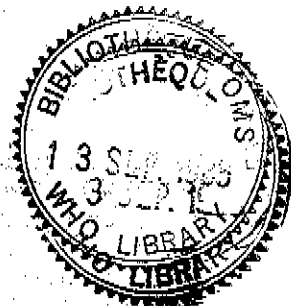




CONFERENCE OF EXPERTS ON THE
 RATIONAL USE OF DRUGS

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NEW DRUG SUPPLIES MANAGEMENT SYSTEM
 FOR RURAL HEALTH FACILITIES IN KENYA¹

A CASE STUDY

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NEW DRUG SUPPLIES MANAGEMENT SYSTEM
FOR RURAL HEALTH FACILITIES IN KENYA

INTRODUCTION

1. The Ministry of Health in Kenya has committed itself to a programme for improving the health services of the rural population of the country, which comprises the majority of Kenyans. At the heart of the programme is a network of rural health facilities - health training centres, health centres, and dispensaries. Currently, 227 health centres and 682 dispensaries are in operation, providing comprehensive health services. The administration and supervision are provided by district health teams.
2. Recognizing the adverse effects of the shortage of drugs, the Ministry of Health in 1979 carried out an in-depth analysis of the problem. The rural health facilities, often in very remote areas, came at the end of a long chain starting with the Central Medical Stores in Nairobi and passing through the district hospitals. Less than optimal planning at the Central Medical Stores, shortage of foreign exchange, and an unsuitable procurement policy often had the result that the drugs most needed by the rural health facilities were not available. Losses through pilferage or damage in transit made the situation worse. Patients would often be forced to walk many kilometres to the nearest government or mission hospital just to find drugs, thus bypassing the rural health facilities. This obviously gave rise to considerable socioeconomic problems.
3. The Ministry of Health has been fully aware of the problems created by the shortage of drugs, particularly in the rural health centres and dispensaries. It has already initiated action to alleviate the problems.

The problems

4. The major problems specifically identified were as follows:
 - (a) Shortage of drugs, owing to poor planning and procurement policies at the level of the Central Medical Stores, made worse by poor transportation and distribution. Many drugs destined for rural health facilities were diverted to district hospitals or lost through pilferage. Whatever drugs finally arrived at the rural health facilities were either grossly inadequate in amount or of the wrong type.
 - (b) Shortage of essential equipment, which was often either missing or in poor working order.
 - (c) Quality. The drugs supplied to rural health facilities were often of poor quality or time-expired.
 - (d) Inadequate diagnosis and prescribing. Health workers were often unable to make an accurate clinical diagnosis or prescribe the right drug in the correct dosage. Much over-prescribing and polypharmacy, often at the insistence of the patient, only made the general drug shortage worse.
 - (e) Attitude of patients. Some patients had become accustomed to misusing the free health service, coming for trivial ailments and demanding different kinds of drugs, which would afterwards be thrown away or distributed or sold to friends and relatives. The health workers found it difficult to resist such pressures.

THE NEW MANAGEMENT SYSTEM

5. In response to these problems, the Ministry of Health in 1980 introduced a new system to ensure that rural health facilities would be supplied with the drugs they needed and health workers trained how to use them.

Objectives

6. The main objectives of the new management system are:

- (1) to ensure that rural health facilities are regularly supplied with adequate quantities of essential drugs according to the needs of patients and within budgetary limits
- (2) to ensure that essential drugs arrive at rural health facilities without loss or breakage and in good condition
- (3) to ensure that essential drugs are used by health workers as cost-effectively as possible, through training in better clinical diagnosis and patient management
- (4) to guarantee the quality of all drugs supplied, i.e., to ensure that they conform to international standards of purity and safety, are of fresh manufacture, and are suitably labelled and packaged
- (5) to inform and educate the public on the proper attitude towards drugs and the health services.

Principal components

7. Essential drugs list. On the basis of the WHO list of essential drugs, adapted to Kenya's morbidity patterns, a list was drawn up of 40 essential drugs for health centres and 30 for dispensaries. These have been found adequate for the rural health centres and dispensaries. It was also laid down that generic names only should be used in labelling and duplication, combinations, and sophisticated forms should be avoided.

8. Essential equipment. A list of medical equipment essential for rural health facilities was established by the Ministry. The equipment was distributed at the start of the new system together with the essential drugs.

9. Drug supplies. A fundamental principle of the new system is that rural health facilities should be supplied with enough, but not more than enough, of the essential drugs needed for their patient population, the needs being based on the disease pattern.

10. Standard treatment schedules. Correct dosages for different age groups, the duration of treatment, the precautions to be taken, etc. were established for all the drugs selected. The objective is to achieve a rational and effective management of basic health problems.

11. Training. An essential part of the new management system is the training of health workers to diagnose the common conditions better and to make more accurate prescription and referral decisions. Emphasis is placed on training in the examination of patients and diagnostic procedures making use of aids such as the WHO flow charts. Thorough information on the essential drugs is given - the indications, precautions, and side-effects, as well as proper storage and management.

