pricing is not effectively controlled by legislation and instead relies on market forces. Prices for the same drugs vary widely depending on where they are bought. Rational drug use goals are further upset by many countries’ dependence on donations – which are often sent in an uncoordinated way.

Yet there have been encouraging developments which will help to solve these problems. In Malawi and Lesotho, for example, donors have begun to contact church groups to ask if certain drugs are needed and they then send them in usable quantities. In Zimbabwe the Consumer Council is lobbying for legislation to control drug prices, and a number of groups attending the workshop have initiated a regional drug pricing survey to address unacceptable price variations.

Spreading the word

Despite so many constraints groups in the region are active in making consumers more aware of the issues involved in national drug policies. For example, the meeting heard that in Mozambique a new consumer organisation has campaigned for rational use of drugs. The group, ProConsumers, has publicised the dangers of using expired drugs and broadcast radio programmes informing people about the dangers of buying drugs from the informal sector. Health Action Centre in Nigeria has relied on creative means to educate consumers, including traditional storytelling and drama presentations to point out drug hucksters’ tricks, such as changing expiry dates, copying labels and substituting ingredients. The Group makes any location a potential learning place, by meeting with consumers in their homes, at schools, in churches and market places, during women’s organizations’ meetings or on buses.

Before the meeting closed, participants discussed the next phase in HAI’s three-year project, Networking for Rational Drug Use in Africa. Plans are already well advanced for a third regional workshop, this time in francophone Africa.

A report of the workshop is available from HAI-Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, the Netherlands.


Zimbabwe launches National Drug Policy

Zimbabwe’s National Drug Policy was formally launched in March 1998 by the Minister of Health, Dr Timothy Stamps, at a colourful ceremony at the Harare Central Hospital. Simultaneously the Policy was launched in four other centres throughout the country. The launch is a culmination of the efforts of all sectors of the health system – including health service providers, the pharmaceutical industry, various ministries and other stakeholders.

A five-year work plan underlies the Policy, and has been in operation even before the formal launch. Dr Stamps stressed that the concept of a National Drug Policy was not new to Zimbabwe and that work on it started soon after the country gained its independence in 1980. At the same time promotion of the rational use of drugs and production of standard treatment guidelines and essential drugs lists had also begun.

The launch of the policy is “the Government’s commitment to the goals described” said Minister Stamps, whilst urging everyone to familiarise themselves with its contents and to identify their individual roles in its implementation.

Also speaking at the launch was the Consumer Council of Zimbabwe’s representative, Mrs Kereta Chikowwe. She explained that access to correct drug information was a fundamental consumer right, and that increased literacy levels in Zimbabwe had increased consumer’s critical awareness. Presenting a copy of the Patients Charter to the Minister, she impressed on him the need for Parliamentarians to have a clear understanding of the National Drug Policy, so that legislation to support the Policy would be put in place.

WHO Representative, Dr Levon Arveshtanian, stressed the importance that WHO attaches to the development and implementation of national drug policies. Other speakers underscored the need for a concerted multidisciplinary approach for successful policy implementation. Finally, the choir from the Harare Central Hospital School of Nursing was on hand to sing the Zimbabwe National Drug Policy into life.
Improving quality of care in Hai Phong Province

John Chalker*

BACKGROUND

In 1993/94 the system of commune health stations (CHSs) in Hai Phong Province, Viet Nam, was in danger of collapse. This was a system that had provided a health station in every commune in Hai Phong with a staff of one or two medical staff, trained for three to four years at the secondary medical school (these schools exist in most provinces to train nurses, midwives and medical, pharmacy and laboratory assistants). The health stations were a focus for all preventative and curative activity. They were mainly financed by the commune, but carried out Health Ministry vertical control programmes as well as providing obstetric and curative care. Each commune has an average population of around 6,000 people, and few people are more than 10 or 15 minutes from their nearest station.

It was this extensive infrastructure that was a large contributory factor to Viet Nam's excellent health statistics on infant mortality and life expectancy, which are comparable to countries with a much higher gross national product.

Since 1989, under the Government’s policy of “Doi Moi” or renewal, private practice in the health sector was legitimised. This new approach, coupled with inflation, meant that in practice investment in the stations virtually ceased. At the same time many private drug sellers (both licensed and unlicensed) appeared. Salaries for health workers reduced to non-wage which led to increasing numbers of health workers starting a private practice or taking up other income generating activities; all illustrated a breakdown of the health services.

The consequence had serious implications for preventive care. With the reduced esteem of the CHSs due to declining curative activity, there was a concomitant reduction in motivation to finance the CHS by the communes. This threatened the very existence of the institutions that delivered the preventive care.

It was the project’s goal to break this cycle of decline.

THE PROJECT

The project was a co-operation between Save the Children Fund UK, and the Hai Phong Provincial Health Bureau.

Limited drug list: we hypothesised that if the commune health stations offered a good service, where common diseases were well managed; where necessary drugs at affordable prices were supplied in the right doses at the right times; where people with more serious problems were referred in a timely way to hospitals; where they had the basic drugs as a well managed revolving fund; and where the necessary basic equipment was present, then several consequences would follow. The first would be that more people would use the CHS. If this were the case, then the small profit made on drug sales would increase. These together would improve the health workers’ morale and financial situation. The second consequence would be that the commune, district and provincial people’s committees would realise what an excellent resource they had in the CHSs and would mobilise more funds to maintain them. In this way the institutions of preventive care would be preserved and the spiral of decline would be broken.

Strategy

We aimed to affect several aspects of quality of care. We would improve the basic medical equipment, drug availability and the level of staff training. In addition we would help them construct a sustainable accounting system for ongoing drug supply, develop standard treatment guidelines, create district supervision of the quality of prescribing and accounting, and improve the rational use of drugs.

Participants at one of the district workshops which drew up standard treatment guidelines

Participants of the commune health stations (CHSs) in Hai Phong Province, Viet Nam, were more than 10 or 15 minutes from their nearest station.

The first would be that more people would use the CHS. If this were the case, then the small profit made on drug sales would increase. These together would improve the health workers’ morale and financial situation. The second consequence would be that the commune, district and provincial people’s committees would realise what an excellent resource they had in the CHSs and would mobilise more funds to maintain them. In this way the institutions of preventive care would be preserved and the spiral of decline would be broken.

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Changing people’s prescribing habits has been shown worldwide to be extraordinarily difficult. These habits are not just formed from a rational knowledge base, but are affected by many financial, social and cultural factors. Prescribing (both bad and good) is a habit. To break the bad habits and establish good habits a combination of “carrot” and “stick” need to be employed over a considerable period. We hypothesised that if good prescribing habits could be established for more than half a year then there was every hope that they would continue. We therefore used other aspects of improving quality of care as both carrots and sticks towards changing prescribing habits.

We reasoned as follows:

1. Carrot

Research: if all work was based on locally found research results, the “top down” image would be broken and we would be seen to be basing our work on the real situation.

Treatment guidelines: if simple guidelines were developed, then it would be easy to judge the quality of treatment. If these guidelines concentrated on the most frequently seen conditions in all districts covering more than 80% of patients, then only some 10 conditions would need to be covered.

2. Stick

Limited drug list: by looking at the guidelines and adding a few more for emergency situations, an agreed list of drugs could be determined.

Participation: if the health workers participated in formulating these treatment guidelines and drug list, they would be more likely to have a sense of ownership of the results.

Retraining: by concentrating on the management of these 10 basic conditions and the limited list of drugs, retraining could be feasible and effective.

Supervision: regular supervision of quality of prescribing from the district health centre would be a vital aspect of in-service training, morale building and developing a unified system.

Drug fund: if the CHS had a sufficient drug fund to stock the needed drugs from the limited list, it could purchase these drugs locally and sell them at a competitive price to the private market. This...
would please health worker and public alike.

Accounting system: developing an accessible, transparent book keeping system. The CHS would help to ensure the existence of an ongoing revolving fund.

Equipment: the possibility for the CHS to choose basic equipment from an agreed list every three months for nine months would act as a real incentive to change prescribing habits.

Patient load: with an increasing patient load, income would increase.

2. Stick

Withholding of equipment: if the agreed treatment guidelines and book keeping system were not followed, then the equipment would not be forthcoming.

Peer pressure: the withholding of equipment would be public knowledge.

Supervision: the regular supervision would also be a form of inspection.

Public expectation: if, through a series of television and radio programmes, leaflets and posters, the public were informed about key aspects of drug use and CHS service, then their demand for irrational treatment would decrease.

Phased Implementation

The project was implemented, district by district, in all 12 districts in 217 communes in Hai Phong covering a population of 1.6 million people. In each district the whole process took up to one year. We started with the rural areas and ended with the urban and island districts. Work started in the first district in June 1994 and the last in January 1996. It covered a series of activities aimed at improving aspects of quality of care.

Pre implementation in each district

Baseline research on key drug use indicators and which diagnoses were being made at CHSS was carried out in all CHSs of the district. This was either done by retrospective examination of out patient books or if these were absent, by prospectively giving prescription pads and examining them after one month.

As a pre-condition for joining the project, each district health office had to agree to set up and run a team of supervisors to monitor the quality of treatment

The supervisors’ motivation and ability to perform was tested. With satisfactory results from the regular supervision of the district teams, at three monthly intervals, each CHS was allowed to choose around US$250 worth of basic medical equipment from an agreed list. This equipment was conditional on following the treatment guidelines and book keeping system.

Initially some CHS staff found it difficult to understand and adhere to the new accounting and prescribing procedures. However, the district health team’s supervisory visits and at least one early visit from a Save the Children team member helped to resolve problems. After this visit, when processing the monthly information for the district, the project wrote to the district health officer highlighting any unsatisfactory practices within particular CHSs, (such as overuse of antibiotics or injections). If, after warnings, bad practices went unchanged, the requested equipment was refused until improvements had been made.

The supervisors’ motivation and abilities were another concern. If highly qualified the supervisors were reluctant to travel around to the CHSs. If they were less highly qualified they were more willing to travel but did not have the authority to advise the medical assistants on their practice. This problem was tackled differently in each district, but on the whole the supervisors managed to collect the necessary information. The head of the district health office reviewed the supervisors’ progress each month when they came in to collect the data. The review was based on the information that had been collected. When information had not been collected for the month because the supervisors had not done their work, equipment distribution was stopped in the whole district. We also stopped delivery if the information seemed unreliable, for example if everything was scored at 100%. The reliability of the
The Information Education and Communication campaign evaluation

**Evaluation**

Two hundred households from five communes were randomly selected and interviewed.

The results showed that the IEC campaign had been memorable:
- 89% of households could recall some IEC messages.
- Only 25% claimed no change in knowledge.
- The other 75% claimed a change in knowledge, practice or both.

The most effective means of communication was the commune public address system. 67% of respondents remembered at least one message from these.

52% of all households remembered something from TV (51% of the households owned a TV).

53% remembered something that their CHS staff had told them.

Newspapers and posters were less effective with only 7.5% and 15% remembering something from these.

The leaflet was not remembered very often (37%), but in the communes where the leaflet was not distributed to each house, respondents were twice as likely not to remember any message.

**Conclusions**

IEC campaigns based on locally made programmes and research-based messages can be very effective and inexpensive in Viet Nam. Commune public address systems are still effective in rural areas. This is based on the decentralised media system of province, district and commune. This has profound implications for future campaigns on, for example, nutrition, weaning practices or HIV.

(A full report of the IEC evaluation is available from the address at the end of the article.)

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**Box 2**

The Information Education and Communication campaign evaluation

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**Table 1**

| Hai Phong baseline, Hai Phong research and Hai Phong latest supervisors’ reports |
|---------------------------------|------------------|------------------|------------------|
| **MONTH** | **August 1994** | **December 1995** | **September 1996** |
| **Patient numbers per CHS per month** | 76 | 115 | 120 | 114 | 137 |
| **ITEM/PT** | 2.3 | 1.4 | 1.5 | 1.5 | 1.4 |
| **% patients given VITAMINS** | 75% | 8% | 7% | 6% | 6% |
| **% patients given INFECTIONS** | 33% | 7% | 7% | 6% | 6% |
| **% patients given ANTIBIOTICS** | 69% | 46% | 45% | 48% | 43% |
| **% antibiotic DOSES OK** | 29% | 91% | 98% | 93% | 98% |
| **% treatments following the STG** | 92% | 93% | 86% | 95% |

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For further information on the Programme contact: The Field Director, Save the Children Fund UK, 218 Doo Can Street, Ba Dinh District, Hanoi, Viet Nam. Reports on the Programme evaluations, including the public information campaign, are available from this address. Other publications are pending.
global survey of public education in rational drug use1 has revealed that efforts in both developing and developed countries are being severely hampered by under-funding, lack of support and a shortage of expertise. The outcome, says the report, is a vicious circle in which projects are poorly planned, weakly implemented, and not evaluated rigorously enough.

