The performance of health services everywhere critically depends on the availability and use of pharmaceutical products. Health workers cannot effectively treat many patients without drugs and vaccines. Indeed, public confidence in health workers and satisfaction with health services depend upon the maintenance of a reliable and affordable supply of drugs. Many countries spend a large proportion of their health care budget on drugs, much of which is wasted because of unsafe and inappropriate drug dispensing, prescription and use, and because bacterial resistance often renders drugs ineffective.

The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them and to the community. Rational use implies assessing the situation, the proper management of the drugs vis-à-vis the patient, and balancing benefit against risk and cost. Such issues are complicated by the fact that they are the joint responsibility of policy makers, health care professionals and patients.

In fact, we still know very little about how providers make decisions about which drugs to prescribe and about how and why patients use or do not use medication. How do training or any intervention strategies affect prescribing practices? What is the impact of current pharmaceutical policies on drug use patterns? What is the real clinical or economic scope of particular drug use problems, such as the misuse of antibiotics? What are the most relevant concerns regarding access to and rational use of essential drugs? How do we determine the most efficient and cost-effective interventions for promoting effective drug use, including managerial, educational and regulatory measures? It is clear that more research is needed to give us the tools to improve the way that pharmaceuticals are prescribed, dispensed and used.

The WHO Action Programme has long recognised the need for such practically orientated operational research. This issue of the Monitor reports on some of this work in areas ranging from the affordability of medicines, to injection practices, public education, and drug stability during international transport. Future issues will cover other descriptive and interventional research. Wherever possible, the Programme attempts to use and to strengthen local research capacity since it is at the national and local levels that research findings are translated into changes in policy and use.

Good operational research follows a clearly defined cycle. Descriptive research is the first essential step, since without objective data and situation analysis it is impossible to identify problems and their underlying causes. The descriptive analysis should lead to a choice of intervention strategies to tackle constraints which at each level of drug management prevent the implementation of sound policies and programmes. The choice of strategies is based on the expected impact of the intervention and on its political and socioeconomic feasibility. Intervention strategies are dynamic, not static. They should be part of a cycle of testing, evaluation and the development of new interventions in the light of experience.

It is common today for the highly sophisticated and expensive techniques of biomedical research to be seen as the only approach. In fact, much useful and precise operational research can be undertaken, using simple quantitative and qualitative methodologies, by people grounded in sound research principles, but who may not have extended formal training in research and statistical techniques. The Action Programme is working on the development of such simple research methods to investigate problems related to the availability of drugs. Research in drug use should not be restricted to an academic "ivory tower". It should seek to involve and thereby gain the commitment to positive change of people at many levels of the pharmaceutical chain. This is our best hope that problems and viable solutions can be identified and tackled.
SENEGAL: Willingness and ability to pay for drugs

COMMUNITY financing has been the focus of a lively debate during the last ten years. In the face of the inability of governments to guarantee the availability of free medicines — and unfortunately, free medicine is a luxury for the vast majority of people in the developing world — the community is required to pay for drugs and/or for other health services.

The primary goal of these initiatives is that individuals already spend quite a large amount of their income on private health care. In the case of Senegal, the government has taken steps to ensure that the burden of the health care costs is shared by the community. Under the partnership plan, the government provides the basic medicines at a cost that is affordable to the majority of the population. The community is responsible for the rest of the cost, which is usually a small fraction of the total cost of the treatment.

Willingness to pay...

However most patients (90%) do not obtain drugs from such centres but only a prescription. This was confirmed by the fact that in the pharmacies and drug outlets surveyed, over 87% of the prescriptions analysed came from the public sector. In 84% of these cases, people purchase the drugs prescribed within the three days following the health centre consultation and 66% of the households bought the majority of their drugs at pharmacies. The difficulty in paying for the prescribed drugs occurs to various degrees in the socio-economic categories surveyed. Less than half the households of criminal servants and retired people, although in a relatively privileged economic position, said that household income was generally sufficient to purchase the prescribed drugs.

Turning to the community...

When income is insufficient, the most widespread response of the families affected is to seek help from the public sector. This is reflected in the fact that 86% of the households surveyed who had access to a public health centre were not paying for the prescribed drugs. The difficulty in paying for the prescribed drugs therefore depends on the socio-economic status of the family; in a majority of cases it is due to poverty of the community.

Ability to pay...

Further results tend to contradict these first conclusions, which hold in reality the difficulties households face in obtaining the financial resources needed to pay for the drugs prescribed.

First, some patients do not go to the pharmacy for days; which means that in the absence of drugs in the health facilities, they probably go without. Although the consultation fee in the health facilities is low — less than U.S. $0.35 in most cases for a child, and between U.S. $0.35-0.70 in most cases for an adult — 20-40% of the patients interviewed said that they would not be able to spend more even if a regular supply of drugs was ensured; 5% were willing to pay between U.S. $0.70-1.75; 27% between U.S. $1.75-3.50, and only 23% more than U.S.$3.50.

Second, of the patients who go to the pharmacy or drug outlet, a number (36%) do not feel they can afford to buy the most expensive drugs (26%) without consideration of medical need, and others sought advice before selecting which drugs to buy from the prescriber (21%) or from the pharmacist (10%).

Among the people who were able to tap other people's resources, solidarity networks seem to play a remarkable role in the search for money to pay for prescribed drugs. The capacity of households to meet the cost of prescribed drugs is proportionately greater (this varies according to region) in households whose head is a political or social, political or trade union organization. Thus, in the survey as a whole almost 85% of households headed by a member of a social organization succeeded in paying for the prescribed drugs, against 62.8% of the households not in that position. 79.1% of households whose head was a religious organization and 76.3% of those in which she/he was a member of a political or trade union organization said that they could generally manage to pay for prescriptions, as against 67.1% and 68.3% respectively of those in that position.

Conclusions

Willingness to pay for drugs: drugs are seen as a priority and households spend precious resources to procure those which have been prescribed.

Turning to the community...

When income is insufficient, the most widespread response of the families affected is to seek help from the public sector. This is reflected in the fact that 86% of the households surveyed who had access to a public health centre were not paying for the prescribed drugs. The difficulty in paying for the prescribed drugs therefore depends on the socio-economic status of the family; in a majority of cases it is due to poverty of the community.

Ability to pay: this is probably much less than hoped by many health policy makers. Any cost recovery scheme should be planned very cautiously to that it does not exclude a portion of the population. Most important, rationalization at all levels in the public sector should be the first step before asking the poor to pay.

Community solidarity: this certainly exists, and we need to determine how to develop this solidarity which reduce rather than enhance inequality and promote real forms of social solidarity.

References


In many countries drugs are seen as a priority and households spend precious resources to procure those which have been prescribed.
STABILITY may pose serious problems for drug products distributed and used in tropical climates. It is acknowledged, however, that stability studies for temperate climates may not be fully relevant to countries with extreme climatic conditions. Success in the study of tropical storage conditions on the quality of medicines is few and the evident extent of the problem has rarely been investigated. In 1987 UNICEF supplied essential drugs to developing countries for a total value of over US $30 million. WHO's Action Programme on Essential Drugs and UNICEF therefore carried out a joint study on the stability of essential drugs during international transport.

The objective of the study was to determine whether present methods of international shipment of essential drugs by sea have any adverse effect on their quality and potency. The investigation was a combined longitudinal study of three shipments of 11 essential drugs each, sent by sea from the UNICEF warehouse in Copenhagen (Denmark) to Lagos (Nigeria), to Mombasa and from there onward to Kampala (Uganda), and to Bangkok (Thailand). The three sea routes together cover 35 (45%) of the 77 countries served by UNICEF and nearly 40% of the total volume of drugs dispatched in 1987. Temperature and relative humidity within the test packs were monitored at three-hourly intervals. For each destination test packs were placed in two different locations within two containers of the same shipment (one pack in the centre and one near the ceiling of each container, and one container in the hold of the ship and one on deck).

The drug products included in the study are listed in Table 1. They were chosen on the basis of indications from other studies that the substance or the product could be unstable, high UNICEF turnover in volume or in value, and medical relevance. All samples were taken from normal UNICEF stock and products in the test and control packs were taken from the same batch. The quality and potency of the drugs were measured before and after shipment.

### Results

The three journeys to Lagos, Kampala and Bangkok took 51, 22 and 27 days respectively, of which 5-10% was spent in European ports, 45-75% at sea and 10-30% in the port of destination before customs clearance. A sample climatic recording from the trip to Mombasa and onward to Kampala is shown in Figure 1. Temperatures recorded within the test packs ranged from -3.5 to 42.4°C and relative humidity from 20-88%. In general the temperature and relative humidity on the three routes showed an identical pattern of a steady rise on approaching tropical waters, followed by periods of high values and moderate fluctuation in tropical harbours, and high values and strong fluctuations during storage and transport on land. Despite some incidental variations the accumulated differences between the various locations on board and within the container were negligible.

WHO defines normal drug storage conditions as dry, well-ventilated premises at temperatures of 15-25°C or, depending on climatic conditions, up to 30°C. In the present study the temperature within the drug packs was at times considerably higher than that, with a maximum of 42.4°C in Mombasa. An important finding was also that the temperature within the packs was 10-20% higher than the ambient temperature. Temperature and relative humidity at sea were less of a problem than during transport and storage on land. It was especially during the periods spent on board in the harbour, in customs bondages in the port area and during transport overland, that the extreme climatic conditions occurred. For Lagos this meant 17 days (33%) and for the Kampala trip 26 days (54%) exposure to the combination of high temperature and humidity that is known to be most detrimental to drug quality.

Three drugs (ergometrine and methylergometrine injections, and retinol capsules) lost potency during international transport. Ergometrine injection showed the largest loss (52.8%), Methylergometrine injection lost 1.7% and retinol 1.3%. None of the other drugs, including the antibiotics, showed signs of instability. Weight variation, disintegration and hardness all remained within pharmaceutical standards. The full results are published elsewhere. 

For retinol this has no medical or practical implications as the product contained an extra 20% of active ingredient and is therefore not being expected to be used inside transport and storage.

An important finding is that the antibiotic in this study did not show any sign of instability. Accelerated stability studies on the unprotected substance and on the unprotected tablets and capsules have often found signs of degradation. It is also known that high humidity is more damaging than high temperatures. However, the only available field study, from Sudan, found no signs of instability in ampicillin capsules, penicillin injection and terracycline capsules within their package. It therefore seems likely that the stability in tropical climates is greatly dependent on the level of protection against humidity, even under exposure to high temperatures. Further studies on the stability of drug products during transport and storage within tropical countries are currently being undertaken by WHO.

The full report of this study is available, on request, from the WHO Action Programme on Essential Drugs.

### Table 1 Drug products included in the study

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylic acid tablets (2x)</td>
<td></td>
</tr>
<tr>
<td>Ampicillin capsules</td>
<td></td>
</tr>
<tr>
<td>Ampicillin powder for injection</td>
<td></td>
</tr>
<tr>
<td>Benzylopenicillin powder for injection</td>
<td></td>
</tr>
<tr>
<td>Ergometrine Injection</td>
<td></td>
</tr>
<tr>
<td>Methylergometrine Injection</td>
<td></td>
</tr>
<tr>
<td>Ferrous salt/folic acid tablets</td>
<td></td>
</tr>
<tr>
<td>Phenoxymethylpenicillin tablets</td>
<td></td>
</tr>
<tr>
<td>Retinol capsules</td>
<td></td>
</tr>
<tr>
<td>Tetracycline tablets</td>
<td></td>
</tr>
<tr>
<td>Tetracycline eye ointment</td>
<td></td>
</tr>
</tbody>
</table>

### Figure 1: Sample temperature and relative humidity recording (Einabba/Kampala)

Legend:
1. In UNICEF warehouse Copenhagen
2. At sea Copenhagen to Mombasa
3. In port area Mombasa
4. Overall transport to Kampala
5. Return journey Kampala to Uppala

### References


4. Drug in containers arriving in port.
Pharmaceutical expenditure in Benin

INTRODUCTION

In many developing countries, a large part of the population does not have regular access to essential drugs. The public sector is unable to satisfy demand, while the absence of purchasing power is often advanced as one of the constraints that restrict access to the drugs distributed by the private sector.

