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DRUG SELECTION, A WAY TO BETTER THERAPY?*

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Action Programme on Essential Drugs

ABSTRACT

In developing countries with a limited health care budget, scarce foreign exchange, and often lack of organized drug supply and manpower, the selection of essential drugs, their availability and affordability should be based on a national drug policy linked to health care needs. A limited list of essential drugs may not provide for the needs of every person, but should meet those of the vast majority. The concept of essential drugs, formularies, therapeutic committees, and educational and training programmes are discussed. Examples are given of essential drug programmes in Rwanda and Kenya, where monitoring and evaluation of the programmes and the education of professionals and public are necessary ingredients for success.

The advantages of an essential drug programme are: (1) reduction in number of pharmaceutical products to be purchased, stored, analyzed, and distributed; (2) improvement in the quality of drug use, management, information, and monitoring.

Key Words: *Developing countries; Drug formularies; Drug selection; Essential drugs; Essential drug programmes; World Health Organization.*

Introduction

Effective and safe drugs are indispensable for good health care. However, the availability of drugs for prevention and treatment in the developed countries is not necessarily governed by need, but rather by demand. The discrepancy between need and availability becomes critical in developing countries where limited financial resources are strained or unable to cope with the immediate basic requirements of the population.

To illustrate this last point, let me quote verbatim from a Chief Medical Officer's letter written to WHO in 1974 entitled "Towards a rational drug supply for developing countries". I quote: "our latest indent is 105 % more expensive than last year's. I need hardly say that this completely makes nonsense of our financial estimates and my Government cannot, in the near future, double the money allocated for medicines."

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Drug selection — what does it mean and where does it take place?

At a *national* level, it is generally a country's drug laws and medical-economic conditions which determine the selection of the drug products to be approved by the authorities for marketing. While one country may have up to 3 000 different active principles registered under 30 000 dosage forms, [1] including strengths and packages, another limits its choice to 2 000 product dosage forms and 800 active ingredients. There are countries where new drug products qualify for registration only if they satisfy a defined medical need in addition to approved standards of quality, efficacy and safety [2]. At the other end of the spectrum, most developing countries have no registration standards or evaluation procedures at all, nor do the authorities know what drugs are available in the country [3].

Therapeutic committes and formularies have been introduced in *hospitals* in many developed countries, not only for economic but also for medical reasons, namely to monitor and evaluate several aspects of drug use [4]. In these developed countries drug formularies recommend or guide in selection; in developing countries, where economic constraints are much more severe, access to drugs more difficult and drug supply systems inadequate, the drug lists or formularies may have to play a stricter role.

In the selection or choice of drugs, the ultimate decision lies with the *doctor*. The most important element in his/her decision to prescribe is the disease to be treated in a given patient. Beyond this, however, the prescriber is influenced by a variety of factors, such as his/her medical training, the setting of the medical practise (whether it is private or in a hospital), local prescribing traditions and habits, economic conditions, the country's health policy (reimbursement schemes, information, distribution etc.), the influence of the drug industry (advertising, compendia etc.) and these factors are not necessarily listed in their order of importance.

Which drugs should be selected?

Because of the great differences between countries a drug list of uniform, general applicability and acceptability is not feasible or possible. A list of essential drugs does not imply that no other drugs are useful but simply that, in a given situation, these drugs are the most needed. Each country has the direct responsibility to evaluate and adopt its own list of essential drugs, according to its own health policy. Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from adequate clinical studies and for which evidence of post marketing performance in general use have been obtained. Each selected drug must be available in a form which assures adequate quality, including bioavailability. The stability of the product under the anticipated conditions of storage and use must also be established [5, 6].

Further criteria for selection are:
- relevance to diseases treated at different levels of health care or facility,
- relevance to the level of training of the health workers,
- medical importance/need,
- therapeutic effectiveness,
- safety of the drug,
- cost of treatment,
- safety in dispensing, (i.e. administration: tablet versus injectable)
- drug expiry date,
- usability against more than one disease/condition,
- how easy for patient to take,
- how easy for staff to dispense,
- whether it is locally produced.

WHO's involvement in drug selection

The idea of essential drugs was conceived by WHO, i.e. the Member States, during the past few years and forms one of the basic components of primary health care. The availability of essential drugs for local health care is one of the indicators used to measure the progress towards attaining the goal of health for all by the year 2000.

The concept evolved from the fact that three quarters of the world's population live in the developing world and use only about 15 percent of the world's drug production; and the vast majority of these people have no access at all to the most essential drugs [7]. The main reasons for this anomaly are the lack of national drug policies, inadequate distribution and supply systems, shortage of technical and managerial expertise and lack of money both by the individual and the Government. To

these must be added limited knowledge and wrong ideas about the need for and proper use of drugs, both among health workers and the public at large. Such wrong ideas derive from lack of objective information on both therapeutic indications and side-effects of drugs [8]. In such situations, drug selection, is not only a way to better therapy but perhaps the only way to therapy.