The report by the Action Programme on Essential Drugs is based on the first ever global survey of public education in rational drug use. The study set out to establish who and what is being targeted by rational use programmes; who is doing the work, how and why; what are the needs and lessons learned; and what future action needs to be taken. The survey included data from about 100 organisations and educational materials gathered from 38 countries (25 developing and 13 developed countries).

Critical need for public education

The report points out that in many parts of the world up to 80% of illness episodes are self-treated with modern pharmaceuticals. And even where formal health care channels are used, it is the consumer – not the prescriber – who determines whether and how the drugs are used. These decisions are based on the shared beliefs of family, friends or the wider community; information from prescribers and dispensers; and promotional material. As a result, consumers need access to accurate and understandable information about the potential benefits and risks of medicines in general, including possible side effects; how they act within the body; and the limitations of pharmacotherapy and other treatment options.

“With the exception of Australia, no country – developed or developing – has undertaken a structured public educational programme, targeting all members of the community and developed by a coalition of stakeholders,” says the report. The authors point out that in developing countries it is not surprising that, in view of the wide range of other competing areas of drug policy, public education in rational drug use is often given low priority. But its neglect by developed countries is more difficult to understand.

“It is more difficult to explain the lack of commitment by developed countries to systematic and structured public education in rational drug use, given the potential economic and public health benefits,” the report states.

Until now few public education in rational drug use interventions have been documented or evaluated. As a result, experience cannot be shared or built on. The DAP survey was intended to help close this gap.

A surprise finding was that there were fewer differences than expected between the types of programmes in developing and developed countries. The most significant was the different media used. While education programmes in developed countries rely on mass media to get their message across, programmes in developing countries reported more frequent use of the mass media, especially radio. In developing countries, the most popular channel of communication was the mass media (76% of projects) followed by workshops (70%) and the distribution or display of printed materials (26%). Developed countries focused mainly on printed materials (61% of projects) and the mass media (56%).

Reaching out to schoolchildren and the elderly

School projects accounted for a large number of education programmes, especially in developed countries, but only Sweden had launched a nationwide programme targeting all schools. Projects ranged from a novel “pill-box” information campaign in secondary schools in Belgium (see Box 1), to projects for younger children in the United States, involving the use of pharmacy students to teach drug safety and compliance, and encourage children to take responsibility for their own health.

Many of the sample school kits submitted had been developed in collaboration with the pharmaceutical industry or pharmacy organizations. Most failed to highlight the risk/benefit equation of drug use, or even that the same active substance may be marketed under different brand names and at different prices. In addition, little effort was made to encourage children to develop a more objective view of the commercial promotion of drugs.

A variety of innovative approaches are being used by groups in both developed and developing countries to get the message across. In Germany, the BUKO Pharma-Kampagne uses street theatre presentations to raise public awareness about rational drug use, while in Australia, the Medicine Information Project makes use of trained elderly volunteers as peer educators to promote rational drug use among the elderly population. Volunteers receive an initial five days’ training, updated four times a year. The topics

Box 1

“Far-Well” and “Medi-Studt”,
The best medicine for students – Belgium

Students are “open” to new information; learning is their job. Students are also prone to using medications, especially in order to study well during examination time.

Knowing this, the higher-educational institutions (non university) in Belgium requested Project Farmaka, a non profit independent organization, to assist. The result, designed and developed by a planning group consisting of a pharmacist, prescribers and students, was an innovative “pill-box” of information destined for distribution in schools and student clubs. The choice of subject matter in these “pill-boxes” was based on the most common illnesses and complaints, and on the most commonly used medicines by students. The main message: “Use a medicine ONLY WHEN IT IS NEEDED.”

But activities went far beyond the simple distribution of the “pill-boxes”. Information stands were set up during school breaks and at lunchtime, with displays and posters. In order to get a “pill-box”, a student had to complete a quiz form with five pertinent questions. Workshops were held with the students to discuss the information. Mass media also participated, with radio interviews and television announcements.

The campaign was well-timed. It was held during the examination period, when students are prone to taking vitamins and “sleep pills”, and to having sleep-related problems. The students were particularly open to discussions about medications, and wanted to learn more. Some schools have established a “medicines panel” to disseminate additional information about problem drugs, and to discuss issues like sports and diet. Other schools are organizing question-answer sessions focusing on medications.

The “pill-box” concept was innovative and sparked people’s curiosity. The materials could be improved, to be sure, and future campaigns will take into consideration more of the students’ views on content, in addition to design.
covered include consumer rights and responsibilities, use of specific medications, assertiveness, problem-solving, as well as presentational and listening skills.

elsewhere, telephone services in Peru and the Netherlands have been forced to expand the service after being swamped with calls on medicine-related health issues.

Weaknesses identified

The authors warn that the use of a wide range of different materials in some developing country projects – inadvertently promoted by funding and supporting agencies – may lower their effectiveness by diluting the message. The report highlights the difficult balance needed between having a few, well-developed and well-used complementary materials and a large number of relatively unconnected ones.

The report reveals that almost half the projects used educational material that was never used. Of those that did pre-test materials, most reported that the materials needed subsequent revision. Although the survey did not extend to the quality of pre-testing, the authors warn that the methodology for this is often lax. Common weaknesses in the material submitted included a proliferation of messages and the over-use of scare tactics, while some required considerable training before they could be used effectively. The report recommends the development of relatively simple methodologies to ensure that all materials can be thoroughly pre-tested and, where necessary, revised before use.

Another weak spot identified in the report is the lack of structured planning. Most projects selected fairly general themes on the basis of “perceived need” and their target groups and expected outcomes were also very broad. However, significantly more developing countries (43%) than developed countries (27%) had based their projects on research findings (including consumer and practitioner surveys, focus-group discussions, and patterns of drug sales).

Of the specific drug problems targeted, developing countries most frequently cited antidiarrheal and antibiotics, while developed countries focused more often on benzodiazepines and other sedatives. The illnesses most often targeted were diarrhoea and malaria in developing countries and asthma in the developed countries.

The report highlights the failure of most projects to evaluate the impact of their activities. As a result, cost/benefit analysis is impossible – deterring many potential donors. Very few projects were able to provide evaluation reports. And, with the exception of rational use of drugs projects in Australia and Viet Nam, most focused on activity monitoring rather than impact assessment.

“This is unfortunate,” the authors point out, “for public education programmes are often accused of a lack of rigour in their work, leading to a questioning of their value and consequent difficulties in obtaining support for such programmes.”

However, the report also warns that the impact of public education strategies is often incremental – moving gradually from initial awareness raising, to knowledge creation, community empowerment and behavioural change. “This may be difficult to evaluate in the short-term – particularly using classical methodologies,” say the authors, “and care is needed that we do not ‘throw out the baby with the bath water’ in an attempt to evaluate impact with scientific rigour.”

In the absence of systematic evaluation studies, many projects gave estimates of the impact of their activities. In developing countries, 40% of projects judged that their project had met its objectives, compared to 66% in developed countries. Meanwhile, 60% of developing countries and 30% of developed countries said the project objectives had been partially met. No developing country and only 4% of developed countries deemed their project to have been a failure. The main problems faced by projects included:
- shortage of funds;
- inadequate external collaboration and support;
- poor coordination;
- shortage of time and personnel;
- opposition from vested interests (both commercial and professional);
- unsupportive legislation.

Of these, the lack of funds was the major problem for developing countries, while for developed countries, the principal constraint was a shortage of time and personnel. On sources of funding, the survey found that developing country projects were most likely to be funded by international organizations or international NGOs, while ministries of health and professional associations were the major source for developed countries.

Tackling the problems

The report notes that if public education is to be properly researched, backed by the necessary tools and knowledge, and be effective and sustainable, it must be adequately resourced – ideally from a variety of funding sources. It says new, more creative and sustainable sources of funding are needed, possibly including:
- a tax on commercial drug information budgets to provide independent information to consumers and to support community projects;
- incentives to dispensers to develop community education projects or extend individual counselling – particularly in countries where dispensing is covered by social insurance schemes;
- independent consumer information for sale at a price that covers recurrent costs.

The report also highlights the need for greater advocacy at international, national and regional levels to promote the importance and rationale of public education in rational drug use. It says there is a need for greater understanding of its potential contribution to public health and savings in health expenditure. Better advocacy, say the authors, would help “avoid simplistic, unsustainable, and token approaches that contribute little to real community empowerment and understanding, but simply pay lip service to the very real information and educational needs of the community in this important area.”

Also needed are opportunities for short-term training and access to simple, practical tools essential for research and development activities, especially for small-scale community-based programmes. The authors point out that no courses exist in the area of public education in rational drug use, and call for the development of an international training course through which educators could strengthen their communication skills and, in turn, train national colleagues through in-country training programmes.

“Organizations or people who intend to carry out public education projects need clear, usable guidelines to help them better plan and structure their activities, including better definitions of the theme(s), the desired outcomes of the project, and the target audience.”

The report also calls for the development of supportive coalitions and partnerships which could help strengthen the work and long-term sustainability of many organizations, especially those working in relative isolation. But it also warns that organizations need to ensure they are not hijacked by powerful interests “less interested in the community’s own perception of needs and empowerment, and more concerned with ‘marketing’ behaviour considered desirable by the dominant group.”

The most encouraging finding of the survey was, despite its current failings, at its best, public education on rational drug use can and does work. Among developing countries this was the second most important lesson learned and for developed countries the third most important. In Bolivia, a primary health care project declared that it was possible to get the community to take responsibility for their health, while rational use of drugs campaigners in Bangladesh reported that effective lobbying had shown that “continuous, logical insistence to producers on rational/ethical production works.”

Elsewhere, in Australia, the Medicine Information Project noted that, “empowering consumers can drive change at all levels of the health system.”

Reference

Advantages of pre-packaged antimalarials

A Ghanaian study\(^1\) has shown that treatment of malaria is more cost-effective, in terms of both time and money when antimalarials are pre-packed in daily doses. Preliminary observations in six districts indicated that some of the major problems in malaria control programmes are: high cost of treatment; high chloroquine consumption (in syrup form); long waiting times at dispensaries; and a large number of untrained/unqualified dispensers who are unable to give advice.

Two types of pre-packaging were used in the study – plastic bottles for chloroquine syrup and sealed plastic bags for chloroquine tablets. The advantages of pre-packaged antimalarials were found to include:

- **Sustainability** – cheap, readily available materials.
- **Acceptability** – to both staff and patients.
- **Reduced cost** because of: reduction in the number of drugs prescribed; smaller volumes of syrup consumed; reduction in the number of injections given; reduction in excess chloroquine consumption.
- **Improved drug management** – easier to balance stocks; easier to monitor drugs issued; reduced contamination; less wastage.
- **Improved case management** – doses given according to weight.
- **Improved compliance** – easy to understand and easy to remember instructions; more effective counselling.
- **Reduced waiting times** in dispensaries.

**Why patients need information**

Other Ghanaian studies have shown how much greater the effect of pre-packaging antimalarials is when better information is provided to patients by prescribers and dispensers. These studies were part of the series being carried out by district medical teams in collaboration with the Health Ministry’s Health Research Unit, in the context of Ghana’s health sector reforms. A Phase 1 study had indicated that many patients who receive chloroquine are not given any information about how many tablets to take or how often to take them. They may also be given either more or less chloroquine than they need. This is important because failure to comply with the full course of treatment affects both the patient’s cure and the drug resistance of parasites.