Some surveys of household expenditure have nevertheless shown that even the poor spend a considerable portion of their income on the purchase of drugs in the commercial sector (pharmacies, authorized points of sale, markets, etc.). Some sociological studies also indicate that both individuals and families are prepared to do without other things, including even essentials, such as food, in order to buy drugs, which are perceived as an even greater necessity. There are not very many studies, however, and there are few statistics on drug consumption. Import statistics are not always reliable, and as soon as there is any local production or a black market, they are misleading and do not give an idea of the amount of money spent by the end consumer.

Several published studies have also stressed the fact that the drugs purchased in the commercial sector often do not match the real health and medical needs of the population. The drugs purchased are sometimes of doubtful efficacy, not suitable for the conditions they are supposed to treat, and these drugs have usually been purchased instead of other drugs that would be more appropriate.

Fuller information on these two aspects (how much is spent on drugs, and on which drugs) should help ministries of health in the developing countries to plan their national pharmaceutical policy more effectively. Many governments, for example, hope to obtain a financial contribution from the community in order to make essential drugs available to the entire population: reliable data on spending on drugs will be useful to obtain a better idea of the solvency of the population at different socioeconomic levels. Although it is difficult to forecast assumptions about the transfer of resources from the private to the public sector, planners nevertheless need to have a more accurate idea of how much is spent on drugs in the country.

Table 1. Distribution of buyers

<table>
<thead>
<tr>
<th>Total buyers</th>
<th>Buyers with prescriptions</th>
<th>Buyers without prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>43</td>
<td>51</td>
</tr>
<tr>
<td>ONP stores</td>
<td>30</td>
<td>34</td>
</tr>
<tr>
<td>Private stores</td>
<td>12</td>
<td>21</td>
</tr>
<tr>
<td>Markets</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td><strong>100</strong></td>
<td><strong>100</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Table 2. Average expenditure on drugs

<table>
<thead>
<tr>
<th>Average expenditure</th>
<th>Average expenditure with prescription</th>
<th>Average expenditure without prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>10.5</td>
<td>6.4</td>
</tr>
<tr>
<td>ONP stores</td>
<td>5.1</td>
<td>3.7</td>
</tr>
<tr>
<td>Private drug outlets</td>
<td>6.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Markets</td>
<td>8.5</td>
<td>3.5</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>8.5</strong></td>
<td><strong>4.6</strong></td>
</tr>
</tbody>
</table>

These fishermen from the village of Gavial, Benin, pursue their traditional way of life, but like other communities throughout Africa they also seek the benefits of modern medicine.

Since drugs are expensive, both in absolute value and in per capita terms, it would also be desirable to ensure that all drugs are effective and are properly used. Knowledge of the types of drugs most commonly purchased would enable government to give more rational direction to their drug selection policy, the training of prescribers and the education of the public.

A DRUG CONSUMPTION STUDY

The Faculty of Health Sciences of the University of Benin, in collaboration with the Ministry of Health of the Republic of Benin and the WHO Drug Action Programme, therefore launched a study in 1987-1988, under the direction of Professor T. Sokodjou, to try to discover how much is spent on drugs, and on which drugs.

The Republic of Benin is situated South of the Sahara and has a population of about 4.5 million; the per capita GNP of US$ 270 is among the lowest in the world. The country's economic situation has deteriorated continuously as a result of the decline of its export income, fluctuations in climatic conditions and the indebtedness of its public sector. The finances of the public sector have borne the brunt of these adverse economic developments.

In regard to drugs, Benin has always pursued the objective of providing the population with essential drugs. It was one of the first countries in Africa to establish in 1964 a National Office of Pharmacy (ONP), a parastate agency to import, distribute and sell, at prices accessible to the population, the most important drugs needed to complement those distributed free-of-charge at health facilities by Pharmaco from the state budget. The ONP has experienced serious management and cash flow difficulties and is now being wound up, while Pharmaco has virtually ceased its activities for lack of financial resources.

The drug situation in 1987-1988, when the study was carried out, was therefore characterized by:

- the existence of a national list of essential drugs for the public sector;
- a very poor and unbalanced supply to health facilities, largely assured with the help of international aid;
- a parasitic sector (ONP stores and pharmacies) in decline;
- a flourishing private commercial sector established mainly in the urban areas (36 dispensaries and 122 stores).

SCOPE AND METHODOLOGY OF THE STUDY

The study was carried out in four regions of Benin representative of the country as a whole in terms of population density, the health care and drug distribution networks, the importance of parallel networks of distribution, and the communications network. Each region included urban, periurban and rural areas.

The data were mostly obtained from two single cross-sectional surveys: one covering drug buyers; the other covering households and using structured questionnaires comprising open-ended and closed questions. Additional information was obtained from a review of public statistics on total expenditure on drugs in the public and private sectors.

In the household survey, a two-stage sampling technique using an existing sample base produced a random primary sampling unit consisting of 20 villages and 20 urban districts. Clusters of households were then established by the usual statistical procedures, and a total of 911 households were interviewed. Each interview lasted 30-45 minutes and focused mainly on the drugs kept in the house and the drugs bought and used in the two weeks preceding the survey (type, quantity, price, type of health problems for which they were purchased, etc.). The survey of drug buyers covered 130 points of sale (11 private dispensaries, 3 ONP stores, 9 private stores and 7 workers, etc.). There were more buyers than sellers essentially because the pharmacist or manager was willing to collaborate with the study. This collaboration existed essentially in permitting the investigator to work in the establishment in question. The buyers to be interviewed were selected at random, with a daily quota of 12 buyers, and the survey was carried out over a period of seven hours per day on four consecutive weekdays.

1,169 buyers were interviewed, and in addition to individual personal data, the questions dealt with the drugs purchased with or without a prescription (name, nature, quantity, price, type of symptoms or disease prompting the purchase, and who prescribed or advised the drugs).

In order to test the operational methods for the survey, a small pilot study was carried out among 40 households and at six points of sale and some improvements were made to the forms for the collection of data. The investigators were recruited from among recently qualified young health professionals and given four weeks' training before going to one of the survey areas, covering such questions as study of the environment, where to find statistics and how to conduct interviews. During the surveys, each region was visited by a supervisor to help the investigators to deal with any problems they had encountered.

MAIN RESULTS

A. Survey of points of sale

11% of the buyers questioned were willing to take part in the study: two out of three were male and nearly 60% of modest means (artisans, small traders, workers, etc.). The remainder were customers at pharmacies and private stores than at the other points of sale (ONP stores and markets). Nevertheless, a large number of people went to markets to buy drugs, particularly in the urban areas (Table 1, column 1).
Prescribed drugs

Half of the drugs bought were purchased on prescription, mainly at the pharmacies (Table 2); 61% of the people who went to a pharmacy to buy drugs had a prescription, as compared to 38% who went to market. 70% of these prescriptions had been written by paramedical personnel (nurses, midwives, and pharmacists) and were for an average of 2.2 drugs. Multiple prescribing was also encountered and 30% of prescriptions were for at least four products. Cross-analysis of the data showed that when a large number of drugs were prescribed, patients tended to select from the full list of items prescribed and that a high proportion of prescribers were only prescribed by 61% of consumers. This tendency correlates with the findings in many other studies and illustrates the difficulties that people have in paying for their drugs; selection between different drugs is more often determined by cost than by their medical importance.

This difficulty in purchasing all items on a prescription can certainly be explained by the high cost: US$5 on average, while 30% of people spent less than US$10 each time. This average cost of US$5 was the same in three of the regions studied but 30% lower in the most distant from the capital.

Expensiveness was similar in the urban and peri-urban areas, but lower in the rural areas. The greatest difference in expenditure, however, was between different points of sale; at pharmacies average expenditure on prescriptions was US$10.2, while expenditure was higher, paradoxically, in markets (US$8.5) than at the private drug outlets (US$6.6) and ONP stores (US$5.1) (see Table 2).

Non-prescribed drugs

A similar volume of drugs is purchased without prescription, in the first place by the people followed by markets (29%) (Table 1, column 3). The two main origins of these purchases are: the pharmacies (52%), for personal insufficiency and drug advertising (47%).

Since people who buy without prescription buy the drugs they can afford, it is understandable that 83% of these purchases comprise not more than two drugs and the average amount spent is only US$4.6. Only 9% of drugs purchased for self-medication cost US$10 or more, as compared with 30% of the drugs bought on prescription (Table 2). Average expenditure is similar in the same three regions mentioned above, and lower in the fourth region; and there are no significant differences between urban, periurban and rural areas.

Average per capita expenditure is highest in the pharmacies (US$6.4) and lowest in the markets (US$3), which contrasts with the cost of drugs bought on prescription. Buyers have much greater powers of negotiation in the cost of self-medication, and many of the poor probably take their prescriptions to markets insinuating that this is where drugs will be cheapest.

Types of drugs purchased

The study also attempted to evaluate the types of drugs purchased, i.e. essential/non-essential, single substance/comboination. Since there are no drugs sold under their generic names in the private sector, essential drugs were defined as drugs included in the national list and sold under brand names. The proportion of essential drugs and single substance drugs in relation to the total drugs purchased, with or without prescription, is the same - 25% (Table 3). These drugs, even when they are sold under brand names, are less expensive than non-essential drugs and combination drugs. It should also be noted that the range of drugs purchased was fairly small in relation to the total number of drugs available in Benin: 308 different drugs were purchased on prescription and 257 for self-medication. It will be seen that antimalarials are exceeded by the number of toxicities and analgesics bought on prescription and that more is spent on these toxicities than on the purchase of anti-infective drugs (Table 4). The two single items on which the most money was spent were an antimalarial - injectable quinine - and a drinkable liquid tonic, sold in ampoules, which has been vigorously promoted in most of the French-speaking countries in West Africa. Questions may be raised as to whether this prescribing is rational and is appropriate to the health and medical needs of the population. Paradoxically, the drugs bought without prescription seem to be in line with major health problems, although tonics and vitamins still account for an important share. Antimalarials and anti-infective drugs come top of the list in both number and value (Table 5), as if the patients were more aware of their own needs or less influenced by drug advertising than prescribers.

B. Survey of households

76% of the households selected took part in the study. 66% of the heads of households covered by the survey had never been to school and 26% had no education beyond the primary level. It may be a problem for these heads of household to understand the proper use of drugs. Most of these households had low incomes (69%); the mean household income was around US$410 and households comprised eight people on average.

In the two weeks preceding the survey, 53% of households had bought drugs, and had been consumed in 65% of households, mostly by people who were ill. In the period of the survey, the households interviewed had spent 16% of their monetary income on the purchase of drugs.

In the households in which people were ill, an average of US$13.5 was spent on drugs that were being taken by the patients, average expenditure per household for patients was highest in the peri-urban area, doubleless on account of the accessibility of these areas. The results suggest that a substantial amount of money is being spent on drugs, often without using them. Although demand for drugs would appear to be relatively inelastic in relation to income, it is clearly evident that many buyers and households are spending more on drugs than they can afford; this results in behaviour such as not buying the items prescribed, recourse to markets where the price of drugs is often lower and is negotiable, self-medication failure or take care of patients. The study provides detailed evidence of the fact that populations are prepared to purchase drugs for the sake of the sick, but that what they can actually afford needs to be studied in greater depth. The results of the study have been widely disseminated and have enabled the Ministry of Public Health in Benin to plan its national drug policy better and to focus its activities on:

- the role of the public sector and improvement of the supply of essential drugs;
- improved prescribing and the reduction of multiple prescriptions;
- wide-ranging information and education of the public to reduce dangerous self-medication, misuse, over-consumption and the proper utilization of drugs;
- greater regulation of the sale of drugs, particularly in markets;
- the establishment of mechanisms governing both prices and products to enable good quality drugs to be sold cheaply in the private sector, and the development of a drug price regime for essential drugs, as the only deterrent to the illicit sale of drugs;
- training of pharmacists to advise on drugs, making them aware of the cost factor;
- strict criteria for the registration of drugs to eliminate a number of products known to be ineffective (amplules of medicines for oral consumption, tonics, etc.) from the market.