The evolution of WHO Essential Drug Programme can be summed up as follows:

1975
The Director-General's report outlines possible new drug policies, refers to clearly implemented schemes of basic or essential drugs, emphasizes the need to extend accessibility of the most necessary drugs;

The World Health Assembly (WHA) passes a resolution (WHA.28.66) on the selection and procurement of essential drugs, stressing the need for developing drug policies, linking drug research, production and distribution with real health needs;

1975—76
Information gathered on selected drug lists from all over the world. At WHO a Unit of Drug Policies and Management is created;

The first working documents prepared in May—June 1976 including background and criteria for drug selection, administrative aspects, etc. This working document is circulated to WHO Regional Offices for comments;

1976—77
Informal consultation and selection of essential drugs, document DPM/76.1, containing background and a model list of essential drugs, circulated for comments to WHO Regional Offices, Member States, Universities, WHO Expert Panel Members and nongovernmental Organizations;

Working papers (DPM/WP/1, 2, 3), 1977, are prepared as background for;

The first WHO Expert Committee, 1977, on the selection of essential drugs, WHO Technical Report Series (TRS) 615, including criteria for selection and a model list [5];

1978
The WHO Executive Board, and the WHA passed resolutions (EB61.R17, WHA31.32) requesting the Director General to initiate an Action Programme on Essential Drugs;

1979
WHA resolution (WHA32.41) requests the Director-General to initiate and establish a special programme on essential drugs, including its administrative structure.

Second Expert Committee on Essential Drugs TRS 641. Updating and revision of model list [5];

1981
WHO establishes an Action Programme on Essential Drugs in February 1981 in conformity with a number of resolutions of the Executive Board and the WHA;

1982
A progress report and situation analysis (A35/7) was submitted to the 35th WHA by the Executive Board Ad Hoc Committee on Drug Policies on behalf of the Executive Board [8]. It says, *inter alia*, that:

- a few countries have formulated national drug policies;
- more than 70 countries have developed lists of essential drugs, for the public sector, based on the WHO model lists;
- others have started quantification of drug needs and development of supply and distribution systems;
- more than 30 country studies were undertaken at the request of WHO Member States and carried out jointly by national experts and WHO staff in the countries and regional offices concerned and from Headquarters; in four countries, experts from the pharmaceutical industry participated.

It includes proposals for a plan of action to implement the WHO Action Programme on Essential Drugs.

1982
Third Expert Committee on the use of Essential Drugs, TRS 685 [6]; Updating and revision of the model list and inclusion of a model list of drugs for primary health care. Expert Committee advised that drug information sheets for doctors, prepared in draft form in response to a recommendation in the first report of the Expert Committee on the selection of essential drugs, be subjected to broad consultation and subsequently issued together with general advice on therapeutic matters in a WHO formulary. Outline of the content of these sheets included.

1983
Implementation of the WHO Action Programme on Essential Drugs, which is a worldwide

collaborative programme between Member States, WHO, UNICEF, other organizations of the United Nations system, the pharmaceutical industry and other institutions both public and private. Its objective is to ensure the regular supply of safe and effective drugs of acceptable quality at lowest possible cost to all in need through health systems based on primary health care.

Examples of application

Having made these general remarks on drug selection and having presented the road to and the background of the WHO Action Programme on Essential Drugs, allow me to elaborate some problems that currently exist in developing countries. To illustrate these, I have chosen two concrete examples (both African countries): one is Rwanda and the other Kenya.

Rwanda. In 1982, WHO held a workshop on Health and Drugs in this country, attended by high level officials from the Ministry of Health, and other Ministries involved with the problem of supplies of pharmaceuticals, i.e. the Ministry of Finance and the Ministry of Trade [9, 10].

The following problems were identified concerning acquisition, distribution and usage of drugs.

- Meagre resources to treat a large population;
- Tradition to use medicines instead of emphasizing hygiene and nutrition;
- Mediocre health care in spite of a relatively large number of medically trained personnel;
- Indiscriminate prescribing often resulting in more harm than good;
- Inequality in distribution between urban and rural areas, to the disadvantage of the latter;
- Insufficient control at the port of entry of medicines;
- Lack of quality control of medicines;
- Proliferation of a wide variety of pharmaceutical products under different names in the private sector and a lack of objective drug information;
- Poor compliance with existing regulations regarding sale and distribution of prescription medicines;
- Periodic shortage of stocks in the central medical stores;
- Very limited possibilities for the rural population to buy medicines in the private pharmacies when the public sector stock is insufficient;
- Deterioration and loss of medicines due to poor storage and handling conditions;
- Non-adherence by private pharmacies to a national list of essential drugs when they order drugs directly from abroad;
- Drugs for the different levels of health services are not allocated and distributed according to needs and levels of prescribers;
- The need of developing and implementing a national drug policy.