The follow-up intervention ensured that prescribers and dispensers provided full information to patients about the duration of therapy and the quantity of chloroquine to take each day. As well as verbal instructions patients were given a diagrammatic explanation to take home.

Following the intervention there was a significant increase in adherence to treatment – from 25% to 50% – in the number of patients strictly complying with these instructions. The proportion of people obtaining at least enough chloroquine on each of the three days of treatment increased from 29% to 54%.

The proportion of children who obtained at least the recommended minimum dose of chloroquine on each of the three days increased from 59% to 83%. Sample sizes used in the study were between 55 and 75 patients.

This work shows that a little time invested in providing appropriate information to the user at primary health care facilities will, in the long run, pay dividends in terms of increased patient adherence to treatment.

For further information contact: World Health Organization, Special Programme for Research and Training in Tropical Diseases, 1211 Geneva 27, Switzerland.

Source: TDR Newsletter No. 54, October 1997.

**Reference**

1. The study was part of a project to improve malaria control in Ghana, financed by the UK’s Department for International Health, Liverpool School of Tropical Medicine (UK), the Ministry of Health in Ghana and WHO’s Special Programme for Research and Training in Tropical Diseases (TDR).

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**TRADING**

Course offers flexible approach to community-based health education

In publicising one of its newest courses, Leeds Metropolitan University in the UK sets out clearly the benefits of health education: the awareness it creates among community, policy makers and health care providers of the advantages of a rational drugs programme and the proper use of medicines; the increase in the skills of health care providers in the delivery of sensitive, appropriate and effective patient education; and the encouragement it gives for community and political action to prevent the misuse of drugs and medicines.

The University is offering a 10-week course in community-based health education and health promotion with specialist options, including one on medicines and essential drugs. Participants either finish after 10 weeks and receive a certificate of attendance or study further by distance learning within their own workplace for a diploma, based on implementation of a project that they designed at Leeds.

The aims of the course are to provide skills in research, planning, management and evaluation of health education, and provide opportunities to apply these skills to a problem from the participant’s own work setting. Applicants should be experienced managers and staff within field projects who require a short course to improve their capacity to plan, implement and manage the health promotion components of projects.

**Module on medicines and essential drugs...**

Among topics covered in this module will be:

- Appropriate use of medicines, including an introduction to: the essential drugs concept and appropriate use of medicines; the work of WHO’s Action Programme on Essential Drugs, international pressure groups and consumer movements; and problems arising from inappropriate use of medicines.
- Health seeking behaviours: self-medication, informal market sectors for medicines and problems of implementing essential/rational drug policies.
- Assessment of needs for health education/health promotion support for appropriate use of medicines.
- Community, social and economic influences on use of medicines and the role of multinational companies.
- Health education and health promotion methods in various settings: national campaigns, mass media, patient education, community self-help groups, community pressure groups, training of pharmacists, and training in the informal sector.
- Planning for programmes to promote appropriate use of medicines: selection of indicators for monitoring and evaluation.

The course is expected to cost £3,000 for academic tuition and field visits, with subsistence/accommodation expenses of approximately £2,500.

For further details contact: Overseas Admissions Tutor, Health Education, Room T505, Leeds Metropolitan University, Calderley Street, Leeds LS1 3HE, UK. Tel: 0113 28322600, fax: 044 113 28383921, e-mail: health.promotions@le.ac.uk
HE development of a personal formulary system by university teachers in the Netherlands is proving to be a valuable tool for students in learning how to prescribe drugs rationally. The personalised compendium of drugs not only helps students learn about the drugs they prescribe, it also helps them choose alternatives in case one drug is unsuitable for a particular patient.

The personal formulary is a practical elaboration of the P(personal)-drug concept, which is outlined in Part 2 of the WHO Guide to Good Prescribing. It consists of a sequential approach for selecting a personal set of drugs for the treatment of specific diseases. By using a loose-leaf notebook and a small manual, practical information about the selected diseases and P-drugs can be inserted, changed or deleted. Later, a personal formulary can be developed.

The personal formulary is divided into sections. The first section is used to list selected diseases. For each disease, a chosen standard drug and non-drug treatment can be described extensively or merely summarised. For example, (Dutch Standard Guidelines):

**Essential hypertension:** start with weight, salt, and stress reduction. If no result:
1. atenolol or hydrochlorothiazide; if no result:
2. atenolol + hydrochlorothiazide; if no result:
3. captopril; if no result:
4. consider calcium antagonist, alpha 1-blocker, or referral.

The second section contains practical information for prescribing the drugs listed in the previous section. Each page has information on a single drug, and the information is organized along the lines of the sequential approach to treating patients (outlined in Part 3 of the Guide to Good Prescribing).

One side of the page contains the information needed to check not only whether a specific drug is indicated for the disease but also whether the drug is suitable for the individual patient (see Figure). If the doctor or student has decided that the drug can be prescribed, they then turn to the other side of the page. Here a prescription can be made out together with the necessary information and instructions for the patient, as well as the date of the next appointment, where appropriate (see Figure). Information about monitoring the drug treatment can also be inserted here. With the loose-leaf system, the content of the personal formulary can be easily changed.

The simplest way is to write or type the information about each P-drug. A computer programme has been developed for this with technical support from the WHO Collaborating Centre for Pharmacotherapy Teaching and Training at Groningen University. Using this programme, the data can be typed, and printed in a standard format as shown in the Figure. Students can also add and remove drugs, and revise any of the information about an individual drug. In this way students build up their own personal formulary. To help make it more personalised, each printout includes the name of the student. The programme can be installed on a computer network – a university network, for example – or on a personal computer.

In the computer network of the Free University of Amsterdam, information on over 90 drugs has been included in the reference database. Clinical experts within the university consider these drugs appropriate for the treatment of 129 diseases and symptoms. At the end of the six-year undergraduate course medical students must be able to treat correctly, within 10 minutes, a real patient suffering from any one of these diseases. At the start of the second year, students receive a personal formulary with a printed version of the basic information on the full range of over 90 drugs and can copy this information to their personal database. Next they are trained in developing and using their personal formulary. Up to the fourth year they practice in small groups by treating both textbook and simulated patients. A syllabus has been developed for this which includes about 20 text-book cases together with treatment plan forms (following the sequential approach of the Guide to Good Prescribing) and suggestions for patient role-playing exercises. During the internships in the fifth and sixth year, the students practice with real patients. Students can buy a personal formulary and the syllabus for US$20. They also receive the Dutch Drug Compendium free of charge from the National Sick Fund.

**T R A I N I N G**

**Personal formulary system helps university students**

**Theo P.G.M. de Vries**

**NEWSDESK**

**Addressing supply issues in the Eastern Caribbean**

**Management** Sciences for Health and the Eastern Caribbean Drug Service offered a special eight-day course on managing drug supply, held in Dominica from 19–28 January 1998. The 18 participants included central medical stores’ managers and hospital drug supply managers from all nine countries in the Organization of Eastern Caribbean States.

The course was specially designed to address the specific drug supply issues of the island countries, including: lack of national drug policies; lack of current quantification of needs, drug donations, medical store management and inventory control and drug utilisation reviews. Participants discussed their own experiences and worked hard to complete realistic work plans and timelines for improvement projects to be implemented upon their return to work. These plans were shared with the Ministries of Health and will receive support and follow up from the Eastern Caribbean Drug Service. "Source: INRUD News, February 1998"
Change at WHO

The first Palestinian conference on rational use of drugs brought together an enthusiastic group of health workers, nurses, pharmacists and doctors from throughout the health sector. Speakers from international and local NGOs, Palestinian universities, and physicians’ and pharmacists’ associations helped to raise awareness of rational use issues. Discussions ranged from the impact of inappropriate drug use to standard treatment guidelines, essential drugs policy, drug information, continuing education for pharmacists, quality assurance and drug donations. The event is seen as an important step in moving to design a health policy that meets the needs of all Palestinians.

Held at Beir Zeit University in October 1998, the conference was organized by the Union of Palestinian Medical Relief Committees with the support of the French Government and the United Nations Development Programme.

For further information, contact: Nadine Kamal, Head Pharmacist, Union of Palestinian Medical Relief Committees, P.O.Box 51483, Jerusalem. Tel: +972 2 5830 679, e-mail: NadineKamal@hotmail.com

Executive Board acts on Revised Drug Strategy

Meeting on 19 May 1998, WHO's Executive Board decided to establish a two-tier method of working to explore the complex issues, (including those related to globalization and trade), raised by Resolution 24 on the Revised Drug Strategy, passed by the Board in 1997. An ad hoc working group would be open to all Member States wishing to participate, and a sub-group would be created to assist WHO in its contacts with relevant partners. These include the World Trade Organization, the World Intellectual Property Organization, the pharmaceutical industry and NGOs. The Board decided that the sub-group would comprise the Chair of the drafting group on the Revised Drug Strategy, elected during the 51st World Health Assembly in 1998, and two Member States from each region (of which at least one would be currently entitled to designate a person to serve on the Executive Board).

As directed by the Board, WHO’s Regional Committees discussed the Revised Drug Strategy at their autumn meetings, and nominated their representatives for the sub-group. The group met for the first time in Geneva in October 1998, and fulfilled its main objective of drafting a new resolution on drug strategy. A total of 59 Member States participated in the meeting. As part of the sub-group’s deliberations a one-day panel discussion was held, which included presentations from interested international and nongovernmental organizations. The Executive Board will discuss the draft resolution at its 103rd session in January 1999.

African countries share information on drug prices

Although the availability of essential drugs in Africa has improved during the last decade, it is estimated that one-third to a half of the 700 million people in the region still do not have regular access to the drugs they need. Over 40% of deaths in Africa are due to infectious diseases for which effective medicines exist, but are not available to those who are ill.

Drug shortages remain chronic in most African countries due to such factors as inadequate national supply systems and weak implementation of national drug policies. Poor knowledge of the international drug market and the lack of effective national quality assurance systems can lead to excessive prices and low quality products. Appropriate and objective information on drug prices and quality standards is therefore essential for drug procurement agencies.

In order to help countries in the region to address these issues, WHO’s Regional Office for Africa, in collaboration with the Action Programme on Essential Drugs, has developed the AFRO Essential Drugs Price Indicator. The programme aims to assist Member States wishing to participate; and as part of the sub-group’s deliberations a one-day panel discussion was held, which included presentations from interested international and nongovernmental organizations. The Executive Board will discuss the draft resolution at its 103rd session in January 1999.
UK study says patients not receiving information they need

Patients in the UK are being denied access to reliable information about treatment options, according to a new study1 from the King's Fund, an independent British health charity. Health professionals either do not know the answers to questions, withhold the information or simply fail to present the whole picture about benefits and risks. Despite endless surveys demonstrating that patients want good, clear information, the study concludes that it is not forthcoming. Yet it is highly likely that good information would save the health service money in the long run, the Fund believes, since it would help patients to look after themselves in terms of prevention and self-treatment.

The study report, Informing Patients: An Assessment of the Quality of Patient Information Materials, demonstrates that good-quality information can improve the effectiveness of patient care. Without it, patients are unable to make informed choices about treatments and are in effect excluded from the decision-making process.

The report details a study in which 62 patients and 28 clinical experts reviewed a wide range of leaflets, videos and audiobooks in current use. It concludes that the information contained was often out-of-date and inaccurate, and sometimes seriously misleading. It did not include full details of treatment options, information about outcomes and treatment effectiveness was often omitted or was unreliable, and patients’ questions were left unanswered.

Change necessary

The patients involved in the study felt that many of the leaflets were patronising and failed to recognise their right to be actively involved in decisions about their care. The report recommends that above all, information should start by answering the questions and concerns raised by patients. The language used should be simple without being patronising. It should be honest about benefits and risks of treatment. So far, the National Health Service Executive has failed to take the initiative on patient information, the report states. Informing Patients recommends that they should fund development and evaluation of materials about common clinical conditions. These could be used alongside the clinical guidelines to be commissioned by the National Institute for Clinical Excellence. There should also be a system for accrediting written and computerized materials, the Fund believes.