<table>
<thead>
<tr>
<th>Table 3. Proportion and cost of prescription and non-prescription drugs</th>
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<tbody>
<tr>
<td>Essential drugs</td>
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<tr>
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</tr>
<tr>
<td>Drugs bought</td>
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<td>Average cost per drug bought</td>
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<table>
<thead>
<tr>
<th>Table 4. Therapeutic categories most often purchased on prescription</th>
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<tbody>
<tr>
<td>Therapeutic category</td>
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<td>---</td>
</tr>
<tr>
<td>Antimalarials</td>
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<tr>
<td>Antivirals</td>
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<tr>
<td>Antituberculars</td>
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<th>Table 5. Therapeutic categories most often purchased without prescription</th>
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<td>---</td>
</tr>
<tr>
<td>Antimalarials</td>
</tr>
<tr>
<td>Antivirals</td>
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<tr>
<td>Antihistamines</td>
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NATIONAL DRUG POLICY

Bhutan: positive impact of ED programme

A recent evaluation of the Bhutan Essential Drugs Programme, national drug policy, including comprehensive pharmacological legislation; the selection of a national essential drug list; the establishment of a reliable and continuous information system to quantify and rationalize drug requirements. This system is working so well that the evaluation recommended that the methodology established could be used as an example and/or practical demonstration for other countries; the training of all hospital stockkeepers in proper supply management; the development and distribution to all health workers of a national standard treatment guide and related training activities.

Drug availability in Bhutan has increased significantly at all levels of health care since the Programme’s inception, concluded the evaluation, while drug prices – a result of improved procurement procedures – were 7% lower than in 1985. According to the study a reasonable level of rationality exists in diagnosis and prescribing, especially among paramedical staff, but the objective of rational use of drugs has not yet been achieved. Recommendations for new and strengthened future programme activities include:

- the establishment of drug committees to provide prescribers with information on drugs and to propose antimicrobial policies;
- the creation of a small scale drug quality control laboratory at present drug samples are sent to a QC laboratory in Calcutta;
- a training programme on drug supply and management for health assistants and basic health workers;
- regular training for paramedical staff in rational prescribing and dispensing and more attention paid to the training of doctors in this area;
- improved drug information, education and communication activities.

Meeting of programme managers in Yemen

In December 1990 staff from the three Dutch-funded essential drugs programmes in Sudan, Yemen and Malawi met in Sana’a to exchange practical experience and to discuss current issues in the field of essential drugs. Representatives from several other countries in the Eastern Mediterranean Region, with a new or established essential drugs programme (Cyprus, Iran, Pakistan, Syria and Tunisia), also participated.

The main topics of discussion were the development of a national drug policy, drug supply management, training in rational prescribing and quality assurance; it was an interesting encounter between programmes in various stages of development. For example, training in rational drug use for rural health workers started in Yemen in 1985 and in Sudan in 1990, but it is only beginning in Malawi. Computerized drug supply and information systems are operational in Cyprus and Yemen but are only beginning in Sudan. Iran is very advanced with a generic policy and Tunisia is considering it. Most of the countries have well-established quality control laboratories, but Yemen is only starting. Malawi, Sudan and Yemen are well advanced in their essential drugs programmes but Pakistan, Syria and Tunisia are in an early stage.

The report of the meeting contains summaries of the presentations and discussions and is available from the WHO Regional Office for the Eastern Mediterranean, P.O. Box 1517, Alexandria, Egypt.

Venezuela focuses on rational use

Within the framework of the current national policy on the rational use of drugs and of economic resources, the Ministry of Health established in April 1990 a Technical Therapeutic Committee composed of representatives from the main health programmes. Technical assistance is also being provided by the Pan American Health Organization/WHO Regional Office for the Americas (PAHO/WHO).

One of the Committee’s initial and most important tasks was to draw up Venezuela’s first list of essential drugs for the public sector, which represents about a third of the total health care institutions in the country. Another important first step towards the goal of a more rational drug use has been the development of a therapeutic formulary, which is being undertaken in collaboration with the Drug Information Centre (CEDIMED) of the Central University of Venezuela.

A further major activity has been an assessment of the national drug situation, covering legislation; registration; quality control; pharmaceutical production and distribution; supply to the public health sector; the development of institutional pharmacies, rational use, and the human resources available in drug management. This comprehensive report also contains the recommendations of a national workshop, held in December 1990, that analysed the preliminary study findings. Government, teaching and professional bodies in the field of pharmacy and medicine, as well as experts from PAHO/WHO, participated in the workshop.

Additional activities extend beyond the national to the regional scene. Within the framework of the Cooperation Andina en Salud (Andean Cooperation in Health) a comparative study has been made of drug registration requirements in the Andean area. This work, together with other PAHO/WHO publications, will provide the background material for a sub-regional meeting, in July this year, to prepare a proposal for the harmonization of drug registration requirements in the Andean area.

(1) Available shortly from PAHO/WHO, Washington, USA and the Office of the WHO Representative to Venezuela, Caracas

National workshop in Tunis

Some 50 Tunisian health professionals recently took three days from their busy routine schedules to discuss rational drug use. They met for a workshop focusing on the new national drug policy. The main components of the policy are the promotion of the national pharmaceutical industry, the use of limited lists of drugs under generic names for various levels of health care in the public sector, and a limitation in the number of different brands importation for the private sector, many of them procured through international tender. As a consequence of the new policy, some degree of substitution by the pharmacist has already been introduced.

The meeting, held in November 1990, was convened by the Ministry of Health, with technical and financial support by WHO’s Regional Office for the Eastern Mediterranean and the Action Programme. Participants included staff members from the Pharmaceutical Department, the Quality Control Laboratory, the Central Pharmacy, the regional directorates, the medical and pharmacy faculties, professional associations and private practitioners.

There was general agreement that the discussions took place in the same atmosphere of openness and consensus that has always characterized the development of national drug policy and drug legislation in Tunisia. A report of the meeting will be available shortly from the WHO Regional Office for the Eastern Mediterranean, P.O. Box 1517, Alexandria, Egypt.
The Preferential Trade Area (PTA) lends its support to essential drugs

The Preferential Trade Area of eastern and southern African countries (PTA) has recently begun a programme with technical assistance from WHO's Action Programme on Essential Drugs (DAP), and financial assistance from Denmark, the Commonwealth Secretariat and UNDP, to develop local production of good quality essential drugs in PTA member states.

A team of pharmaceutical production-quality assurance specialists will be formed and trained, and will assist local producers to maintain standards of Good Manufacturing Practice by regular inspection and technical assistance visits. The operations of the core team will be supervised by the PTA Secretariat in Lusaka, in close coordination with WHO. The programme will work with national pharmaceutical inspectors and other personnel, so as to build up national expertise and to dovetail into the operation of such quality assurance systems as the WHO Certification Scheme.

The objective is to enable PTA member states to buy more of their essential drug needs from within the area, thus saving on delivery times and foreign exchange. Furthermore, the PTA payment/clearing house system will facilitate trade, by avoiding the need for buyers to have to pay in foreign exchange.

Supporting the programme on Good Manufacturing Practices/Quality Assurance (GMP/QA) is an initiative to compare prices of PTA producers with those of overseas suppliers; initial data indicate that some PTA producers are competitive with world market prices. When factors such as delivery times, foreign exchange and financing costs are taken into consideration, as well as high shipping charges from Europe and other main supply points, it may well be that PTA producers have the competitive edge. The PTA Secretariat will implement a price information system.

Several countries in the PTA are still operating procurement systems for pharmaceuticals and medical supplies that date from before World War II. In some cases they are cumbersome and bureaucratic, and cannot respond to the needs of national health services for short-term supplies as and when foreign exchange and budgets become available. It is probable that such systems are contributing to the difficulties in drug supplies that are experienced by several PTA countries.

Recognising this, member countries have requested the PTA Secretariat, with the assistance of WHO, DAP, to implement a programme of training in good procurement management. This is being financed partly by the German Pharma Health Fund, and partly by Denmark. The programme, which will run from early 1991 through to end 1993, will seek to train all personnel involved in the pharmaceuticals procurement process in national and NGO health systems.

Though it is difficult to change established systems of procurement, through training in procurement management it may be possible to alleviate or even avoid many of the difficulties that are currently besetting PTA member states, and enable essential drugs to be purchased more cost-efficiently than at present.

A PTA/WHO conference to officially launch these activities is scheduled for July 1991, venue to be decided. Further information can be obtained from: PTA Secretariat, Ndike House Annex, Haile Selassie Avenue, Lusaka, Zambia. Tel: 229725, Telex PTAZA 40127, or Action Programme on Essential Drugs, WHO, 1211 Geneva 27, Switzerland.

Pioneering new course on drug management and rational use

Aberdeen's Robert Gordon Institute of Technology has developed a new and very practical oriented course for pharmacists from developing countries. "There is a fairly widespread lack of practical experience in effective drug management on the part of pharmacists and other health professionals," says Professor Michael Richards, Head of the School of Pharmacy, explaining the rationale of the course. "This has created an urgent need for further training of mid-level pharmaceutical and other health personnel, especially those who are working in the public sector. Such training must be relevant to the functions that such people are expected to perform in the pharmaceutical supply system," he emphasises. "The Aberdeen course will be unique in that it addresses this need by using typical problems experienced in the participants' home countries thus making the training directly relevant to each person's work situation. A problem solving approach will be used in order to provide participants with the knowledge and skills to evaluate new situations and to develop appropriate policies and procedures to achieve the required objectives." The 12 week course was designed by a small group of pharmacists with extensive experience in developing countries, in cooperation with staff from WHO's Action Programme on Essential Drugs. The curriculum covers such areas as national drug policies, drug selection, estimating requirements, procurement procedures, local production, financial resources, quality assurance, distribution, stock management, standard treatment schedules, teaching skills, legislation, curriculum development, action plans and critical analysis. The first course will be held from 26 June to 20 September 1991. Applications and requests for further details should be addressed to: School of Pharmacy, Robert Gordon Institute of Technology, Schoolhill, Aberdeen, Scotland AB9 1FR, UK, Telephone 0224 633811. Fax (0224) 639559.

West African quality assurance seminar

Representatives from health authorities of West African countries met from 3-5 December 1990 in Lomé, Togo for a seminar on quality assurance of pharmaceutical products in international trade. The meeting, which was organized by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), in collaboration with the WHO Regional Office for Africa, focused on product registration; quality assurance versus quality control; counterfeiting; product information; marketing and distribution.

Participants concluded that priority areas needing technical and financial support are:

- a review of drug legislation and the development of regulatory control services, including inspection guidelines and procedures;
- analysis of experience with and criteria for establishing quality control laboratories; their functions, personnel needs, management, maintenance and financing;
- the creation of intercountry working groups to exchange information, review common problems and approaches to develop methodology, manuals, training seminars, etc.