The list is overwhelming at first sight. Where should a country start when faced with so many shortcomings?

As a first step after the workshop, a National Drug Committee was formed in 1983 and a list of essential drugs drawn up already in 1979, but never put into effect until now, is being brought into focus and used as a starting point. Selection of drugs for each level of the health services has started and treatment standards along with a drug formulary will be prepared in the fall of 1983 with the assistance of a WHO consultant. One of the most difficult tasks will be to determine the actual therapeutic needs and estimate the quantities required by each level of the health service. Statistics are non-existent or unreliable; procurement and distribution are usually based on prescribed quantities and consumption of the previous year with just 10 % added to be on the safe side.

In a setting like Rwanda, what is better for the patient and the health workers? Is it complete freedom for selection or certain restrictions? I wish to emphasize that restrictions in this sense do not mean depriving the patients of appropriate treatment. Restrictions regarding the choice of drugs may not however be very popular among a group of physicians who, until now, have ordered or chosen the product they wanted or were used to. The need for therapeutic committees is obvious here: these committees should establish formularies in consultation with the health care workers. They should also provide objective and up to date information and advocate economic and rational prescribing under the generic names. The central role of the pharmacist is indisputable in providing guidance and information to these committees as well as in monitoring and evaluating the drugs prescribed and used in a hospital. The pharmacist can further supply suitable literature references, information on

particular dosage forms, packages, price comparisons etc.

Kenya. My second example refers to Kenya where the Ministry of Health launched a programme to improve the level of health care for the rural population of Kenya. At the initial stage, WHO provided experts to assist the essential drugs programme drawn up by a national task force. This Kenyan essential drug programme included a situation analysis, the setting up of an appropriate drug management and supply unit, a standard list of essential drugs, preparation of manuals for clinical diagnosis and management of patients, standard treatment schedules, drug ration kits (that is drugs prepacked in sealed boxes), public information on drugs, etc. Most of this latter work was done by the Ministry of Health in collaboration with the Danish International Development Agency (DANIDA) and WHO experts [10, 11].

When it came to selection of drugs in Kenya, WHO's recommendations were adapted to Kenya's morbidity pattern. 40 items were selected for health centers and 30 items for dispensaries, according to levels of mecical education of the health workers. The following weight factors were used to chose a drug:

	Weight factors
Therapeutic effectiveness	4
Safety in use	4
Safety in dispensing	3
Cost	3
Multiple usage	2
Facility to take by patient	1

The fundamental principle in the new Kenyan system is to provide rural health facilities (RHF's) with just enough, but not more, of the essential drugs needed for their patient population, based on the National Morbidity Data.

Example:
Disease incidence × (times) correct dosage = drug requirement; e.g. dispensary A has 30 cases of adult malaria per month 30 cases × 12 tablets = 360 chloroquine tablets per month.

The drugs are rationed and supplied in ration kits according to patient workload in a health centre or dispensary, that is one ration kit per 3,000 new patient attendances per month for health centres and one ration kit per 2,000 new patient attendances per month in a dispensary.

Standard treatment schedules have been prepared with the objectives of:

— better patient management,
— more effective treatment,
— rational usage,
— economy,
— safety.

Training of health workers is a very important part of the Kenya Essential Drug Programme, this includes:
— accurate clinical diagnosis,
— correct treatment/prescription,
— proper use of drugs.

After rationalising the selection and use of drugs, the procurement and quality control needed particular attention, strict specifications for quality, labelling, packaging and shipping were demanded, manufacturers and suppliers were screened and inspected. With a limited number of drugs packaged in ration kits, distribution also improved. Storage and dispensing conditions were made easier and more uniform, the drug quality, a most important component, could be more easily monitored at the various steps from manufacturing, through packaging, shipping, port clearance, transport, storage and dispensing to the patient.

As a result of these policies, Kenya's past acute drug shortage, wastage, misuse and inadequate therapeutic practises have shown considerable improvements at health centers and dispensaries. To assure continuous success, political commitment, financial support, proper quality specifications, control and monitoring plus training of health workers are necessary ingredients.

Conclusion

In conclusion I like to summarize the main advantages of drug selection and essential drug programmes in developing countries, they are:

Reduction in the number of products to be
purchased
analyzed
stored
distributed
(in other words ease in logistics)

Improvement in the standards of:
use of drugs
management
monitoring of drug usage
(to know which drugs are used where and how)

Improvement of:
information on drugs
training

Easier recognition of:
adverse reaction in populations using relatively few drugs.

I believe all these factors will help to build a road to better therapy.

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