A patient participating in one of the focus groups for the research, said: “When they measured my cholesterol levels, I tried to find out what the numbers meant, what the safe levels were and the role of triglycerides. I also asked whether the tamoxifen I am taking for breast cancer would have an effect on my cholesterol and on my heart. “I was completely brushed aside; they ignored the knowledge I had acquired from my own research and I was told not to read too much!” They also said no one else had complained about lack of information. I’m still none the wiser about the facts and my own condition.”

The King’s Fund is urging the Government, the National Health Service Executive and health authorities to support good quality information, to enable patients to participate in decisions about their treatment and to improve the effectiveness of clinical care.


Reference

1. Materials were studied about the following conditions: back pain, cataract, depression, glue ear, high cholesterol, hip replacement, allergy, asthama, endometriosis and stroke.
Controlling research data and updating for the Internet: journal editors revise guidelines

A group of editors of general medical journals met informally in Vancouver, Canada, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group, which expanded, evolved into the International Committee of Medical Journal Editors, and has gradually broadened its areas of concern.

Opinions differ on how editors of medical journals should handle the question of commercial influences on research that they report. After reflecting at length on this complex issue, the International Committee of Medical Journal Editors (still commonly known as the Vancouver Group) altered its guidelines when it met in Boston, USA, in May 1997.

On the issue of controlling research data, the Vancouver Group agreed that “Scientists have an ethical obligation to submit credible research results for publication, and should expect to do so. As the persons directly responsible for their work, the authors as individuals should not enter into agreements that interfere with their control over the decision to publish.”

On the precise influences that a sponsor might have in a research setting, the authors as individuals should not enter into agreements that interfere with their control over the decision to publish.

On the issue of controlling research data, the Vancouver Group agreed that “Editors should require authors to describe the role of these sources, if any, in study design, collection, analysis and interpretation of data, and writing of the report. If the supporting source had no such involvement, the authors should so state. Because the biases potentially introduced by the direct involvement of supporting agencies in research are analogous to methodological biases of other types (e.g., study design, statistical and psychological factors etc.), the type and degree of involvement of the supporting agency should be described in the methods section. Editors should also require disclosure of whether or not the supporting agency controlled or influenced the decision to submit the final manuscript for publication.”

The second issue that the Group tackled was the standards for posting medical and health information on the Internet. The principles that apply to advertising in journals must now be adapted for the Internet. The Vancouver Group tackled this rapidly changing area with the expectation that their statement will need to be revised as web technology develops. The Group agreed that: “Electronic publishing (which includes the Internet) is publishing. Authors, editors and publishers of biomedical journals who post medical and health information on the Internet connected to these publications should follow the policies established by the International Committee of Medical Journal Editors as Uniform Requirements for Authors Submitting Articles to Biomedical Journals and related statements.

The nature of the Internet requires some special considerations within these well established and accepted policies. As a minimum, sites should indicate the names of editors, authors, and contributors to their articles, and their affiliations, relevant conflicts of interest; documentation and attribution of references and sources of all contents; information about copyright; disclosure of site ownership; and disclosure of sponsorship and commercial funding.

Linking from one health or medical Internet site to another may be perceived as recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites. If links to other sites are posted as a result of financial considerations, such should be clearly indicated. All dates of content posting and updating should be indicated. In electronic, as in print layout, advertising and promotional messages should not be juxtaposed with editorial content. Any commercial content should be clearly identified as such.”

In practice this guidance means that advertising banners for drugs should not appear on the same screen as editorial content. Also all links from one website to another should be carefully reviewed.


IDA celebrates and looks to the future

The International Dispensary Association (IDA) celebrated its 25th anniversary in November 1997 with a symposium entitled “25 years of Essential Drugs: the Challenge Remains”. Over 100 people gathered at the Royal Tropical Institute, Amsterdam, to hear seven speakers representing international governmental organizations, national authorities from recipient countries, researchers and pharmaceutical suppliers. The symposium was chaired by Professor Graham Dukes of Oslo’s Institute of Pharmacotherapy.

The opening paper set the current scene, arguing that the money available for drug treatment of populations is insufficient and often not used optimally. Sometimes the wrong drugs are purchased, often they are poorly distributed and very commonly they are used unnecessarily, the audience was told.

IDA’s emphasis on quality

Quality assurance issues were highlighted in papers from representatives of the International Federation of Pharmaceutical Manufacturers Associations and IDA. The latter explained how IDA has integrated a full quality assurance system in its operations. In this way it has overcome one obstacle to the wider use of generic drugs in countries where resources are limited. Speakers from Sudan and Uganda presented their views on “Acceptance, Acceptability and Availability of Essential Drugs”.

They stressed the need to ensure that generic drugs of assured quality were trusted and accepted both by prescribers and patients. They argued that all countries need to develop and maintain a national drug policy to ensure continuing progress in the pharmaceutical sector.

A representative from DAP discussed WHO’s role, stressing that it would continue to be complementary to that of bilateral organizations, industry and non-profit suppliers in moving from assistance in acute relief situations to the stage of progressive development.

The time reserved for discussions and questions saw a lively interaction between the audience and speakers. Debate ranged over many topics, including the importance of national drug policies and rational drug use; the need to control drug donations; the harmonisation of registration rules; the role of national quality control laboratories; and the need to further develop the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

On this memorable occasion IDA had sought to provide a forum for the exchange of facts and ideas – to look at what has been achieved in the area of essential drugs and what remains to be done. Guests left the symposium with a much better understanding of the problems and the opportunities in this critical area.

Primary health care systems for the 21st Century – the need for vision and values

Taking stock of the challenges to health that will confront the world in the coming century and assessing their implications for future health systems is a daunting task. Yet this was the remit of the Seventh Consultative Committee on Organization of Health Systems Based on Primary Health Care. The Committee met in Geneva in February 1997, and, in view of the far-reaching implications of its findings for WHO’s future agenda, it was decided to issue a short Statement summarising its conclusions.

Copies of the Statement and the full report of the Seventh Consultative Committee on Organization of Health Systems Based on Primary Health Care are available, free of charge, from: World Health Organization, Division of Analysis, Research and Assessment, Health Systems Development Programme, 1211 Geneva 27, Switzerland.

Professor Graham Dukes, opening IDA’s symposium
### Increased local production of essential drugs on agenda in Africa

The first meeting on the local production of essential drugs in the African Region was held in Praia, Cape Verde, from 14 to 18 September 1998. Organized by the WHO Regional Office for Africa, it was attended by 44 participants from 19 countries in the Region. They included directors of pharmaceutical services and national supply agencies, national drug regulatory authorities, local drug manufacturers and specialists in local production, as well as representatives of the United Nations Industrial Development Organisation, the West African Pharmaceutical Federation and WHO.

In his opening speech, the Prime Minister of Cape Verde insisted on the need to promote the development of a viable local pharmaceutical industry. The industry should be capable of producing good quality drugs at affordable cost, within an appropriate regulatory environment, in order to improve the population’s accessibility to essential drugs.

Participants held in depth plenary and group discussions on five major themes:

- information exchange on the local production of pharmaceuticals;
- mechanisms to improve management and increase local production;
- bulk purchasing mechanisms at national, intercountry and regional levels;
- strategies for improving quality assurance and regulatory mechanisms;
- industrial production of traditional medicines and their use in the health care delivery system.

### Brazil’s doctors turn on to evidence-based medicine

Twenty thousand Brazilian doctors, approximately 10% of the country’s total, regularly watch a primetime television show dedicated to promoting the practice of evidence-based medicine. The Brazilian Cochrane Centre and the Sao Paolo Medical Association created the programme, Medicina Baseada em Evidencias, three years ago. It regularly attracts an audience of some two million, to watch the presenter, a doctor trained in evidence-based medicine, interview experts on medical topics. The show’s message is spreading beyond Brazil’s borders, via satellite to viewers in Argentina, Paraguay and Uruguay.


### Drugs sold on Internet: WHA acts

Delegates at the Fifty-first World Health Assembly (WHA), in May 1998, expressed concern at the advertising, promotion and uncontrolled sale of medical products by electronic communication. There are fears that this rapidly developing phenomenon may present a hazard for public health as well as a risk for the individual patient—particularly with regard to fraudulent product information and lack of individual counselling for consumers. At the 1997 Assembly delegates had already expressed their wish to see the meeting becoming an annual event, in order to evaluate progress made on local production and related issues. He also confirmed WHO’s readiness to assist Member States in their pharmaceutical sectors.

Delegates concluded that the meeting had proved a good opportunity to exchange experiences related to local production of essential drugs in the Region. It was also the first step towards the development of the existing potential of the pharmaceutical industry in Africa. For this potential to be realised, participants agreed that there was a need for greater political commitment, development of national drug policies supportive of local production, improved management, and human resources and technology development.

A report of the meeting is available from: Essential Drugs Programme, WHO Regional Office for Africa, P.O. Box 773, Belvedere, Harare, Zimbabwe.

### Goodbye AHRTAG, welcome Healthlink Worldwide

Healthlink Worldwide is the new name for Appropriate Health Resources and Technologies Action Group (AHRTAG) which has been active in the field of health information since 1977. The new name reflects the organization’s focus on health and describes its way of working globally—linking information and health workers, linking partners, linking policy and practice.

Healthlink Worldwide continues AHRTAG’s aim of improving the health of poor and vulnerable communities by strengthening the provision, use and impact of information. Working with more than 30 partner organizations in developing countries, Healthlink Worldwide runs programmes to support particular health needs. These include continuing education and training for health workers in Africa and the Middle East, and programmes on AIDS and sexual health, child health and disability.

Healthlink Worldwide’s practical training and education materials in printed and electronic forms reach nearly two million health and development workers all over the world. The organization provides technical support to partner organizations and others in setting up and developing resource centres and information services. This work draws on the organization’s extensive collection of health learning materials from developing countries.

For further information contact: Healthlink Worldwide, Farringdon Point, 29–35 Farringdon Road, London EC1M 3BJ, UK. Tel: +44 171 242 0606, fax: +44 171 242 0041, email: info@healthlink.org.uk, website: http://www.healthlink.org.uk


### Fears for the future

Consumer groups were critical of the current lack of controls on companies, with HIV issuing a report at the Assembly calling for new international agreements to regulate product promotion and sales on the Internet. The group wants commercial or educational information from commercial sources to have the same regulatory standards for content as advertisements in other media, and direct links to a company’s home page should be regulated as if they originated from the company.

DRUG INFORMATION

Getting the message across: communications and pharmacovigilance

BRUCE HUGMAN

The difficulty of balancing benefit and risk in drug therapy, drug scares, patient non adherence to treatment, anxiety and uncertainty about the risks of drugs, and secrecy and suspicion in pharmaceutical matters, were among the pressing concerns which gave rise to an international conference on Effective Communications in Pharmacovigilance, held in Erice, Sicily, in September 1997.

Over 70 professionals from 30 countries, representing patients, doctors, nurses, pharmacists, pharmaceutical companies, lawyers, academics, regulators, journalists and communications experts put their collective brain power to the question of how drug safety information could be better communicated between all interested parties in the ultimate interest of patient welfare.

It was acknowledged that even the best scientists and clinicians may lack the specialised skills of effective modern communications, and that insufficient time and priority had been given to discussion and training in this area. Much more attention needed to be paid not only to the content of communications, but also to their form, production quality and the media chosen for their dissemination.

The danger of secrecy

The climate or context in which communication takes place was also seen as a critical variable: in a climate of secrecy, suspicion and uncertainty would flourish, and leaks of information and media scares would be all the more likely. These, in their turn, would lead to an undermining of public confidence in medicine, in the judgement of doctors, and in the integrity of clinicians and pharmaceutical companies in general.

Participants from developed and developing countries alike agreed that a climate of openness and trust, particularly in relation to the activities of regulators and pharmaceutical companies, was an essential prerequisite to a better understanding of benefit-risk issues and to increasingly rational therapy. Accessibility of information was a core requirement. Practitioners needed to be encouraged to see feedback of information from practitioners needed to be encouraged to see feedback of information from...
United and committed: Asia-Pacific’s drug bulletin editors meet

Information is a vital component in ensuring the efficacy and safety of medicine, and commitment to providing such information is evident in the increased number and quality of drug bulletins in the Asia-Pacific Region.