The meeting stressed that each country needs to define its national drug policy to serve as a framework and guide for coordinated actions.
RESEARCH

Qualitative Research with a Kenyan flavour

Joseph Mburu, Lynne Cogswell, Elisabeth Crane, Ian L. Todreas

"Maybe it isn't the health worker's fault that I got sick again! I'll just take all the medicine the way she told me and see what happens..." - Kenyan woman, protesting session

Improving public understanding of appropriate drug use is an important part of Kenya's National Programme on Essential Drugs. Part of the strategy has been to develop communications materials on the benefits of correct, and the dangers of incorrect, use of medicines. In order to develop effective materials that encourage drug compliance, programme staff used two qualitative research methods: focus group discussions and pretesting.

Developing health materials

Ideally, health messages and materials further the objectives of a project with respect to a particular health problem. The materials development process usually begins with identifying the target audience's communication needs concerning that issue. To achieve this, a team representing the various sectors involved in a programme's implementation conducts qualitative research to assess current knowledge, perceptions, attitudes, and practices of the target audience as well as the best channels for reaching them. The information gathered is then used to produce and disseminate culturally appropriate materials and messages, which form a communication bridge between health providers and recipients.

Focus groups

In contrast to quantitative research, qualitative research cannot provide statistical data about people's behaviour. But it can illuminate the reasons why people act as they do. Qualitative research methods include focus group discussions (FGDs), in-depth interviews, participant observation, and pretesting. FGDs are often used to gather information for developing communication materials. They are a quick and relatively inexpensive means of ascertaining a target audience's beliefs and practices regarding a particular topic. A facilitator directs the discussion and elicits the concerns, knowledge, and opinions of a group of six to ten persons of similar key characteristics and background while a notetaker records responses.

If conducted correctly, FGDs will prod participants to present the community's needs in their own words, uncovering local expressions and mores. They will also reveal the need to address "secondary audiences" - people who influence the target audience's behaviour, such as parents or religious leaders. When programme staff recognize and draw on positive social customs within a culture, they are better able to bridge the differences between their own knowledge and local perceptions. The results of focus group discussions are carefully analyzed. By grouping responses by theme or topic, patterns in audience attitudes, opinions, and practice begin to take shape. The themes can then be used to develop effective messages.

Pretesting

Once draft materials have been designed, another qualitative research method, pretesting, is used to evaluate the drafts with the target audience.

Patient education at Nakuru, Kenya.

Often those who design a poster or booklet assume that everyone will be able to "read" the visuals and understand the text. But sometimes members of the target audience have not been exposed to many visuals; have had little or no formal schooling; or interpret symbols, pictures, and text differently.

In pretesting, an interviewer shows draft materials to members of the target audience and asks open-ended questions to find out whether the intended audience is conveyed and whether materials are understood and liked. A notetaker records comments and suggestions that are later incorporated into the drafts. Pretesting can involve several rounds of tests, and each new or revised version is pretested again, until the material is well understood by and acceptable to a large majority of the audience.

All too often, organizations develop new material and realize too late that it needs revision. But so much time and money have already been invested in the activity that neither the testers nor the programme managers are likely to give credibility to negative comments and different interpretations.

FGDs and pretesting engage the target audience in the materials development process from the earliest stage, contributing to a project's success in three ways. First, as 'experts', the target audience provides useful information for designing and improving the materials so they will be both relevant and meaningful to the community. Second, their participation fosters a sense of 'ownership', a stake in the project, that encourages commitment to help it succeed. Finally, FGDs and pretesting link programme staff to the target audience. The relationship that develops often refreshes the staff's dedication and the target audience's willingness to cooperate. These efforts contribute positively to a project's expansion and longevity as well as its immediate objectives.

A Kenyan experience

In Kenya, the Essential Drugs Programme of the Ministry of Health developed a pilot project to combat misuse and misinformation about drug regimens to promote adherence among "providers" (mostly nurses, doctors, and pharmacists) as trustworthy and knowledgeable. PATH assisted the Ministry in developing information and education elements of the project, which called for developing an appropriate approach to address needs, fears, and misunderstandings regarding drugs and drug use.

The project began with a qualitative research phase using focus group discussions, in-depth interviews, and observation to assess communication needs. Programme staff conducted 19 FGDs with 171 clients and 9 FGDs with 63 providers. In addition, they interviewed 36 providers and observed client/provider interactions in 4 locations.

Several important issues emerged during the FGDs. The investigators discovered that most clients knew little about the importance of strict adherence with a drug regimen. Few people understood that drugs had to be taken at certain times under certain conditions or that failure to complete regimens diminished the effectiveness of drugs. The discussions illuminated an uneasiness surrounding the cause and meaning of drug side effects. Furthermore, many consumers reported that they had been purchasing drugs from "hawkers" or local, unauthorized sources.

These findings helped create five messages concerning drug compliance. The three primary messages are:

- Return to your clinic or hospital if you have problems with your drugs.
- Use only authorized providers.
- Follow all directions carefully and completely.

Results from FGDs also indicated that a combination of two media would be most appropriate to convey these messages. A poster and cassette combination appealed to providers because this conveyed information effectively to illiterate clients, did not require time to operate, and provided a pleasant change from lectures. Clients agreed, and felt that the media were easily adaptable to their own languages (not all providers speak the language of their clients, and they often work through interpreters). They also thought that a poster and cassette combination was a novel idea and thus attractive.

Poster and cassettes

Using this information, programme staff decided to develop a series of five pictorial posters with Swahili text and a 15-minute cassette produced in Swahili, Masai and Kamba, for use together or separately. After drafts of the posters were illustrated and tapes prepared, three rounds of individual and group pretesting were undertaken with both clients and providers in three districts. To determine whether the media could stand alone, they were pretested both as part of a package and separately. The scripts, posters, and recordings were modified and sometimes shortened according to the feedback received. Some of the language in the posters and voice vocabulary was inappropriate or difficult to understand. For example, "watcha", slang for "be careful", was understood but middle-aged and older Kenyans found it somewhat offensive.

"Return to your clinic or hospital if you have problems with your drugs!"
RESEARCH

Poster from Kenya ED programme patient education project. "Follow all directions carefully and completely".

"Jhadhari", almost a direct translation of "be careful of", was a well accepted and understood alternative.

In the second and third rounds of pretesting, the pretest format was expanded to see whether clients could apply the three rules to real life situations. One pregnant woman reported that she used to stop taking medicine as soon as she felt better and invariably fell ill again. She had concluded that the health worker was not giving her the correct medicine. During the project evaluation, she was heard saying: "Maybe it's not the health worker's fault that I got sick again! I'll try taking all the medicine the way she told me and see what happens..."

Her comment after the pretest indicated an immediate shift in attitude and, perhaps, a subsequent shift in behaviour. The last round of pretesting showed that more than three-quarters of the audience found the materials understandable and acceptable. Both clients and providers felt the materials effectively addressed common concerns. The final package, along with tape recorders, were supplied to 24 health centres in 3 districts, and subsequently, posters were distributed throughout Kenya.

Did it work?

A three-month evaluation of the project was made to measure its success and possible wider applicability. At the start of the evaluation 50 providers in each of the 24 sites learned how to use and evaluate the materials.

They then used the package at least once a week – more if it fitted into their schedules – and displayed the posters in at least one central, permanent location. At the end of three months, the programme staff returned to collect quantitative data, and interview clients and providers who had been exposed to the cassettes and posters, as well as providers who observed clients using the package. They also themselves observed the use of materials and talked to clients to gauge their reactions.

Providers at all sites considered the package to be an effective health education tool, capable of changing behaviour positively, especially when used frequently. Providers and health educators who used the cassette/poster packages successfully during health talks, waiting times, and "brassa" (community meetings) held at the clinics as well as during "micro teaching" lessons in surrounding villages.

Each of the primary messages emphasized in the package has yielded specific behavioural changes. The message "Return to the clinic if you have problems" not only encouraged more clients to do so if necessary, but also gave them confidence to seek clear, comprehensive instructions about their drug prescriptions before leaving the clinic.

"Use only authorized providers" has also promoted behaviour changes. Several "miti shambas" (unauthorized clinics) have closed and "[drug hawkers] (unqualified practitioners of Western-type medicine) and freely express their fears – reflecting greater trust of providers and furnishing useful information about their health care needs.

The message "Follow all directions carefully and completely" has led to fewer clients returning to complain of illness because they have failed to complete their drug course. More clients are asking what they need to know about compliance in addition to what they have learned on the cassette, and several have returned to the clinics to say, "I actually am better now!"

Fruits of success

Changing behaviour to encourage proper drug use is a considerable challenge, but one which can be mitigated through the research, design, and production of culturally appropriate messages and materials. The evaluation of the public education project in Kenya.

I

In recent years there has been increasing concern over the widespread misuse of injections. Numerous studies point out that injections are preferred over oral medications by patients and healers for a variety of health problems, even when their administration is not medically justified. In developing countries, where the practice of medicine is less controlled, a variety of unofficial practitioners such as drug peddlers, pharmacists, and traditional healers, are reported to administer injections. Even in government health services, injections may be misused due to lack of training of health personnel and patient demand. Such inappropriate use of injections is an unnecessary burden to household and health centre budgets that are generally already severely stretched. Furthermore the unhygienic use of injections raises concern about the possible transmission of a range of potentially serious pathogens, including Hepatitis B and HIV.

More information needed...

To improve the use of injections, more information is needed on who is administering them; how often and why they are given; whether and to what extent they are used without medical justification; and what hygienic measures are taken. To answer all these questions, the Action Programme on Essential Drugs, in collaboration with EPI and GPA, launched in 1990 a research project in three developing countries: Indonesia, Senegal and Uganda. The research, which is exploratory in nature, will use quantitative and qualitative methods to estimate the extent to which injections are used, to determine the type and degree of inappropriate and unsafe practices, and to gain insights into why injections are so popular.

Developing a common methodology...

In order to finalise the research plans, an informal workshop was held in May 1990 in Geneva. This followed a series of country visits during which researchers had been identified and a provisional research protocol discussed. The overall aim of the workshop was to finalise the national protocols and to strengthen the research capabilities of the country teams. 13 researchers from the countries involved, from WHO Headquarters and from the University of Amsterdam participated and worked together to improve the protocols and to develop a common methodology and perspective. Various medical anthropological techniques which can be used in the study, such as interviews with key informants, case studies and fieldwork discussions were presented. Epidemiological perspectives and methods, notably the sampling procedures, were also covered and a number of injection use measures were developed.

During the final session, the country teams presented their revised research proposals, from which it was apparent that the workshop had led to substantial refinements of the research protocols and to the standardization of core data collection instruments and data analysis techniques. This will enable comparison of results, without compromising the need for country specific modifications in the conduct of the research. Apart from leading to improved research protocols, the discussions also provided some preliminary insights into how injections are used in the countries involved.

The report of the workshop will be published shortly and the provisional research protocol is available to anyone interested in pursuing similar studies. Both documents may be obtained on request, from WHO's Action Programme on Essential Drugs.
From ORS to case management of diarrhoea

Since the introduction of oral rehydration salts (ORS) solution in the late 1960s, its role and benefits in the management of diarrhoea have gained wide recognition. The majority of health professionals in both developing and industrialized countries now regard oral rehydration therapy (ORT) – which is the use of appropriate fluids including ORS – as the most effective treatment for patients who are suffering from dehydration due to diarrhoea. Dehydration (the loss of body fluids and salts) is a frequent result of diarrhoea and can rapidly become fatal in children. So, ORT is an effective means of preventing children from dying of diarrhoea – a serious problem in developing countries. It is estimated that in the developing world there are around 1.5 thousand million diarrhoea episodes and 3 million deaths in children under five each year. The worldwide application of ORT could save the lives of the great majority of these children. Not surprisingly, the medical journal The Lancet once described the discovery of this therapy as “potentially the most important medical advance this century”.