Thirty editors, representing countries extending from Pakistan to New Zealand, attended the first Asia-Pacific Regional Meeting of the International Society of Drug Bulletins (ISDB), held from 6–7 October 1997 at the Universiti Sains in Penang, Malaysia, the meeting showed that, despite their diversity, bulletins in the region share common issues, opportunities and challenges. These include the need to provide information on safe and effective drug use to consumers. This is especially true in countries where consumers can access prescription medicines with little or no advice from health professionals. The need for bulletins to be reader-friendly was highlighted, as in many countries bulletins were competing for doctors’ reading time against the profusion of pharmaceutical company literature.

Working together

The meeting, which received DAP support, was highly interactive with numerous workshops on offer. Lengthy debate followed the sessions which focused on criteria for producing useful, quality bulletins. The need to marry scientific information with practical implications was discussed, as were readability, author credibility, referencing and peer review. Participants developed an action plan covering issues such as collaboration, improving access and use of technology, and establishing an evaluation methodology for bulletins.

The willingness of editors to share, learn and commit to providing quality drug information in the Asia-Pacific Region was evident throughout the meeting. The challenge is to put into practice the many ideas and concepts that were discussed before the next meeting, which is planned for 1999.

A report of the meeting is available from: International Society of Drug Bulletins, PO Box 459, 75227 Paris Cedex 11, France Tel: +31 47003320, fax: +31 47002964, e-mail: ISDB@compuserve.com

WHO information on the move: introducing the blue trunk library

Ready-to-use “mini-libraries” have been compiled by WHO Library Services, to help ensure that district health teams in English- and French-speaking African countries receive the medical and health information they need. The selected books are contained in blue metal trunks for their protection and easy transportation. Priority is given to practical manuals edited by WHO. Modules on essential drugs, general medicine and nursing, maternal and child health, diarrhoeal diseases and primary health care are among those available. As well as choosing the books, WHO Library staff index and package them, and have created an electronic database to go with the mini-library.

Providing much needed publications is only one part of the blue trunk library project. Another element concentrates on raising the awareness of health workers about the importance of information, and of strengthening documentation services in ministries of health. The aim is to set up a network capable of sharing medical and health information in Member States.

The price of the mini-library, containing around 100 books and four journals is US$2,000, including administrative, transport and training costs.

For further information contact: World Health Organization, Office of Library and Health Literature Services, World Health Organization, 1211 Geneva 27, Switzerland.

Meetings & Courses

International Congress on Clinical Pharmacy

To help commemorate the 20th anniversaries of the founding of both the European Society of Clinical Pharmacy and the American College of Clinical Pharmacy, the two organizations are holding an International Congress. Scheduled for 11–14 April 1999 in Orlando, Florida, the main theme of the Congress will be Documenting the Value of Clinical Pharmacy Services.

For further information contact: Theda Mansholtstraat 5b, 2331 JE Leiden, the Netherlands. Tel: +31 71 572 24 30, fax: +31 71 572 24 31, e-mail: secretariaat@escp.nl

Efficient drug management

The Robert Gordon University’s tenth postgraduate certificate course, “Efficient Drug Management and Rational Use”, will be held from 17 May to 16 July 1999. Run in collaboration with the Action Programme on Essential Drugs, the course is intended for health care professionals, especially pharmacists, who are involved in the management and control of pharmaceuticals at national, institutional and programme levels. Fees are £3,300, including course books/materials and accommodation.

For further information contact: Marta Everard, Course Tutor, School of Pharmacy, The Robert Gordon University, Schoolhill, Aberdeen AB10 1FR, Scotland, UK. Tel: +44 1224 626559, fax: +44 1224 262555, e-mail: awdmd@rgu.ac.uk

Problem-based pharmacotherapy teaching course

This course introduces a logical, step-by-step approach to patient problems: setting therapeutic objectives, selecting appropriate (pharmaco)therapy, and monitoring the response to therapy. It also emphasises the importance of correct prescribing and good patient-doctor communication. Intended for teachers of pharmacology and therapeutics, the course (developed at the University of Groningen in the Netherlands) is now available in a growing number of countries.

The next course based at the University of Cape Town, South Africa, will be held from 29 November to 8 December 1999. For further information contact: Department of Pharmacology, Medical School, University of Cape Town, Observatory 7925, South Africa. Tel: +27 21 406 6355, fax: +27 21 448 0886.

And make a note...

Course dates for the University of Groningen course are 19 to 30 July 1999. For further information contact: Dr Wessel Sloof, WHO Collaborating Centre for Pharmacotherapy Teaching and Training, Department of Clinical Pharmacology, University of Groningen, A. Deusinglaan 1, 9713 AV Groningen, the Netherlands. Tel: +31 50 363 2810, fax: +31 50 363 2812, e-mail: summer.course.pharmacot@ med.ru.nl, web site: http://www.indepth.org/courses

The problem-based pharmacotherapy teaching course will be held in the Philippines, in 1999. For further information contact: Professor Tony Smith, WHO Collaborating Centre on Pharmacotherapy Teaching and Training, University of Newcastle, University Drive, Callaghan NSW 2308, Australia. Fax: +61 6 289 8846, e-mail: smith@mail.newcasu.edu.au

La Plata, Argentina, will be the venue for the first South American course (this will be held in Spanish), in either July or November 1999. For further information contact: Professor Hector Buschiazzo, School of Medicine, National University of La Plata, 60 & 120 (1900) La Plata, Argentina. Tel/fax: + 54 21 820117.
Dear Editor,

By chance I recently came across a copy of your journal, the Essential Drugs Monitor, and although it was a 1993 issue it was very educative. Since completing my pharmacy studies in Ukraine and returning to Ghana I have found misuse of drugs (particularly antibiotics and sedatives) on a massive scale. I have come to the conclusion that irrational drug use is mainly due to the lack of effective sources of information for patients, pharmacists and doctors. At my community pharmacy I have tried in my own small way to educate people, but their insults and the potential loss of revenue for my business sometimes overwhelm me.

The Monitor gave me the idea of creating an effective, independent drug information service, where information will be given free of charge, or when necessary, for a token fee. While I work on turning this idea into reality, I would appreciate it if you could continue to send me a copy of your journal, the Essential Drugs Monitor. While I work on turning this idea into reality, I would appreciate it if you could continue to send me a copy of your journal, the Essential Drugs Monitor.

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Drug donations in Rwanda

Dear Editor,

Drug donations to developing countries have become a key factor of international humanitarian assistance in the field of health. People respond enthusiastically to each emergency appeal made by NGOs, out of a desire to help those most in need. Nevertheless, the well-intentioned but uninformed individuals and institutions that wish to make their modest contribution can hardly imagine the harmful consequences that result from large-scale donations for the recipient countries. Lack of training in the management of essential drugs often means that part of the donations are useless.

In almost two years experience in Zaire and Rwanda, during the refugee crisis of 1994–1996, I witnessed the arrival of tons of drugs that nobody had requested. Many of them are still stored there – either they have expired or the local population does not know how to use them – pending a means of eliminating them without risk either to health or to the environment.

At the time, any form of assistance was welcome, but attempting to make use of the unclassified drugs arriving from Spain took away valuable time from an essential task: distributing drugs to pharmacies and health centres, and advising local workers on their correct use.

For more than three months, four of us, pharmacists responsible for managing drugs provided by Spanish assistance, had to spend on average four hours each day sorting out those that were suitable to immediate needs. Those we threw away included drugs that had expired, others that were useless to the diseases prevalent in the area, others in amounts which were insufficient to treat a patient, many not included in WHO’s Model List of Essential Drugs and many others.

Despite all these drawbacks I must emphasise that many of the drugs were used and helped to treat thousands of patients, thereby saving considerable expenditure. Nevertheless it might have been preferable to load one of the humanitarian assistance aircraft sent from Spain with urgently needed drugs which had been purchased directly from specialist firms. Alternatively the drugs might have been sorted more systematically in Spain before they were sent, so that the work of the hundreds of volunteers taking part in the campaigns and of the pharmacists working in the field could be truly effective.

Since self sufficiency in drugs for all countries is a long way off, we have to be realistic and work in more than one direction at once. As donations will still be needed in the future, we should direct our efforts towards ensuring that 100% of the donations made are actually of use to the recipient. To this end society must be informed and educated.

Knowledge of the problems, of its causes and possible solutions, the realisation that the situation can be changed and a commitment to put change into practice is the main challenge facing health professionals in general and health cooperation NGOs in particular.

—Natalia Herce,
Pharmacist and Medicus Mundi’s Project Manager in Rakoma, Rwanda.

Indian survey reveals doctors’ misgivings on training in RUD

Dear Editor,

Criticism about the lack of input on rational therapeutics in India’s undergraduate medical curricula was voiced by a number of participants at a national consultative meeting on the rational use of drugs (RUD) held in Calcutta in 1995. Delegates called for an increased focus on needs-based clinical pharmacology teaching at undergraduate level, and for the gap between students’ knowledge about drugs and knowledge of their optimal use to be narrowed.

Concerns expressed at the Calcutta meeting prompted a survey of 2,200 junior doctors in India. This has shown that most junior doctors do not have an adequate conceptual understanding of the essential drugs concept during their training. Carried out by the Calcutta-based NGO, Foundation for Health Action, the pilot survey aimed to discover what recently qualified doctors thought about the adequacy of their undergraduate training in rational use of drugs. It also sought their opinion on the feasibility of initiating a compulsory refresher course on rational use towards the end of medical training.

A structured multiple-choice questionnaire was given to the doctors, who worked in various disciplines at seven training institutions in four regions of the country. Analysis of responses showed that most participants wanted standard therapeutic guidelines to be produced for commonly occurring ailments. Almost all were in favour of a compulsory refresher course on rational drug use for interns during the internship period. It is anticipated that such a course would be held for two hours weekly over four weeks, and run collaboratively by staff from departments of pharmacology and clinical medicine. The emphasis would be on causes and consequences of therapeutic failures, assessment of therapeutic outcomes, alternative drug therapy, adverse drug reaction monitoring, drug interactions, and risk-benefit and cost-effectiveness of drug therapy. The study concludes that there is an undoubted need for reinforcement of knowledge. In particular it demonstrates a need for further inputs on prescribing guidelines in the later stages of the undergraduate curriculum.

—Krishnangshu Ray,
Assistant Professor of Pharmacology, Department of Pharmacology, Calcutta National Medical College, 32 Gorachand Road, Calcutta-700014, India, and Pijush Konar Sarkar, Professor of Pharmacology and Director, School of Tropical Medicine, Calcutta, India.

Sub-titled “Therapeutics is something more than prescribing drugs,” this publication advises doctors on how to work effectively, rationally and ethically. Looking in depth at some of the major problems they face, it will be of value to doctors in Pakistan and elsewhere who wish to improve their skills. In three sections, the book first provides guidance on the fundamentals of rational therapeutics – how a patient should be approached, and factors involved in making an optimal therapeutic decision. Effective communication skills are a prerequisite for a successful doctor-patient relationship. The author views as some of the shortcomings of medical education, including: too little planning therapeutic interventions, how to remain up-to-date about drugs, and best practice in prescription writing.

The book’s second section analyses what influences doctors’ judgement and decision making. In it, the author views as some of the shortcomings of medical education, including: too little attention given to applied aspects of pharmacology and therapeutics, and too little emphasis on teaching problem-solving techniques, critical evaluation of drug information, and preventive aspects of medicine.

During clinical and internship training, time, equipment and guidance are rarely in short supply. In contrast, once they have qualified, many doctors have to work unsupervised with too many patients and limited facilities. As a result new graduates have to adapt their training to their working situation. The book warns against some irrational methods of patient evaluation and management doctors may learn during the adaptation process. In view of the difficulty in obtaining objective information on drugs it discusses the influence the pharmaceutical industry may have on doctors’ choice of treatment. In the complex interaction between doctor, patient and family members all bring their own set of values and cultural beliefs, social and financial pressures, personal likes and dislikes, and family and professional priorities. The publication looks at how these factors can influence a doctor’s therapeutic approach and prescribing behaviour.

In conclusion the book highlights the irrational use of some common drugs and provides guidelines on using them optimally. Antibiotics, psychotropics, nonsteroidal anti-inflammatory drugs, antiepileptics and vitamins are among the drug categories covered.


The publication presents an overview of the challenges and conditions faced by health systems in the Caribbean Community (CARICOM) member countries. It highlights the general health status of the Caribbean people, as well as policies and legislation that impact health programmes. The publication then describes those health programme areas which correspond to the major causes of morbidity and mortality in the Caribbean.

Available from: PAHO Sales and Distribution Centre, PO Box 27, Annapolis Junction, MD 20701-0027, USA. Price: US$56, US$26 in Latin America and the Caribbean.


Why is the TRIPS Agreement important for the pharmaceutical sector? Are patents the right way to stimulate research and development? What are the implications of TRIPS on local drug production? These are some of the questions addressed by speakers at the World Council of Churches, Pharmaceutical Advisory Group meeting held in Geneva in October 1997. The meeting report is now available and provides a useful insight into the complex issue of Trade-Related Aspects of Intellectual Property Rights.

Available from: The Bookshop, CMC World Council of Churches, P.O. Box 2100, 1211 Geneva 2, Switzerland. Price: CHF 3.


This report identifies national and international policies that have facilitated or hindered the availability of praziquantel, especially in the world’s poorest countries in Africa, where schistosomiasis is endemic. Analysis of praziquantel’s production and pricing illustrates more general problems in the design of national and international policies for tropical disease products, and suggests strategies for future research and action.

The report raises questions about the international systems that affect the availability of new drugs in poor countries. It looks at how these systems could be improved for each of the four major actors discussed in the report: national governments, the pharmaceutical industry, international agencies and nongovernmental organizations.

The latest in DAP’s series on health economics and drugs informs people in the health sector with no particular legal background about the impact of globalization on access to drugs. In particular it focuses on the World Trade Organization agreement on intellectual property (the TRIPS Agreement) that may have repercussions in the pharmaceutical field. The first part of the document gives an introduction to the international commercial system from the General Agreement on Tariffs and Trade to the advent of the World Trade Organization. The second part analyses the section on patents of the TRIPS Agreement in relation to access to drugs.


The updated 3rd edition of the European Pharmacopoeia provides a single regulatory reference for the quality of medicines in 25 European countries, including those of the European Economic Area. The supplement contains 120 new standards or “monographs” and 130 revised monographs that incorporate the latest scientific advances. These 250 new harmonised European monographs became obligatory in 25 European countries on 1 January 1998, superseding the national standard where one existed on the same subject.

In total the Pharmacopoeia contains approximately 1,300 European standards on subjects ranging from synthetic molecules to biologicals to vaccines for human or veterinary use to quality health services is a universal right. Each country must shape health sector reform in accordance with its priorities and social and economic conditions. Pharmaceutical sector reform must be incorporated within health sector reform and should seek to ensure that all individuals have access to essential drugs and to quality health services. The publication focuses on five areas central to reform strategy: the roles of the public and private sectors; drug financing alternatives; pricing policies; generics strategies; and rational use of drugs.


Do health services work proactively or reactively? Why are pharmaceuticals important? What is health sector reform? What is the scope of pharmaceutical reform? What can be done to ensure that reform leads to progress and not simply change? These key questions, addressed by this publication, are particularly important when increasing pressures on health systems and economic changes in many Latin American and Caribbean countries make health sector reform imperative. Directed particularly to decision makers in health and finance, the publication helps them to evaluate and put into operation necessary changes.

The authors argue that the fundamental principle of optimal health sector reform is that access to quality health services is a universal right. Each country must shape health sector reform in accordance with its priorities and social and economic conditions. Pharmaceutical sector reform must be incorporated within health sector reform and should seek to ensure that all individuals have access to essential drugs and to quality health services. The publication focuses on five areas central to reform strategy: the roles of the public and private sectors; drug financing alternatives; pricing policies; generics strategies; and rational use of drugs.


The publication gives practical advice and support to district medical officers and district health teams in planning, organizing, managing and evaluating health services. Since the first edition in 1984 health care costs have escalated, even in richer countries. There is increasing emphasis on preventive and promotive care – the fundamental principles of which primary health care is based. The authors argue that they can have oriented their services on which primary health care is based, the authors argue that they can have oriented their services to team members in planning, organizing, managing and evaluating health services programs. A new edition includes many of the evolving principles of management which have been adapted for application to health care, and which will be of use in restructuring health services. Drawing on their experience in a number of developing countries, the authors have produced a valuable aid for medical, health and nursing personnel involved in the planning, organization and running of district health services.


Bacterial meningitis is an important cause of childhood morbidity and mortality, and a number of differences exist in its management from one region to another. This is a report of a WHO meeting to review current treatment and make recommendations for future practice. Chapters cover four issues concerning the management of bacterial meningitis in children in developing countries:

- The choice of antimicrobial therapy and the implications of antimicrobial resistance; the pharmacokinetics and current use of chloramphenicol; the role of dexamethasone; and fluid management in bacterial meningitis.

Available, free of charge from: World Health Organization, Division of Child Health and Development, 1211 Geneva 27, Switzerland.

Drug bulletins and newsletters
- The WHO Regional Office for Africa’s Essential Drugs Programme has produced the first in a series of monthly newsletters. The AFRO Pharmaceuticals Newsletter will report on what the Regional Office is doing in the pharmaceutical field in collaboration with Member States, and on developments in the Region’s pharmaceutical sector. For further information contact: Dr Moses Chisale, WHO Regional Office for Africa (Attention EDP/AFRO), P.O. Box BE 773, Blenvedere, Harare, Zimbabwe.
- A change of name for Drugs Today, the newsletter of the Christian Medical Association of India, which is now called Rational Drugs.
Pharmacotherapy discussion groups in the Netherlands under the spotlight

GEERT KOCKEN

A FACT-FINDING study of pharmacotherapy discussion groups in the Netherlands has highlighted a major shift towards establishing standards and guidelines for prescribing, coupled with a growing determination to monitor compliance by general practitioners (GPs).

The study, carried out by the Dutch Institute for Effective Use of Medication, reveals that the number of discussion groups has increased by a third to more than 800 over the past five years, and that up to 95% of the country’s GPs and pharmacists are now involved.

The nationwide network of local pharmacotherapy discussion groups was launched by the Institute in early 1992 (see EDM-20). The idea was to promote rational drug use by bringing together GPs and pharmacists to exchange information about pharmacotherapy and develop local guidelines.

Since then a team of 16 advisers (communications consultants) have helped establish regional networks as well as providing support to individual groups of GPs and local pharmacists which meet regularly.

The aim is to draw on the expertise available within these two professions in order to improve the prescribing practice of individual GPs.

Latest findings...

The new survey was initiated in 1997 to update information about the organization and operation of pharmacotherapy discussion groups and to find out whether any changes had occurred since the 1992 study. The number of groups had increased from 629 in 1992 to 827 in 1997, and 85% of these took part in the latest survey.

The study found that an increasing number of both GPs and pharmacists played an active role in organizing group activities (up from 78% in 1992 to 88% in 1997). Most groups meet six times a year and about two-thirds of them are assisted by an adviser recognized by the Dutch Association of General Practitioners.

Contacts with specialists in hospitals – a need highlighted in the earlier study – have become more frequent (41% compared with 27% in 1992). The Institute for Effective Use of Medication is currently trying to improve communication between pharmacotherapy discussion groups and hospitals at the interface between primary and secondary care. The discussion group infrastructure offers a good opportunity for improving intermediate pharmaceutical care.

The study identified a major shift in the objectives of discussion group consultations since the previous survey. While information exchange and discussion on prescribing practices are still high on the agenda, there is an increasing emphasis on the need to reach agreement on standards, policies and guidelines. The study noted that up to 95% of the country’s GPs and pharmacists are now involved.

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The study showed that 68% of groups were using relevant prescription data, due in part to efforts by the Dutch Pharmacological Society, health insurance companies and the Dutch Institute for Effective Use of Medication to ensure the availability and proper use of relevant data. At present, the figures are used mainly to gain an insight into existing prescribing patterns. For just over half the groups these data serve as a tool in policy development, while 44% of groups using the data do so to check adherence to the policies and guidelines agreed within the discussion group.

One of the conclusions of the 1992 survey was that regular monitoring of prescription data was essential in order to bring about effective change in prescribing practices. However, only a minority of groups currently monitor GP's prescription practices for compliance with agreed group guidelines and policies. More widespread monitoring of data would offer a way of comparing prescribing practices among colleagues, and of verifying compliance with agreed standards, policies and guidelines.

What GPs and pharmacists think...

Over 80% of GPs and pharmacists rate the pharmacotherapy discussion group process as “useful” or “very useful”, while two-thirds of them also said it was efficient. However, 8% of groups are less satisfied, complaining that the results are not specific enough.

The GPs said they had gained a better understanding of the scope of their prescription practices, partly as a result of participation in a group. In addition they reported improved relations with other GPs and pharmacists. Meanwhile, the discussion group system has helped define the pharmacist’s role as an adviser to the GP. Pharmacists are now paying more attention to supervising medication schemes and giving advice to GPs, due in part to their participation in pharmacotherapy discussion groups.

Pharmacists also say they are now more inclined to contact a GP when they have a query. Another improvement, noted by both GPs and pharmacists, is that both parties have a clearer understanding of how tasks should be shared between them.

On ways of improving the discussion group system, almost a third of the groups maintained that consultations need to become more efficient, while over 40% said the agreements reached should become less voluntary – a view expressed more frequently by pharmacists than GPs. Greater use of prescription data would not only help develop and clarify policies but, more importantly, also enable groups to more effectively monitor compliance with agreed policies and guidelines.

Prescriptions watchdog...

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The way ahead...

Regular assessments of the effectiveness of the pharmacotherapy discussion group network remain essential in order to modify goals and develop fresh approaches, methods and content. Other challenges include the development and implementation of regional formulations – exploiting the full potential of computerized data – and an increase in international cooperation. Elsewhere, coordination is already underway, with similar discussion networks in Belgium, Canada, Germany and the UK. In November 1998 the Institute collaborated with the WHO Regional Office for Europe in organizing a consultative meeting to share problems experienced with guideline implementation and to discuss pharmacotherapeutic committees.

Meanwhile, Institute advisers are working on new programmes – generics prescribing, polypharmacy among the elderly, pharmaceutical care and transmural pharmacotherapy (where people are referred from hospital to have their prescription dispensed in a community pharmacy) – to ensure that all GPs, pharmacists and specialists have expertise in auditing and cost-effective use of medication. In addition, the Institute continues to offer a range of new working materials and support to pharmacotherapy discussion groups to boost their effectiveness. This can include evaluation exercises, help in solving cooperation problems or in starting up compliance monitoring, or efforts to revitalise the discussion group process whenever it gets bogged down.

* Geert Kocken is a health consultant at Stichting Doelmatige Geneesmiddelen Voorziening (DGV) Dutch Institute for Effective Use of Medication, Postbus 3089, 3502 GB Utrecht, the Netherlands. Tel. +31 24 360 711, fax: +31 24 360 6644, e-mail: berkdv@wxs.nl
The concept of essential drugs first launched over 20 years ago has been widely adopted today by countries throughout the world. But its implementation is proving a lot more difficult than envisaged.

The idea – providing priority drugs to meet the health care needs of the majority of the population – was simple, socially just, and both technically and economically sound. By having a carefully designed list of a limited number of drugs, procurement could be made easy, the drug storage problem simplified, prescribers would have safe and effective drugs, and costs could be reduced.

The system entailed no reductions in health services, and health administrators did not have to make difficult choices between the competing needs of different groups or assess the social and health implications of different strategies. The money allocated for pharmaceuticals – 20%–40% of limited health care budgets – could now be spent on less expensive, essential drugs, facilitating wider access to drugs without any increase in costs. Rarely had administrators been offered such a clear, simple solution to so many problems. The essential drugs concept was an idea whose time had come. But the simplicity was beguiling.

Although the concept was well accepted by most countries, its implementation has proved a daunting task. More than two decades after it was conceived, the essential drugs concept has still to make the full impact that was anticipated – demonstrating that technical soundness and economic rationality do not necessarily ensure political viability.