However, it is now clear that the effective management of diarrhoea requires more than just the treatment of dehydration. Correct case management of a child with diarrhoea involves both family and health workers. The key rules are:

- The prevention of dehydration has to start at home by giving the child increased amounts of fluids, such as rice water, tea, gruel, and other appropriate fluids that are commonly used in the community.
- If the child becomes dehydrated (which may occur despite increased amounts of fluids), it is important to take her him to a health worker for assessment and treatment. A child with dehydration should be treated with ORS, which guarantees fast and optimal rehydration and prevents further dehydration.
- The child should be fed normally during and after the diarrhoeal episode. This prevents malnutrition and, just as importantly, helps a quick recovery. Scientific research has clearly shown that children who receive adequate nutrition during diarrhoea recover faster than those from whom food is withheld.
- Children who are severely dehydrated – usually only a small proportion – should be rehydrated intravenously.
- Drugs are indicated only for dysentery and suspected cases of cholera. Very clear guidelines exist for the selective use of effective and relatively cheap antimicrobials in such cases. Although in many countries large quantities of “antidiarrhoeal” preparations or antidiarrhoeics are being used for the management of diarrhoea in children, there is absolutely no scientific rationale for this practice (Fig. 1).
- For the vast majority of diarrhoea cases, a laboratory diagnosis is not needed. Most diarrhoea is self-limiting and can be handled satisfactorily simply by correctly applying the above recommendations.

**The impact of national CDD programmes**

Since the early 1980s practically all the developing countries have implemented diarrhoeal disease control (CDD) programmes. Many of these programmes have had success through the acceptance of ORT by the general public and health professionals. Moreover, CDD programme activities have led to a considerable increase in access to ORS and use of ORT at the global level since 1980. ORS is currently being produced in about half of the developing countries.

Surveys conducted in a number of countries indicated that, on average, the hospital admission rate for diarrhoea dropped by 61% after the introduction of ORT and the average case-fatality rate was reduced by 71%. An additional advantage of such changes is a significant reduction in hospital costs for diarrhoea treatment; some hospitals have reported a saving of as much as 60%. It is estimated that improved case management has had a significant effect on childhood mortality, although it is difficult to measure the decline in diarrhoea-associated deaths that has resulted from the activities of CDD programmes.

**The drug use problem**

Despite the progress made, appropriate case management of childhood diarrhoea tends to be the exception, rather than the rule. Although the rational management of diarrhoea includes a selective use of drugs, the reality in most developing countries is that inappropriate drugs are used routinely for a large proportion of diarrhoea cases. Surveys carried out in four Asian countries have shown that use of drugs is far more common than the use of ORS. While ORS was used in 99% to 21% of all episodes, other drugs were used in 22% to 68% of episodes (Fig. 2). Multiple drug therapy was very common (Fig. 3). This unnecessary use of drugs is extremely costly. For instance, in the period 1988-1989, it is estimated that in Peru more than US$2 million was spent on antidiarrhoeal preparations. This expenditure cannot be justified.

**Figure 1:** Excerpt from the revised WHO diarrhoea treatment chart “Management of the Patient with Diarrhoea”

**Use of drugs for children with diarrhoea**

- **ANTIBIOTICS** should only be used for dysentery and suspected cholera. Otherwise, they are ineffective and should NOT be given.
- **ANTIFILARIAL** drugs should only be used for:
  - Amoebiasis, after antibiotic treatment of bloody diarrhoea for Shigella has failed or trophozoites of E. histolytica containing red blood cells are seen in the faeces.
  - Giardiasis, when diarrhoea has lasted at least 14 days and cysts or trophozoites of Giardia are seen in faeces or small bowel fluid.
- **ANTIDIARRHOEAL DRUGS** and **ANTIEMETICS** should NEVER be used. Note: has proven multiple uses. Some are dangerous.
Disadvantages of the irrational use of drugs for diarrhoea

The use of anti-diarrhoeal drugs and the routine use of antibiotics are not only unjustified, they also have many disadvantages.

One of the most serious is that they divert attention from the correct management of diarrhoea. When prescribing, dispensing, and administering a drug, the doctor, the pharmacist, and the mother might think that they have done what is best for the child with diarrhoea. However, preventing and treating dehydration, feeding, and monitoring the condition of the child, may have been neglected. Taking an anti-diarrhoeal drug does not prevent dehydration.

Another disadvantage of most drugs used for children with acute diarrhoea is that they have no proven value for this condition. Although the most commonly used products claim to diminish the severity or duration of diarrhoea, they do not reduce the life-threatening fluid losses that can be associated with childhood diarrhoea. Carefully designed studies have shown that these drugs reduce neither the number of stools passed by a child with diarrhoea nor the period of illness.

There are also very negative economic consequences. Countries incur considerable costs in acquiring anti-diarrhoeal drugs. For most developing and developed countries the share of drugs in the national health budget is very large. WHO has estimated that drugs account for more than 40% of health care costs. Governments and families often spend scarce resources on unnecessary drugs; poor families may even have to sell food for this purpose.

Many drugs used for children with diarrhoea have serious side-effects, such as central nervous depression, gastrointestinal toxicity and an increase in the severity or duration of the diarrhoeal episode. Doctors and mothers often attribute the side-effects of drugs to the disease, rather than to the drug. Nevertheless, side-effects are found when properly looked for. Inappropriately use of antimicrobials also contributes to the emergence of resistance in microorganisms. It has recently been reported from Viet Nam that 50% of isolated *Shigella* strains are resistant to ampicillin, chloramphenicol, tetracycline and sulfamethoxazole. Over 97% of the strains are resistant to ampicillin one of the four antibiotics. The proportion of strains resistant to trimethoprim increased from 0.7% in 1984 to 10.6% in 1987, which gives cause for concern, in view of the fact that co-trimoxazole is the drug of choice for dysentery in Viet Nam.

These are all reasons why doctors should not prescribe such drugs, pharmacists and drug vendors should not sell them, and families should not buy them.

A new WHO publication on the rational use of drugs in diarrhoea

In recent years, national CDD programmes have increasingly turned to WHO for technical information on the efficacy and safety of drugs used to treat children with diarrhoea.

Whatver strategies and activities a country may select and implement to counteract the irrational use of drugs, an indispensable first step will be to obtain scientific information on the quality of these actions. Scientific data on the pharmacological products used for diarrhoea have been appearing in the literature since the 1930s, and during the last three decades many studies have been carried out. Unfortunately, the majority of these reports are not easily available to national CDD programme managers or drug regulatory authorities. In response to the many requests from countries, the WHO CDD Programme decided to review all the available literature on the efficacy and side-effects of the most commonly used anti-diarrhoeals and antimicrobials. Experts from all over the world reviewed the resulting report, which has just been issued as a WHO publication "The rational use of drugs in the management of acute diarrhoea in children". (See also Published Lately).

The book contains an introductory chapter on the correct case management of diarrhoea in children and reviews nine of the most commonly used anti-diarrhoeal drugs, grouped into three categories: antimotility drugs, antimicrobial agents, and absorbents (Table 1). A similar conclusion is reached for each of the nine products: There is no rationale for the production and use of any of these products for the management of acute diarrhoea in children.

What next?

The information in this new publication should be made widely available to policy makers, health professionals, health educators, and trainers of doctors, nurses, pharmacists, and other health staff. In addition, CDD programmes are to develop teaching materials that account for the current situation in case management of diarrhoea in children, to the design and implementation of educational, managerial and regulatory activities.

Source: WHO Division of Diarrhoea and Acute Respiratory Disease Control.

Table 1. Table of products reviewed

<table>
<thead>
<tr>
<th>Antidiarrhoeal Drugs</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No evidence that it alters the course of acute diarrhoea, or that it diminishes the losses of fluids. Central nervous system toxicity may occur in therapeutic doses, and bactillary dysentery may be aggravated.</td>
</tr>
<tr>
<td>Loperamide</td>
<td>No evidence that it diminishes the losses of fluids or electrolytes when administered in conventional doses. Adverse effects on the central nervous system have been observed in therapeutic doses. Paralytic ileus has been associated with its use in infants and children.</td>
</tr>
<tr>
<td></td>
<td>No proven value in the treatment of diarrhoea; may actually increase the severity or duration of diarrhoea. Promotes resistance to antimicrobial agents.</td>
</tr>
<tr>
<td>Hydroxyquinolines</td>
<td>Have not been shown to be effective for routine treatment of diarrhoea. Have been associated with severe neurological disorders.</td>
</tr>
<tr>
<td>Nonabsorbable sulfonamides</td>
<td>Lack of efficacy in the treatment of <em>Shigella</em> dysentery or other intestinal infections. There is concern about their toxicity.</td>
</tr>
</tbody>
</table>

References:

I RATIONAL USE

Drug supply by ration kits: report of an evaluation

O N E method which has been tried to improve drug supply to rural facilities in developing countries has been to pack drugs in sealed ration kits. In itself this principle is not new; army operations and emergency relief organizations have used drug kits for a long time. What is relatively new, however, is to calculate the contents in such a way as to match the regular needs of the receiving institutions. Facilities then no longer receive drugs according to their demands, but according to their estimated workload. The aim of the system is to supply as precisely as possible and in appropriate quantities, only those drugs that are needed, thus avoiding both shortages and waste. A second objective is to promote more rational prescribing by means of a "forced" selection of essential drugs, in a list that would prevent overprescribing.

In 1988 and 1989 the WHO Action Programme on Essential Drugs carried out an evaluation of the kit system in developing countries, and the report has just been published. The evaluation is based on an analysis of all published and unpublished literature, country reports, working papers, questionnaires sent to the 12 national programmes that use (d) ration kits, and interviews with key people. The report, which contains summaries of the various country programmes, descriptions of the kits (selection and quantities), much statistical data and a comprehensive bibliography, is available from the Action Programme on Essential Drugs on request. Only the main conclusions are highlighted here.

Advantages of drug ration kits

Availability of essential drugs

The greatly improved availability of essential drugs in rural health facilities is without any doubt the most successful result of the kit system. Practically all documents agree on this effect, which is also supported by evidence from two quantitative studies that have been carried out to measure the degree of improvement. There are various reasons for this improved availability. An important factor has been that the programmes that use the kits were actually paid for and supplied by external donors; this alone of course is enough to improve availability! However, there are also good examples of kit programmes being continued and (partially) paid for from regular governmental budgets (Democratic Yemen, Kenya).

There is no doubt that logically the kit system is much easier to handle and administer than an indent system. However, in the planning stage a careful analysis has to be made of the real needs. After that, ordering, receipt and stock control are relatively easy. Palletizing during storage and transport is more difficult and has probably diminished, although hard data are not available. Diversion to other levels of health care is rare, as it is usually very clear that the kits are specifically for rural facilities. Wastage by expiry is reduced, because the drugs in the kit are better selected, are usually stable, are frequently used and can easily be redistributed if they happen to accumulate.

Rational prescribing

The impact of the kit system on rational prescribing is not clear as very few studies have been made and these are mostly not comparable. The results from one study suggest that there was an improvement but it was not apparent whether this was due to the kit system alone, to the training programme or to both.

It is obvious that rational prescribing of drugs is not feasible if essential drugs are not available, and that the increased availability of essential drugs therefore creates the conditions under which rational prescribing becomes possible. In this respect the kit system contributes to rational prescribing, although it does not necessarily result in it.

There are several other mechanisms by which a kit system may contribute to rational prescribing. Drugs in the kits are selected by a group of experts and are supplied in reasonable quantities; very few non-essential drugs are included. This is usually quite different from the situation in which the district hospital pharmacist shares her kit (often empty) drug supply with the rural facilities. The study in Democratic Yemen proved not only that the availability of essential drugs was greatly improved by the kit system, but also that the number of non-essential drugs was reduced considerably.

This rationalization of drug selection, together with a reasonable estimation of needs, improves the availability of only the essential drugs and leaves very little room for irrational substitution by either the district supply system or the prescriber. The range of available drugs therefore rationalizes and limits the therapeutic alternatives.