Essential drugs concept under fire

At the outset, direct opposition to the essential drugs concept came mainly from the pharmaceutical industry – unconvinced by the argument that lost sales on more expensive drugs would be offset by the enlarged market for essential drugs. However, initial outright rejection of the concept was followed by grudging acceptance that it was cheaper even if it involved more similarity than those employed in the public sector. However, this opposition has lessened, over time.

Another frequent criticism is that the essential drugs list is a “second class” list, determined on the basis of financial stringency rather than the effectiveness of the drugs. However, the belief that countries will abandon the list, once the economic situation improves, and switch to better drugs is based on a misconception. The list does not include less effective drugs simply because they are cheaper. The aim is to include more cost-effective drugs that can be used by the majority of the population. For example, among the H2 receptor blockers, ranitidine has an advantage over the much less expensive drug cimetidine, in that it can be used by the elderly and has fewer interactions with other drugs. However, cimetidine was chosen for the model list not only because it was cheaper but because it has similar efficacy to ranitidine, and because the majority of patients using it would be neither elderly nor receiving drugs which could interact with cimetidine. While a particular health technology may be superior in a few situations, another cheaper one may be equally effective in the majority of situations – making it more cost-effective.

The essential drugs list is also criticised for failing to include a drug for a particular disease. However, the list was never meant to cover all diseases. The aim was to ensure the availability of drugs to treat the majority of diseases that occurred in a specific country. The exclusion of a drug from the list does not prevent it from being purchased if needed. The fact that the essential drugs concept accommodates this should be seen as its strength.

Impact in developing countries

Over 120 developing countries have now adopted the essential drugs concept and developed a national essential drugs list based on the WHO Model List. The exclusive use of generic drugs in the list has contributed to increasing awareness of generic names. While some countries have closely followed the criteria for selection of drugs, others have lists that include over 350 products (Pakistan) or two or more similar drugs rather than the recommended single drug (Tanzania).

More expensive doesn’t necessarily mean better

From each therapeutic category. Some of these variations may be due to attempts by doctors to get a particular drug included in the national essential drugs list – thereby enabling hospitals to buy the drug and ensuring its inclusion in reimbursement schemes.

As countries have increasingly recognised the need for a national drug policy, the national list has provided the cornerstone for this policy development. Meanwhile, the knowledge that a limited list of drugs can meet the majority of health care needs has also created an awareness that “more is not necessarily better” and that “cheaper is not necessarily better”. The list has also enabled health administrators to assess whether appropriate drugs are being supplied.

Although the essential drugs concept has consistently focused on the importance not only of the selection but also the proper use of the drugs, progress in encouraging the rational use of drugs has been slow. Even where essential drugs are available, their full potential is not being realised. This is mainly due to the failure to provide unbiased drug information for prescribers. Whereas suppliers of other forms of goods routinely spend a proportion of sales revenue on evaluating how the goods are used, very few developing countries have access to independent drug information – let alone the capacity to spend a proportion of their drugs budget on providing information on the rational use of drugs. It is estimated that both developing and developed countries currently spend less than 1% of their drugs budget on rational drug use. However, the essential drugs concept has been influential in preventing the import of ineffective drugs.

In some developing countries, the implementation of the essential drugs concept has been hampered by efforts to industrialise. Many governments hoped that a vigorous and profitable pharmaceutical industry, producing drugs that were mainly outside the essential drugs list, would contribute to a general increase in both living standards and improved health. As a result, essential drugs were ignored and sometimes difficult to obtain, while more expensive, non-essential drugs were freely available. Now, after finding that the impact on living standards is less than anticipated, some countries are rethinking their policy and are likely to place greater emphasis in future on essential drugs. This development should help increase the
accessibility and affordability of essential drugs.

Although the essential drugs concept was designed to meet the health care needs of the majority of the population, the private sector has tended to drag its feet in implementing the concept. This is largely due to fears that the resulting changes in the pharmaceutical sector might have an adverse effect on multi-national corporations, the urban elite, and, to a lesser extent, physicians. In order to succeed, the concept should have broadly-based support which reaches to the highest political levels. However, with the exception of the Philippines and Sri Lanka, this has rarely occurred.

The lack of acceptance of the essential drugs concept within the private sector is also due to the fragmented nature of health care in this sector in developing countries. Patients pay for their drugs “out of pocket” and are individual buyers who purchase what the doctor prescribes. However, large health care providers such as insurance schemes, which are common in the developed world, can persuade prescribers to use a restricted list of drugs known to be effective. When such schemes are established in the developing world the same trend towards using known effective drugs would develop.

A RESPONSE TO RISING PRICES

Acceptance of the essential drugs concept and the essential drugs list faced different hurdles in developed countries, due to the different socioeconomic and industrial circumstances. In the developed countries, governments saw the pharmaceutical industry as a vibrant one, providing useful products as well as contributing to the economy through the employment of skilled labour, the production of substantial export earnings, and a contribution to scientific and industrial research. Money was usually available to buy more expensive pharmaceutical products and it was believed that restricting access to these products would be counterproductive in the long run. Unlike the developing countries, health care providers in developed countries (either the state or state-sponsored social insurance schemes) had immense buying power and could negotiate a reduction in prices. However, these products are becoming increasingly expensive and are often beyond the reach of cash-strapped health service providers. As a result, both government and health service providers in the private sector have now adopted the essential drugs concept – albeit by another name.

Most countries have adopted a two-stage procedure for introducing a new product into the health system. In Australia a new drug is scientifically evaluated for quality, safety and efficacy. Once registered, a drug is then assessed for possible inclusion in the reimbursement scheme. Approval at this stage depends on evidence of cost-effectiveness. This two-stage process has resulted in the registration of drugs, such as finasteride, that are expensive but minimally effective – without their approval for reimbursement.

Elsewhere, in the UK, where 17 benzodiazepines are available, the National Health Service supplies only five of these, each a generic drug. Although the other 12 benzodiazepines are equally effective, they are more expensive and not reimbursable. Although this is not a strict interpretation of the essential drugs concept (which allows only one drug from a therapeutic class) a focus exclusively on drugs that are known to be safe, effective, and cost-effective is in keeping with the spirit of the concept. However, both countries promote the export of these drugs – a clear example of industrial priorities overtaking health ones outside the country’s own borders.

INTERNATIONAL ORGANIZATIONS PROMOTE THE CONCEPT

Although, initially, a number of international organizations failed to appreciate the relevance or importance of the essential drugs concept, today most accept and promote it as a good tool for organizing the pharmaceutical sector and improving health care. The World Bank, which plays an increasing role in the health sector in the developing world, has based most of its activities in pharmaceuticals on the concept and national drug lists – mainly to facilitate managerial efficiency.

UNICEF’s activities involving pharmaceuticals have been guided by the essential drugs concept in order to ensure equity, and donor countries/institutions have focused on national lists when supplying drugs. Meanwhile, the guidelines for drug donations developed by WHO and other agencies have also stressed the importance of donating only drugs that are included in national lists.

The Model List is revised regularly by WHO with the latest revision in 1997. The number of items included has risen from 208 in 1977 to 306 today – as new products are added and older, less effective products removed. Programmes covering malaria and cancer control have helped refine the selection of drugs included in the list. Meanwhile, the participation of the pharmaceutical industry associations provide an opportunity for them to discuss the List as well as propose products for inclusion. On several occasions, inclusion of a drug in the Model List has encouraged pharmaceutical companies to either continue manufacturing the drug or to start manufacturing it.

 BETTER IMPLEMENTATION NEEDED

The essential drugs concept is today a key issue on the international health agenda. Together with the concept of primary health care, it is one of the major achievements of WHO over the last two decades, and its most durable pharmaceutical initiative. Other initiatives, such as promoting the local production of pharmaceuticals, have achieved neither the sustainability nor the prominence of the essential drugs concept. Yet, while the concept’s scientific validity remains unchallenged, it has still to be implemented to its full potential. One of the problems is that it is a public health concept and not a curative intervention. When drugs are made available in this way it is taken for granted and not seen as a major advance. Because of this, it is a difficult concept to promote.

Another problem is the wide range of objectives involved: equity in the provision of basic health care needs, efficient use of available resources, and responsiveness to societies rather than to market forces. While this elicits widespread support, the involvement of numerous players with different strengths and objectives can hamper the concept’s implementation.

In developed countries, the weak implementation of the essential drugs concept has been driven by fears that the international pharmaceutical industry would suffer – a prospect that generated strong opposition from powerful groups and governments. Meanwhile, in some countries, implementation strategies have not been carefully thought through. Effective implementation of the concept requires careful planning, backed up by strong political commitment at country level, together with a clearer understanding of the role of the different players involved. Better implementation of the essential drugs concept could make all the difference between success and failure.

References


New Belgian committee promotes rational prescribing

In his Belgian Minister for Public Health, Dr Marcel Colla, has set up a scientific committee aimed at encouraging rational and cost-effective prescribing. The committee, which will implement a project for “independent information on medicines” will be made up of representatives from the Belgian pharmaceutical information centre, the transparency commission, the Health Ministry, the pharmacists’ inspectorate and general practitioners’ associations, Le Journal du Médecin reports. Other health professionals, such as specialists and pharmacists, may also be asked to participate. A number of product categories have already been put forward for examination, including anti-ulcers, antidepressants and antibiotics for upper respiratory tract infections.
**RATIONAL USE**

**MSF Research Group on Essential Drugs: fighting for the underprivileged**

JACQUES PINEL *

Like other medical aid organizations, Médecins sans Frontières (MSF) is facing new problems as international pharmaceutical trade is reorganized to the detriment of the world’s poor. In a new initiative MSF has set up a “Research Group on Essential Drugs”, which will benefit from the knowledge and experience of MSF’s medical teams in 50 countries. The teams not only work with national decision makers and prescribers but are in contact with a wide range of people, and can provide valuable insight into the current problems. In seeking solutions the Group will also use MSF’s influence in industrialised countries. In collaboration with other specialists, members will initiate activities to defend the health of people who are underprivileged in terms of their access to drugs.

**Vital drugs may disappear**

The therapeutic options available for treating tropical diseases have generally existed for a long time, and people often wait in vain for new drugs. Pharmaceutical research and development have frequently been abandoned because there would be no return on the required investment. The same market economy logic has resulted in drugs that are obsolete in developed countries no longer being made – even when the drugs are still useful in developing countries (where price affects both access and adherence to treatment).

**Need to guarantee quality**

In developing or recently industrialised countries, the technology and the legal framework needed to guarantee drug quality are often missing. Local supplies can therefore include good quality drugs and unacceptable or even dangerous drugs, with adverse consequences both on occupational health (infective treatment) and public health (development of resistance).

**Action:** In collaboration with the pharmaceutical sector, the MSF Research Group will set up a network for drug quality monitoring, that will identify countries, manufacturers and distributors with good control procedures. The network will also draw attention to dubious or definitely dangerous production lines or illegal distribution circuits that are discovered.

**Making all essential drugs affordable**

Cost and the lack of coverage for the poor restrict access to treatment in developing countries. Overall, the price of essential drugs, which is usually presented as the primary cause of their inaccessibility, has come down, thanks to the development of generic essential drugs policies, initiated mainly by WHO and UNICEF. But it is important to remember that not all essential drugs are old: recent drugs, which are therefore protected by patent, remain beyond the reach of developing countries.

**Action:** By making contact with the manufacturers and international organizations concerned, ad hoc agreements can be made to take account of both the commercial constraints of pharmaceutical companies and the resources of poor populations. However, more lasting solutions must be sought to match the prices of vital modern drugs with the resources of poor countries. The current debate on AIDS treatment illustrates the urgency of the problem. With other organizations working on the same question, the Research Group on Essential Drugs will help to promote the idea of international solidarity in access to drugs.

**Promoting rational use**

Achieving the rational use of essential drugs involves a constant struggle: it becomes imperative in times of shortage. There is still much work to do in promoting the essential drugs concept, in view of the number of useless or dangerous drugs that are still used in most countries. At the same time, a considerable proportion of available essential drugs is badly managed. In terms of information, independent medical journals and guides can provide prescribers and other health professionals with reliable advice, but in most countries, most pharmacotherapeutic information is distributed by drug companies. Dubious promotional activities and misleading advertising are frequently found in countries where control of information, when it exists, has little effect.