The kit system alone cannot prevent the irrational prescribing of those essential drugs that are available in the kit. Reports on drug shortages of very common essential drugs (acetylsalicylic acid, penicillin, chloroquine, etc.) that seem to occur, despite sufficient quantities in the kit, suggest that overprescribing occurs. For this purpose most kit programmes include a training programme in which health workers are trained in the diagnosis and treatment of a limited list of common diseases, using treatment guidelines which are reflected in the selection of drugs in the kit. The need for such training programmes cannot be overemphasized and the review of kit programme has shown that many programmes were deficient in this respect. However, this need for training in rational prescribing is universal and is certainly not limited to kit programmes.

Kit programmes can contribute to rational prescribing in yet another way. The careful selection of essential drugs, based on the disease pattern in rural facilities and standard treatment guidelines, which is necessary in a kit programme, is an important element of training programmes for basic and in-service training, as well as of supervision guidelines. Of course, be said of successful training programmes that are not based on kit supply systems but on a careful selection of drugs alone (e.g. Zimbabwe), but the fact remains that the kit system are often coincided with, or even underlay, the standardization of training.

Quality of care

Quality of care depends on much more than kits alone and this also applies to essential drugs. In general, improving the availability of essential drugs alone leaves plenty of room for irrational prescribing, and the rational use of drugs is therefore an increasing part of essential drugs programmes and has become the second most important objective. However, rational prescribing cannot exist without a good diagnosis, and a good diagnosis is based on good history-taking and physical examination. It is therefore not surprising that many training programmes which were initiated within essential drug (supply) programmes ended up in covering diagnostic criteria and all other aspects of curative care, preventive activities and record keeping, thereby closing the gap between primary health care (PHC). A health care system without a clear national policy in which the different components of PHC have been integrated, will never succeed in the long run. The essential drugs programme can play an important role in stimulating other programmes, but it is the PHC programme and the national health policy that should ensure the integration.

It can be concluded that a good supply of essential drugs and medical items removes an important excuse for bad quality health care and exposes mercilessly any other oversights in the system, such as a lack of training, motivation and supervision. If a ration kit system is chosen for distribution, the need for a strong training programme becomes even more evident and without such training and proper supervision the quality of care may show only little improvement.

Disadvantages of kit systems

Two problems have always been regarded as serious disadvantages of the kit system: the difficulty in estimating requirements, and the inflexibility of the system (with respect to different regions and seasons as well as long lead times). Both can in fact be seen as a problem of matching need and supply. Problems in estimating the needs perceived in the field have been confirmed in evaluation reports. Initial quantification is indeed a problem as there is often a lack of data. However, all programmes reached a more or less stable kit content within a few years. There is a growing experience in other countries a stable system can be reached even faster. All programmes now agree on
There remains the problem of cost-sharing. In the one programme in which a kit system was closely linked with cost-sharing, drug problems arose with accumulating stocks of drugs that were already parochialized for the community. In principle the issues of kit supply and cost sharing are different and both can co-exist, provided the kit system is only used as a managerial tool in selecting and distributing the drugs, and that a good system is created for buying back any surplus drugs.

Conditions under which a kit system can operate

Before a kit system can operate, drugs have to be selected. This requires a list of the most common diseases that are to be diagnosed and treated at each level of health care, and a treatment guideline which includes, at least, the selection of the first-line drugs. The list of essential drugs and guidelines should also be the basis for the undergraduate training in pharmacies and for in-service training and supervision.

Funding of the drug supply will have to be secured and this requires from the government a real commitment to the needs of the rural population. This usually implies a commitment to the Health for All strategy through primary health care. The kit system should be part of a national drug policy, and in fact part of a national health policy. A solid document that describes the drug needs of the public sector and the financial implications for the government in a clear and reasonable way can be an effective support to the minister of health in securing the necessary funds.

A third condition is the presence of a well-trained and dedicated management team which is capable and willing to arrange for many different training and supervision activities.

In the early stages of the programme, the drug use pattern should be monitored very carefully, and arrangements made to adapt the kit content at relatively short notice. Shortages and surpluses need to be evaluated and corrected. A district buffer stock should be treated with a small number of drugs for emergency situations with regional variations (malaria, schistosomiasis) and for emergencies (e.g., ergotism, cholera, and other injectable drugs). After the programme staff have gained experience with the kits, a system of local packing, either by Central Medical Stores or by local manufacturers should be considered.

Under which conditions would a kit system not be suitable? Apart from the absence of the conditions described above, there are a few situations in which the kit system may be less attractive. It has been suggested that the kit system is not really necessary in areas of high population density, or, in general, in areas where the different health facilities are relatively close together (e.g., urban areas). This can even be extrapolated to situations in which transport and distribution are relatively easy and well organized. However, this argument focuses only on the logistic aspects of the kit system and ignores its effects on standardization of drug selection, supply and rational treatment.

The kits may also not be needed if there is no basic shortage of drugs in the public sector. Kits could nevertheless be useful in case of lack of management capacity or if prescription needs to be rationalized and costs need to be contained. Another specific situation occurs when there are relatively few rural clinics in comparison with the number of district hospitals, or if there are very few institutions in general (e.g., in small countries). In these cases consideration could be given to preparing individual kits for each institution.

The problem of climatic or seasonal differences should be regarded carefully before it is decided to create different types of kit. In theory the system becomes less attractive if there are too many different kits. In most programmes there is a marked tendency to reduce the number. Generally, a standard kit can be adequate if a district buffer stock is maintained with a few extra drugs. In many countries there is no difference. In such cases, the kit is used for dispensing and health centres, or between kits for health centres and hospital outpatient departments.

In four countries kits are also used for district hospitals. The core concept is usually to supply a basic range of essential drugs, mainly for use in the outpatient department (where most of the drugs are used anyway). In Uganda the hospitals receive the same kit as the peripheral health facilities. In the Nile Province in Sudan all district hospitals receive a special hospital kit with 83 drugs, plus another 31 drugs in bulk.

Limited experience so far suggests that kit systems for hospitals work well.

The final stages of the journey are often the most difficult.

Two remarks should be made. The first is that there is only one known example of kits being used for large referral hospitals. The reasons are probably that such hospitals are usually close to the distribution centre, that transport is no problem, that needs are very divergent and that many different drugs are needed. Nevertheless, the low availability of drugs in referral hospitals in some developing countries suggests that a standardized supply of basic drugs, as given to district hospitals, could be very helpful and this is exactly what has been done in Sudan. The referral hospitals have maintained the possibility to order some extra drugs, but the number of different kits was kept as low as possible.

The second point is a practical one. Many hospitals treat as many as 2-300,000 outpatients per year and need huge amounts of basic drugs (approximately 100-200 Kenyan dispensary kits

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Table 1. Types of health facilities receiving drug kits, with number of drugs per kit.

<table>
<thead>
<tr>
<th>Country</th>
<th>Village Health Worker</th>
<th>Dispensary Health Centre</th>
<th>District hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>20</td>
<td>24</td>
<td>30</td>
</tr>
<tr>
<td>Bhutan</td>
<td>20</td>
<td>24</td>
<td>40</td>
</tr>
<tr>
<td>Benin, Yemna</td>
<td>30</td>
<td>24</td>
<td>31</td>
</tr>
<tr>
<td>Guinea</td>
<td>20</td>
<td>24</td>
<td>30</td>
</tr>
<tr>
<td>Kenya</td>
<td>30</td>
<td>24</td>
<td>30</td>
</tr>
<tr>
<td>Mozambique</td>
<td>30</td>
<td>24</td>
<td>30</td>
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<tr>
<td>Sudan</td>
<td>30</td>
<td>24</td>
<td>30</td>
</tr>
<tr>
<td>Tanzania</td>
<td>30</td>
<td>24</td>
<td>30</td>
</tr>
<tr>
<td>Uganda</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Zambia</td>
<td>30</td>
<td>24</td>
<td>30</td>
</tr>
</tbody>
</table>
RATIONAL USE

per year). With such quantities it is not very practical to distribute the drugs in relatively small kits: bulk supply is more logical. However, a standardized supply system can be used with a limited supply list and quantities calculated "on paper" which do not necessarily have to be packed in a kit. This is done in Democratic Yemen and Sudan.

With regard to the sustainability of the kit system, the most important problem is funding. Most drug supply programmes that were started with outside financial support have faced difficulties when donor funding was to be replaced by government financing. Nevertheless good examples exist of government which have successfully implemented kit programmes from their own resources (Democratic Yemen, Kenya).

A kit system does not have to be continued forever and several alternative solutions can replace it after a number of years. A simple kit system for standard drugs can be used together with an increasing number of extra drugs from a district buffer stock; the allocation of drugs can be done "on paper" without physically packing the drugs in a kit (e.g. for large health centres or hospitals); larger institutions can receive individual kits. Each system can be very successful, provided that the operation of the kit system for the rural facilities has first achieved recognition of their basic needs.

In summary, drug ration kits can be a very useful logistic tool in situations of scarcity, in situations in which adequate drug supply management at the central and district level is lacking, or when communications and transport are difficult. Kits are particularly useful for rural health care but have also be used successfully for outpatient departments of general hospitals.

A balance between advantages and disadvantages

The potential benefits of a kit system can be summarized as follows: Availability of carefully selected essential drugs is greatly improved; this has usually been combined with management support for rural drug supply, an increased awareness of the needs of the rural areas and increased confidence in the system by health workers and the public. All this together constitutes a basis on which more rational prescribing is possible; essential drugs are available, there is little room for substitution by either the supply system or the prescriber, and standardized training and supervision can be established.

Problems of estimating needs, regional differences and accumulating surpluses are mostly temporary and have usually been corrected within the first two years of a programme. Problems with funding for rural drug supply and the actual training in rational prescribing are not limited to kit systems and are rather part of an essential drugs programme in general. The only typical problems is the somewhat difficult but not impossible combination of kit systems and cost-sharing.

In the field questionnaire the respondents were asked whether in their opinion the advantages of the kit system outweighed the disadvantages, and all answered a wholehearted "yes" to this question. One respondent wrote: "A drug kit system is already a success the moment the drug kits arrive in the health facilities. The continuous availability of a certain number of drugs in, let's presume, sufficient quantities is an improvement of 200% because most of the time the number and quantities of drugs are supplied arbitrarily."

On the other hand there are two programmes in which the kit supply system was discontinued, which indicates that the balance can be otherwise. In both cases the situation was special. In Somalia the kit was wrongly designed and probably not based on a proper analysis of local needs; it was one of the early kit programmes and the problem would nowadays probably not have happened. In the NGO project in Benin the kit system was stopped because the programme covered only a small and densely populated area with a good distribution system and strong expatriate management support; the use of kits was therefore not considered necessary but this situation is not generally applicable.

It can be concluded that the kit system offers an adequate solution to a logistic problem, and creates the conditions under which other components of an essential drugs programme, and especially training in rational prescribing, can be pursued. A kit programme may be part of an essential drugs programme but cannot replace it.