**Action:** Through collaboration with other parties that are equally concerned with the correct use of drugs and with prescriber training, the Research Group on Essential Drugs will help improve the quality and distribution of reliable information on drugs. The Group will also provide the appropriate managerial tools for underprivileged environments.

**Cooperating on research**

Some therapeutic regimens can be modified to ensure greater efficacy, to reduce secondary effects, costs and drug resistance, and to improve adherence to treatment. Assessment of the efficacy of short courses of treatment, or study of the appropriate g长城 groups of areas of operational research that have been selected to improve the therapeutic effectiveness of existing drugs.

**Action:** The Research Group on Essential Drugs will encourage independent research institutes to conduct studies or clinical trials. Networking with the MSF/EPICENTRE teams on cooperation in local studies is necessary.

The Research Group on Essential Drugs, in collaboration with existing networks, hopes to become a source of information for both decision makers and field workers, and a force for ideas and action to improve health, particularly in countries which are currently disadvantaged.

* Jacques Pinel is Coordinator of the Research Group on Essential Drugs, Médecins sans Frontières, 8 rue Saint-Sabin, Paris Cedex 11, France.

**Reference**

1. The EPICENTRE teams are responsible for epidemiological programmes and data collection.

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**Pakistan’s largest Province focuses on drug sector reform**

The Chief Minister of the Punjab, Pakistan’s largest Province, has initiated a major campaign to reform the pharmaceutical sector. Disturbed by increasing news of spurious/substandard drugs and aware of the non-implementation of the 1988 Drug Rules, the Chief Minister, Muhammad Shabbaz Sharif, has set up a Task Force to try to find a long-term solution to the problems. As a start he has suspended all of the Province’s drug inspectors and put a moratorium on issuing any new licences for setting up retail pharmacy outlets.

**No compromise on quality**

The Government is publicising its campaign in front-page articles in all the main local and English language newspapers, which invite suggestions from the public on how to improve the situation in the pharmaceutical sector. The campaign received a major boost with a special report on a range of drug quality and rational use issues which appeared in a Sunday newspaper.

Although the issue of spurious/substandard medicines is central, in the Task Force’s first meeting the authorities made it clear that they are very serious about changing the whole system. Three sub-committees were formed: one to review the Drug Act of 1976 and the 1988 Drug Rules, the second to screen the Province’s medical stores in the light of existing licensing policy and to take steps against those violating the law; and the third to suggest measures, including further legislation, against unqualified people practising medicine.

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**Reference**

Making injections safe

During 1996, in the developing world, routine immunization of children under one year and immunization of women of childbearing age with tetanus toxoid (TT) accounted for nearly 800 million injections. In addition to routine immunization, emergency disease-outbreak control operations delivered more than 240 million injections in the same year.

As part of the drive to eliminate neonatal tetanus as a public health problem, 74 million women are being targeted in high risk areas of developing countries. By 1999 this will generate an estimated 220 million injections in special immunization activities.

By the turn of the century, hepatitis B vaccine should be in use worldwide, and new vaccines should be in the process of being introduced into immunization programmes. Acceleration of special activities aiming at better measles control will be in progress, with elective mass immunization potentially targeting about 3.1 billion children under 15 years of age by 2005.

These increases in immunization services, including elimination and initiatives which aim to improve the safety of injections; these include the introduction of steam sterilisers, development of auto-destruct syringes, and development of training materials and courses.

As part of an overall strategy to further improve the safety of immunization injections and emphasise the need for “one sterile syringe and one sterile needle for each injection”, it is essential to prevent the reuse (within or outside the health sector), of large numbers of the syringes introduced into countries for mass campaigns.

WHO and UNICEF have agreed to implement a strategy to assure that special attention is paid to the safe administration of vaccines during mass immunization campaigns. They have issued the following policy statement which defines their position.

WHO-UNICEF policy statement for mass immunization campaigns

“The reuse of standard single-use disposable syringes and needles places the general public at high risk of disease and death.

The auto-destruct syringes1 presents the lowest risk of person-to-person transmission of blood-borne pathogens because it cannot be reused. The auto-destruct syringe is (a) the preferred type of disposable equipment for administering vaccines; and (b) the equipment of choice for conducting mass immunization campaigns.

“Safety boxes”2: puncture-resistant containers for collecting and disposing of used disposable and auto-destruct syringes, needles and other injection materials reduce the risk posed to health staff and the general public by contaminated needles and syringes.

For all elective and emergency mass campaigns, vaccines must, as a rule, be systematically supplied together with auto-destruct syringes and safety boxes as a “bundle” (see below).

All donors supporting immunization campaigns are requested to finance not only the vaccines but the safe administration of the vaccines by planning and implementing the “bundling” strategy as well as supporting training and supervision of the process during the campaigns.

WHO and UNICEF recommend that auto-destruct syringes and safety boxes are used in all elective and emergency mass immunization campaigns. Donors are requested to “bundle” the supplies: vaccine, auto-destruct syringes and safety boxes.

What is “bundling”?

The term “bundling” has been chosen to define the concept of a theoretical “bundle” which must comprise each of the following items:

- Good quality vaccines
- Auto-destruct syringes
- Safety boxes.

The implication is that none of the component items can be considered alone, each component must be considered as part of a “bundle” which contains the other two. “Bundling” has no physical connotation and does not imply that items must be “packaged” together.

CDMU’s new leadership training on rational use of drugs

In the first in a series of leadership training courses on rational use of drugs in the developing world, doctors and senior health workers to the Udayant Jesuit Institute, Calcutta, in February 1998. The course was organized by the Community Development Medicinal Unit, Calcutta, a non profit voluntary organization which maintains a drug distribution network for NGOs in India’s eastern region.

While many CDMU courses provide information on essential drugs and rational therapeutics, on this occasion the aim was specifically to train leaders who could disseminate this information, and assume a major role in putting theory into practice. The five main modules generated lively debate and covered: the essential drugs concept and its implications; drug formularies; treatment guidelines for common diseases; drug control, drug policy (including patents) and drug promotion in India; and inventory management.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Cost of a safe administration (US$)</th>
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</thead>
<tbody>
<tr>
<td>TT</td>
<td>0.16</td>
</tr>
<tr>
<td>Measles</td>
<td>0.26</td>
</tr>
<tr>
<td>DT</td>
<td>0.19</td>
</tr>
<tr>
<td>Td or DT</td>
<td>0.18</td>
</tr>
<tr>
<td>Yellow fever</td>
<td>0.27–0.31</td>
</tr>
<tr>
<td>Meningitis</td>
<td>0.31–0.41</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>0.65–0.85</td>
</tr>
</tbody>
</table>

1. Yellow fever and influenza vaccines are not considered for the purposes of this policy statement.

2. Designed to collect and transport syringes and needles (without caps) safely, to minimize the risk of accidental needle-stick. The safety boxes are supplied flat-packed for simple, one-step local assembly and should be maintained in the cold chain of controlled syringes and needles (WHO Standard Performance Specification E10/IC.1 or E10/IC.2).

Costs

Indicative costs for the safe administration of vaccines most commonly used in immunization campaigns are listed below. Each estimate includes the cost of one dose of vaccine (in 20 or 50 dose vials), one auto-destruct syringe (about 10US cents), and a fraction of the cost of the safety box (less than US$1.00 for 100 syringes).

For copies of the policy statement [ref. WHO/EPI/H/97/04] and further information contact: World Health Organization, Global Programme for Vaccines and Immunization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Tel: + 41 22 791 4373, fax: + 41 22 791 4193, e-mail: gpv@who.ch

1. Designed to give a single standard dose of vaccine after which the syringe blocks permanently, preventing further use of contaminated syringes. The needles are either fixed or standard, but non-detachable, to prevent reuse (WHO/EPI Standard Performance Specification E8/DS1).

2. Designed to collect and transport syringes and needles (without caps) safely, to minimize the risk of accidental needle-stick. The safety boxes are supplied flat-packed for simple, one-step local assembly and should be maintained in the cold chain of controlled syringes and needles (WHO Standard Performance Specification E10/IC.1 or E10/IC.2).

3. Price range calculated from lowest and highest bids to UNICEF.

4. The WHO Expanded Programme on Immunization does not recommend campaigns with hepatitis B, but some countries may decide to do catch-up campaigns for a target-age group after the introduction of the vaccine in the routine immunization programme.
Stepping beyond with Community-Directed Treatment

The mass distribution of ivermectin to communities was used to test the concept of Community-Directed Treatment in a study which was completed in 1996. Although ivermectin had been donated to the countries, the primary health care systems were not efficient at delivering it in the right quantities to the right people. Therefore, a multicountry study was conceived in which ivermectin-delivery systems designed and implemented by communities themselves were compared with those designed and implemented by control programmes. The study involved eight sites in five African countries, which together covered a total population of some 1.5–2 million. Study findings showed that, in all respects (effectiveness, acceptance, coverage), community-designed systems were better than programme-designed systems. Community-directed distributors adhered well to treatment procedures, and were able to differentiate between those who should and should not receive the drug; they gave the correct dose, to within half a tablet, in over 90% of cases; and they were able to identify severe adverse reactions and refer such cases to the nearest health facility. The study was successful to the extent that Community-Directed Treatment has now been adopted by the African Programme on Onchocerciasis Control and 19 countries are committed to making it work.

The value of “ownership”

What are the reasons for the success of Community-Directed Treatment? Primarily, success rests in the philosophy of ownership and empowerment. During the study, and as the communities became more confident, the part played by “ownership” became quite clear. Giving communities the freedom to design their own system, to select the distributors they want, and to change the system when necessary, means flexibility. Programme-designed systems, in contrast, are relatively inflexible.

Benefits that can be expected from Community-Directed Treatment include less diversion of drugs (the possibilities of diversion are less when the people are in charge themselves); better indicators for sustainability (less dependence on health care from outside); and least distraction of village life (having a distraction – to go about getting it – thus taking the concept of Community-Directed Treatment a step further (usually the health service tells the community what information it wants and then gets it). Other points of contact between the health service and Community-Directed Treatment include supervision and training. In the multicountry study, some basic supervision by local health service staff was associated with better performance in terms of treatment coverage than no supervision at all. And the “open” training (when the community could look on) not only reinforced acceptance by the community but also resulted in indirect monitoring of the trainees’ performance by the communities themselves. Involving health workers at the interface right from the start, in meetings with the community, in the training of distributors and in supervision, helped overcome resistance.

Another issue to be addressed concerns cost sharing and cost recovery. In the multicountry study, ivermectin was mostly provided free of charge. But in Cameroon, where a programme of cost recovery was in place, coverage was less. We need to know, therefore, how paying for a drug affects performance, since drugs are not always free of charge and Community-Directed Treatment is applicable only in mass treatment programmes.

Here lots of people without signs and symptoms of the disease, who may not perceive the need for treatment, have to be reached.

The next phase

These are some of the issues that will be looked at in the next multicountry study planned for 10 onchocerciasis sites in Africa. The challenge now is to see if Community-Directed Treatment works in “real life”, as opposed to the experimental conditions of the multicountry study. The challenge is to persuade governments and control programmes to accept the philosophy – to accept that people can be empowered and that they have the intelligence, willingness and ability to look after themselves.

But can the concept of Community-Directed Treatment be extended any further? It is only suitable for mass treatment, where a single drug is to be given in a single distribution (no more than twice per year). It must be easy to determine who should and who should not receive treatment. And, preferably, there should be no need for laboratory diagnosis. Some obvious candidates, therefore, might be lymphatic filariasis, schistosomiasis and intestinal parasites. A study of Community-Directed Treatment in lymphatic filariasis is already planned for eight sites in Africa and Asia. With time, communities may be able to take on responsibilities of a different nature, such as disease surveillance. The gameaworm programme has shown that villagers can be used as village-based health workers for control programmes and this approach has not been fully exploited. And what about the Expanded Programme on Immunization? The health care system must be persuaded to think of programmes other than drugs that could benefit from the Community-Directed Treatment approach.

All in all, Community-Directed Treatment could be a technically important means of health delivery. At the very least, it promises to be the most cost-effective and sustainable variant of community-based mass delivery/distribution systems for chemotherapy-based disease control programmes.

Reference