Table 2. 21 drugs most frequently included in drug ration kits, in descending order of frequency

<table>
<thead>
<tr>
<th>Acetylsalicylic acid, tabs 300 mg</th>
<th>Paracetamol, tabs 500 mg</th>
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</thead>
<tbody>
<tr>
<td>Procaine penicillin, inj. 3-4 MU</td>
<td>Ferrus salt (plus folic acid), 60/0.25 mg</td>
</tr>
<tr>
<td>Gentian violet, powder 25 g</td>
<td>Tetracycline eye ointment, tube 5 g</td>
</tr>
<tr>
<td>Aluminium hydroxyde, tabs 500 mg</td>
<td>Chlorocrocine, tabs 100-150 mg base</td>
</tr>
<tr>
<td>Lidocin 1.2 %, inj., 20-50 ml</td>
<td>Phenytoin sodium, tabs 500 mg</td>
</tr>
<tr>
<td>Ephedrine, inj. 1 mg</td>
<td>Ergotrin, inj. 0.2 mg</td>
</tr>
<tr>
<td>Mecamylamine, tabs 200-250 mg</td>
<td>Corintrimoxazol, tabs 400/80 mg</td>
</tr>
<tr>
<td>Benzylpenicil, sol. 35 %, 1 lit</td>
<td>Chlorhexidina, ointment, sol (ml)</td>
</tr>
<tr>
<td>Diacepan, inj. 10 mg</td>
<td></td>
</tr>
</tbody>
</table>

References


More on rice-based ORS for children with diarrhea

The report of research findings on rice-based ORS (Essential Drugs Monitor, No, 10, 1990) summarized findings from several clinical trials comparing standard ORS that contains glucose (20 g/litre) with an ORS in which glucose was replaced by cooked rice-powder (50-80 g/litre). The principal findings were that both stool output and duration of diarrhoea were less in patients given rice-based ORS. This effect was much greater in infants with cholera (stool output during the first 24 hours of treatment was reduced by 33%) than in children with acute non-cholera diarrhoea (first 24 hours stool output reduced by 17%).

Based on these and other findings, WHO recommends that rice-based ORS could be used to treat cholera patients. However, further research is needed before its use could be recommended in children with acute non-cholera diarrhoea. This research should determine: (i) the effect of rice-based ORS on stool output during the entire course of diarrheal episodes, not just the first 24 hours; (ii) whether a similar effect can be achieved by giving standard ORS with boiled rice and other recommended foods; and (iii) whether rice-based ORS is both safe and effective in infants below 4 months of age or severely malnourished. When this information is available, it would be possible to determine whether the advantage of rice-based ORS is sufficiently great to justify the substantial cost and effort required to replace glucose-based ORS as the global standard for children with acute non-cholera diarrhoea.
TRADITIONAL MEDICINE

Medicinal plants and primary health care: Part 2*

TRANSFER OF TECHNOLOGY

The WHO Programme on Traditional Medicine is now part of the WHO's global programme concerned with drug management and policies. Perhaps the key reasons for this move are, first, the recognition of the importance of plants as sources of products of medicinal value and, second, the recognition that an adequate technological infrastructure is required for this potential to be realised. The specific technologies needed are found in the pharmaceutical industry. Where countries are in the process of building up such an industry, the natural resources that they possess in the form of medicinal plants should be exploited to their fullest potential. Only a fraction of the world's plants has been studied. Yet from this immense reservoir of knowledge, many benefits can be derived. These include the discovery of new drugs and the development of new medicinal products.

Considerable numbers of plants that have not been studied represent a potential rich resource for the developing world to explore. This is where modern technology can play a useful role. It took several decades for the drugs previously mentioned to move from initial studies to become included in the modern pharmacopoeia. Today's technology can speed up this process tremendously.

The application of modern scientific methods in the cultivation, selection, manufacture, and clinical trials of herbal medicines is the most appropriate way to transform traditional trade into modern industrial practice. In this connection, the Chinese and Japanese, who have been leaders in this field, can provide useful examples of how such methods can be applied.

One example of a successful application of this approach is the use of modern technology in the development of new drugs from plant species. This approach has been particularly successful in the development of new anti-tuberculosis drugs.

International Cooperation

At the 1987 UNIDO Consultation on the Pharmaceutical Industry in 1987, WHO and UNIDO, agreed to:

- assist developing countries in conducting pharmacological and clinical trials on plant-derived products to ensure regulatory requirements for safety and quality standards;
- conduct special educational programmes to publicize the proper use of plant-derived herbal medicine;
- undertake consultations at the national level on the development of traditional medicinal plants, with special emphasis on quality standards and safety;
- provide a view to promoting the wider use and acceptability of herbal medicines.

As a follow-up to the recommendations made at this consultation, a UNIDO Workshop on Cooperation among Developing Countries on the Development of the Pharmaceutical Industry was held (New Delhi, 1990) to consider the industrial use of medicinal plants, including herbal remedies, and ways to promote technical cooperation among developing countries for the development of the plant-derived pharmaceutical industry.

The need for national policies and regulation on herbal remedies or traditional medicines, as well as quality standards and information, was also taken up by the Fifth International Conference of Drug Regulatory Authorities (ICDRA) (Paris, 1989) in a workshop on the subject. This was followed up by a series of meetings and consultations to draw up guidelines for adaptation by countries.

The WHO TRADITIONAL MEDICINE PROGRAMME

Making full and proper use of their traditional systems of medicine represents an important step for countries that are attempting to improve the health of their people. WHO's Programme on Traditional Medicine collaborates closely with countries in this work in areas ranging from national programme development, research, education and training, to information exchange.

National Programme Development

WHO collaborates with Member States in the review of national policies, legislation and decisions on the nature and extent of the use of traditional medicine in their health systems. This includes assisting ministries of health in establishing mechanisms for the introduction of traditional remedies into primary health care programmes, in assessing safety and efficacy, and in ensuring adequate supplies of raw and processed materials and quality control.

Safety should be the overriding criterion in the selection of herbal medicines for use in the health service system. Different procedures for screening, chemical analyses, clinical trials and regulatory measures should be applied to the various groups of products, namely: whole or parts of plants; crude extracts; or pure phytochemicals.
TRADITIONAL MEDICINE

Whereas a less stringent procedure could be applied to the first two groups, the procedure applied to the last group should be identical to that for synthetic drugs. In addition to the need for dosage and control, there is also occasionally the need for reference substances. Until they can be made available, WHO has appointed national laboratories, of which the WHO will assist in identifying national laboratories which could supply samples of natural substances to be used for reference purposes.

The Programme also collaborates with a wide range of non-governmental organizations. For example, it is working with the World Federation of Proprietary Medicine Manufacturers (WFPM) to assist in the development of pharmaceuticals and medicinal plants. This is an important step in supporting the industry, especially developing ones, to reduce the heavy economic burden of providing essential drugs for their population.

There are also 27 WHO collaborating centres for traditional medicine: five in the African Region; three in the Region of the Americas; one in the Eastern Mediterranean Region; three in the European Region; three in the South-East Asia Region, and twelve in the Western Pacific Region. The meeting of Directors of WHO Collaborating Centres for Traditional Medicine (Berlin, 1987) recommended that a concerted effort be made to orient research efforts and studies to provide solutions to public health problems, particularly at the primary health care level.

Collaboration was also the focus of a WHO sponsored meeting of experts from developing countries on traditional medicinal plants (Arusha, 1990), which explored practical ways of strengthening overall South-South Cooperation on the national use of medicinal plants in the health services.

Research Activities

Research is a broad area of endeavour that includes health systems, clinical and scientific investigations. Health systems and operational research currently under way involve studies on the potential and limitations of the use of traditional health practitioners in primary care in district health systems; surveys of traditional medical practices; inventories of medicinal plants and other natural substances used; and comparative studies of modern and traditional medicine to weigh their respective advantages, clinical and economic, and the cultural acceptability of the two systems.

Clinical and scientific investigations as rigorous as those required for modern medicine are also needed. National establishments engaged in research on traditional medicine are being identified and contacted by WHO. Within the context of an overall health research strategy, WHO encourages research to investigate the safety and efficacy of many of the remedies used by traditional health practitioners.

For viral diseases or syndromes, such as AIDS, for which no vaccines are available, therapeutic agents capable of selectively blocking the replication cycle of the virus are clearly needed. One recent initiative is the Traditional Medicine Programme which is the investigation of traditional medicinal plants considered to have anti-viral properties or activity against opportunistic infections occurring in patients with AIDS. Two American scientists have demonstrated an anti-HIV or anti-reverse transcriptase activity in vitro; for example, castanospermicin, derived from the Australian chestnut tree, and glyzericin, derived from liquorice. Such natural products have been tested in limited clinical trials in some countries. A meeting was organized (Geneva, 1989) in collaboration with the biomedical research unit of the WHO Global Programme on AIDS, to consider the systematic and scientific assessment of samples which represent a high "hit-rate". Considering the initial project goal of collecting 300 samples by the end of 1990, a projected total of some 11 to 12 active plant species can be expected to serve as candidates for biosynthetic directed fractionation and eventual isolation of active principles. It is WHO's policy to ensure that the benefits from the development of drugs as a result of such collaborative efforts are, as far as possible, made widely available on an equitable basis.

As a further step in the collaboration between the Traditional Medicine Programme and the Global Programme on AIDS, a joint meeting on Traditional Medicine and AIDS: Clinical Evaluation of Traditional Medicines and Natural Products was held in Geneva in September 1990. The meeting elaborated guidelines and protocols for the clinical evaluation of safety and efficacy of traditional remedies. The protocols will provide guidance for the conduct of clinical studies on medicinal plants and serve as a framework for the comparison of clinical trial results within and between regions.

Information dissemination

Finally, the exchange of information is a vital role that WHO plays not only in traditional medicine but also in virtually every aspect of public health. The International Traditional Medicine Newsletter, published by the Chicago Collaborating Centre gives individuals and institutions the means of exchanging information and of keeping in touch with developments in other parts of the world. This newsletter is also being developed and maintained a computerized database, Natural Product ALERT (NAPALERT) including data on properties of natural products which includes ethnomedical, pharmacological and phycological profiles. Information is available on request and, in the case of developing countries, without charge. This centralized, computerized service makes possible a great saving of time, effort and financial resources.

In 1990, WHO participated in the International Garden and Greenery Exposition in Osaka, Japan. A herb garden was formed as part of the display based on the theme of medicinal plant cultivation and conservation in their natural habitats, in accordance with the Chiang Mai Declaration, "Saving lives by saving plants." A booklet describing the plants in the garden and their medicinal and culinary properties were available for visitors and to the general public.

In recent years there has been a surge of public interest in the use of traditional remedies and alternative medicines. The public has received extensive coverage in the press and has published some ethno- botanical and unverified, and some even dangerous. Therefore, ensuring safety in the
Monitoring Drug Quality in the Caribbean

Patience A. Dennis

Quality control, an essential element in drug manufacturing.

A n important responsibility of the health authorities of the Region is to provide a basic supply of good quality pharmaceuticals that are safe and effective. In 1970 a meeting of the ministers with responsibility for health in the English-speaking Caribbean requested the Pan American Health Organization (PAHO) carry out a study to determine the feasibility of establishing a drug testing laboratory for the Caribbean. Arising out of the PAHO recommendations, and with the assistance of PAHO and the Canadian International Development Agency (CIDA), the Caribbean Regional Drug Testing Laboratory was established in 1980 and located in Jamaica. Its purpose was and still is to provide the Region with an efficient, well-equipped institution to monitor the quality of pharmaceuticals used in the region, both those imported and those produced locally.

The Laboratory's work is funded by contributions from the governments of the 14 participating territories in a ratio based on population. The Government Chemist of Jamaica serves as its Director and is advised on all operational aspects by a Technical Advisory Committee. Initially the work load of the Laboratory was minimal. Since 1986/7, however, there has been a sharp increase in the volume of samples sent for analysis to the Laboratory and a significant improvement in the Laboratory's response-time.

The production of good quality drug products includes considerations of identity, purity, potency, dose uniformity, stability, safety and efficacy. The standards of purity required for pharmaceutical chemicals are determined by several factors which take into account impurities likely to arise as a result of all known methods of manufacture; impurities which may be toxic, those which may interfere with the intended use of the product and the required stability of the drug. Carribean standards also guard against the possibility of accidental contamination or deliberate adulteration. Standards set allowable limits of tolerance for the chemicals and form the basis for verifying the quality of the finished product. The amount of active ingredient and the uniformity of the dosage unit are important in studies of efficacy and safety of the product and determine its usefulness in treatment, particularly of chronic diseases.

Inadequate care in storage or unsuitable storage conditions may cause the decomposition and loss of potency of some products, particularly those having temperature requirements for storage. Even when correctly manufactured, formulated, packaged and stored, drugs can undergo some physical and chemical changes as a consequence of exposure to moisture, light or other radiation, atmospheric oxygen and micro-organisms. It is important, therefore, to verify that products maintain their pharmaceutical quality for a reasonable time.

The evaluation of efficacy poses several problems for the drug control agency as factors such as genetic variation which affect enzyme activity normally cause varying results. The concentration of a drug delivered to the tissues and the period of time during which the concentration is maintained is referred to as its bioavailability. Some drugs such as digoxin, phenytion, warfarin and tetracycline are known to have problems of bioavailability. Different preparations of these drugs may contain the same labelled amount of active ingredient but may vary in bioavailability. Dissolution and disintegration tests are used as surrogate tests for bioavailability.

Roughly 7-8% of all analyses done from 1987 to 1989 yielded unsatisfactory results. Some arose as part of a territory's routine checks on stocks. During 1987/89 these tests represented 20% of products which failed to meet compendial standards. In 1988/89, 12% of products were unsatisfactory, and in 1989/90 20% of the products analysed did not meet the pharmacopeial limits. The explanations for these high percentages were various and include the fact that some products had passed their expiry dates. A few samples were submitted because of obvious discoloration and others as a result of physical complaints. During 1989/90 40% of aspirin samples analysed, 27% of furazolidone samples and 40% of paracetamol samples submitted to the Laboratory failed to meet compendial standards. This sort of information generated by the Laboratory is used by the Technical Advisory Committee to develop the surveillance schedule that is circulated to the responsible persons in each territory. This schedule is part of the Laboratory's work plan for each year. Its purpose is to allow for the most efficient use of the analysts' time, reduce costs, maintain, and ensure an ongoing evaluation of the product from the manuacturer, sources and storage conditions as possible. The territories' own priorities and problem samples are, of course, given priority over the samples for surveillance.

The results of the Laboratory's work have significant implications for drug quality control and procurement in the region.

* My P.A. Dennis is Director of the Caribbean Regional Drug Testing Laboratory

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Part 1 of this article appeared in EMDT-10.

This clear, authoritative, objective and evidence-based reference provides information essential to those concerned with improving the rational use of drugs in the management of acute diarrhoeas in infants and young children and with tackling the immense problems posed by the prescribing of clinically useless and potentially dangerous drugs. Noting that diarrhoeal diseases continue to claim some 4 million young lives each year, the book gathers the information needed to argue against the widespread use of medicines that have not established clinical benefits, are frequently harmful, and - most importantly - may delay or replace effective treatment measures. The book also responds to the problem of antibiotic resistance and the corresponding need for unnecessary widespread use of antimicrobial medications.

Drugs judged effective are dealt with concisely in a table listing four first-choice antimicrobials, and six alternatives in general use. In the management of cholera, shigellosis, dysentery, amoebiasis, and giardiasis, apart from these cases of specific etiology, readers are informed that antidiarrheal drugs and antidiarrheals should never be used for children, as none has proven practical value and some are frankly dangerous.

The statement is then substantiated through a thorough review of data on antidiarrheal drugs widely used in paediatric practice. These include two antimitotic drugs (diphenoxylate hydrochloride and loperamide), four antimicrobial agents (neomycin, streptomycin, oxolinic acid and nonabsorbable sulfonamides), and five adsorbants (kaolin, attapulgite and activated charcoal).

For each, the book provides a critical presentation of experimental and clinical data on pharmacology, mechanism of action, efficacy, adverse effects and use. Critical is for evaluating efficacy and cost the ability to reduce stool volume and electrically neutralize toxins.

On the basis of this review, the book concludes that none of these preparations has any documented benefit, and some actually prolong diarrhoea, and others have been shown to produce severe and, in some cases, fatal side-effects. The book further concludes that the continued production, promotion and sale of these preparations for paediatric practice cannot be justified.

Backed by officials in the WHO Diarrhoeal Disease Control Programme, and checked for accuracy by an international group of experts, the book presents information of vital importance to the sound and effective management of diarrhoea in children. Its clear and authoritative advice should prove useful to paediatricians, pharmacists, and other health workers, doctors and nurses, as well as to officials in national diarrhoeal disease control programmes.


This document is a first attempt to provide an analytical framework for public health planners and administrators of endemic countries:

1. to determine estimates of the prevalence of schistosomiasis
2. to determine the quantity of praziquantel needed to treat all infected persons with a single dose
3. to propose a basis for long-term calculations of praziquantel in endemic countries. It emphasizes the limitations of current methodology and available data to calculate both the prevalence of schistosomiasis to supplement the requirements of a single drug such as praziquantel.


The book closes on an optimistic note: "The opportunities are there!" It says, "It is a challenging, but exciting, prospect, and there will be deviations along the path on all sides. However, the benefits of the changes that could occur offer comfort, that, if not before year 2000, then at least sometime in the not-too-distant future, there can be a healthy pharmacological industry to support the existing with a world population that has access to health for all."
The main part of the manual presents model training material organized to complement the three main strategies for drug misuse prevention: treatment, education and community interventions. The book includes a sample full colour teaching poster accompanied by a set of questions intended to test understanding and stimulate discussion. A final chapter assembles basic facts and practical information about the disease itself, the parasite, modern diagnostic tests and their cost, and the new drugs that have made treatment safer and more effective.

Any health worker familiar with the contents of this manual will be in a good position to explore community attitudes, find ways to communicate messages, and develop locally acceptable lines of action that can contribute greatly to the control of schistosomiasis.

Available in English (French and Spanish in preparation) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price Sw.Fr.11.-/US$18.80, and in developing countries Sw.fr.7.70.


This book provides model prescribing information for some 33 essential drugs used for the prevention and treatment of protozoal and helminthic infections, including filariasis, malaria, leishmaniasis, schistosomiasis and the trypanosomiases. The book is the result of a cooperative production involving internationally accredited experts, WHO's Expert Advisory Panel on Drug Evaluation, selected members of the various WHO expert advisory panels on parasitic diseases and several non-governmental organizations.

The contents are organized according to diseases, moving from amoebiasis and giardiasis to intestinal, liver and lung flukes. Each disease or group of diseases is first introduced with concise information about its causes, modes of transmission, clinical features, and geographical prevalence, followed by general advice on prevention and treatment. Prescribing information is then provided for first-choice and alternative therapeutic and prophylactic drugs. Information includes uses, dosage and administration, contraindications and precautions, use in pregnancy, adverse effects, drug interactions, and advice on storage. Some rare parasitic diseases such as rhinosporidiosis, leishmaniasis and onchocerciasis are discussed. The book concludes with a discussion paper on a new drug policy for Peru. A copy of the sixth revision of WHO's Model List of Essential Drugs is also included.

Peru's approach is a good example of how to achieve an effective start in designing a rational use of drugs strategy by drawing on all available national resources. The book could be a valuable source of ideas and information to any essential drugs programme beginning to strengthen activities in this area, although the language (Spanish) might limit its use to the Spanish-speaking parts of the world. Available in Spanish only from: PAHO/WHO, Casilla 2117, Lima 100, Peru.


Since the foundation of Groningen University's School of Pharmacy, many questions have been asked by pharmacists working in developing countries concerning the state of drug development in tropical countries and this area has become a focus of investigation by the Science Shop.

The present publication is one of a number of reports concerning the use of drugs in developing countries and arose from the results of an inquiry into problems concerning the production, distribution and stability of drugs in the tropics. As a result of this inquiry a study was set up to develop tablet formulations particularly suitable for use in tropical countries. The results were applied to develop standard tablet formulations which are based on native excipients and which are physically and microbiologically stable.

The book provides an introduction into the influence of tropical diseases on tablet stability and then presents standard tablet formulations suitable for use in such.

MAC approves US$24 million DAP budget

The Action Programme on Essential Drugs’ Management Advisory Committee (MAC) met for the third time in Geneva on 19-20 February 1991. Over 50 participants representing 26 countries, other international organizations and non-governmental organizations reviewed the Programme’s accomplishments during 1990 and discussed future directions.

Programme Manager, Dr Fernando Anzana, told the meeting that increasing numbers of men and women are not only acquiring knowledge and expertise in the area of essential drugs but are also showing the desire to participate in working towards more rational drug use and management. DAP itself has adopted a conceptual framework for its priorities and approaches, in each case tailored to individual countries’ needs and circumstances. Country support, as planned, had received the main thrust of attention and budget allocation from the Programme, while development activities and operational research were specifically designed to strengthen country activities. Evaluation was also a key factor and the Programme was in the process of refining social and economic indicators and identifying constraints, opportunities, and gaps in the process of adopting and implementing essential drugs programmes.

The previous MAC had emphasised the importance of updating the World Drug Situation report, said Dr Anzana. In 1990 the groundwork was started on this, through surveys in 57 countries, and it was hoped that the update would be completed by the end of 1991. The Programme had strengthened its collaborative ties with a wide range of international, non-governmental and other bodies whose work included the pharmaceutical area. Particular attention had also been given to strengthening collaboration with the WHO regional offices.

The Programme Manager concluded by stressing the vital leadership role he saw for the Action Programme not only because of WHO’s international health mandate but also because of the crucial role that essential drugs play in any health service. “We are committed to the principles of ‘essential drugs’, he said “and therefore leadership and advocacy will continue to be fundamental pillars in the process of building stronger, sustainable national programmes on essential drugs.”

In the course of the two day meeting, participants reaffirmed their recognition of the Programme’s importance in building health for all strategy and praised its achievements during the year. The MAC approved a budget for the 1990-91 biennium of approximately US$24 million: calculated to maintain the current level of expenditures adjusted for increased costs.

Next year’s meeting will take place in Geneva on 25-27 February 1992 and will include technical discussions on themes such as rational use, defining research policies, setting up drug indicators at country level, and the expansion of activities in the African Region.

Zambia’s Essential Drugs Programme is targeting the rational use of drugs with two new information and education initiatives. The first is a quarterly newsletter, launched in October 1990, and covering a wide range of drug management and prescribing issues. The second is a very clear and comprehensive manual for health workers on the management and use of drugs in primary health care. The manual is divided into three sections. The first provides prescribing information on 34 essential drugs covering pharmacological action, dosage, storage, uses, side-effects, precautions and contraindications, and important but often omitted from such manuals, information for the patient. The second section covers the management of drug supplies: how to get, look after and organize supplies. It emphasizes the use of stock control cards to record the movement of drug supplies and enable health workers to keep proper monthly stock records. The final section is on clinical diagnosis and treatment. This stresses the importance of taking a full patient history, conducting a physical examination, carrying out some investigations, and principles of rational drug use. It also describes some common major diseases and provides treatment guidelines.

Generic drugs meet purity and quality standards announces FDA

In tests of more than 400 drug samples, the Food and Drug Administration announced that it has found that virtually all “narrow therapeutic range” generic and brand name drugs meet applicable standards of purity and quality. The agency tested these samples of generic and branded versions of 24 kinds of drugs, for which quality specifications are generally considered to be critical, and found only one drug product made by two firms that showed minor deviations from acceptable limits. The 24 drugs are prescribed for such uses as contraception, epilepsy, infections, high blood pressure and asthma. Narrow therapeutic range drugs have the potential to be ineffective and possibly harmful if they don’t deliver the labeled amount of the active ingredient within narrow limits. Most other drugs have much wider margins for safety and effectiveness.

All met the required quality standards except five batches of aminophylline tablets from two manufacturers which were found to contain incorrect amounts of a necessary stabilizing ingredient, the deficiency did not pose a health hazard. Nevertheless the manufacturers have recalled the five lots.

“These results should be reassuring to consumers who use generic drugs,” HHS Secretary Louis W. Sullivan, M.D., said, “since the drugs that were examined are the kind that critics of generics are most likely to claim could cause problems.”