DRUG LEGISLATION AND QUALITY CONTROL

12. The drug legislation came into force in 1964, but has undergone several revisions since, with additions and deletions. The legislation covers all the trade in pharmaceuticals as well as the conduct of the profession of pharmacy. It includes legal specifications for the manufacture, importation and exportation, and distribution and storage of pharmaceuticals, as well as requirements concerning advertisement, labelling, and packaging. The Pharmacy and Poisons Board is the authority responsible for the enforcement of the regulations. It performs the functions of a central administrative agency.

The Pharmacy and Poisons Act (Cap. 244)

13. The Pharmacy and Poisons Act is mainly concerned with the distribution of poisons as defined in the Act, but only very briefly and somewhat inadequately addresses the issues of manufacture, packaging, labelling, advertising, etc. The Act, however, specifies that the manufacture of poisons shall only be made from licensed or registered and approved premises; and that only those products whose manufacture has been approved by the Pharmacy and Poisons Board shall be manufactured. Most manufacturing enterprises have adopted the "Orange Guide" as their official guidelines to good manufacturing practices (GMP).

The Dangerous Drug Act (Cap. 245)

14. The Dangerous Drug Act is very comprehensive and detailed as concerns the handling, trade, and production of narcotic drugs.

The Food, Drugs and Chemical Substances Act (Cap. 254)

15. The Food, Drugs and Chemical Substances Act, in the absence of a drugs act per se, contains supplementary legislation controlling the manufacture, labelling, and transport of drugs. It is, however, inadequate as it touches only the basic hygiene aspects of pharmaceutical manufacture.

Importation of drugs

16. Importation of drugs is granted only on authorization by the competent authority (the Pharmacy and Poisons Board) of the Ministry of Health, and only to licensed, authorized, and registered wholesalers (pharmaceutical distributors). Individuals and retail pharmacies may import drugs only by special dispensation, as for instance when an individual or pharmacy is the domiciled agent of an overseas principal.

17. Special provisions govern the importation of narcotic and psychotropic substances. They conform strictly to the guidelines established under the Geneva Convention I and II and the International Convention on Psychotropic Substances, to which Kenya is a signatory. The control authority maintains a record of all import authorizations issued in any one year. It also regularly forwards returns for both narcotic and psychotropic substances to the United Nations Narcotics Control Board.

18. The above acts also control the exportation of drugs from Kenya. Only authorized and licensed wholesalers and manufacturers may export drugs, authorization being provided by the appropriate export permit from the Ministry of Health. Records are maintained for all export authorizations granted in any year.

PROCUREMENT OF DRUGS

19. There are both statutory and administrative specifications regarding the labelling and packaging of drugs. The basic drugs purchased on tender by the Ministry of Health are obliged to have the statutory markings "KG.KMD" on the container or label. In addition, all the products must be appropriately labelled with the generic (and other) names, dosage, strength, presentation (formulation), quantity contained, manufacturing date, including the formula (composition), expiry date, batch, number, name, and address of the manufacturer and any special usage and storage precautions.

20. In the procurement of essential drugs for the new management system, strict specifications have been drawn up for drug type, dosage form, packaging, labelling, quality, and delivery. Before contracts are awarded, potential suppliers are visited and screened by joint Ministry of Health/UNICEF/WHO technical teams. As far as possible, local manufacturers have been favourably considered, as long as they fulfilled the necessary requirements for good manufacturing practices and quality. It is one of the management system's principles to give support to reputable local manufacturers and to build up the nation's independence and self-sufficiency for at least the basic essential drugs. As a check, samples are taken randomly from stocks in the Central Medical Stores as well as in the rural health facilities and sent to UNICEF in Geneva for analysis. The results are usually obtained within three to four weeks.

DRUG REGISTRATION

21. The first edition of a Kenya Pharmaceutical Index listing all the drugs in the market was published late in 1984. Since the enforcement of product (drug) registration in April 1982 the proliferation of drugs in the market has been effectively curbed. To date there are between 5000 to 6000 drugs in circulation. Of these it is expected that only about 2000 items will have been registered by the end of 1985. Government institutions have a list of basic essential drugs comprising some 200 items from which they are obliged to draw their drug requirements. This list of essential drugs has been largely derived from the WHO model list of essential drugs. There are 40 drug items for health centres and 30 for dispensaries.

22. Each dosage form and strength requires separate registration. A technical evaluation committee is charged with scrutinizing and recommending for registration all the applications received. Product registration must be renewed every five years for products externally manufactured and three years for products locally manufactured. The specifications on product quality control in respect of registration are aligned to the requirements of the WHO guidelines on good manufacturing practices.

23. Owing to lack of physical, financial, and human resources, some of the regulatory control programmes are deficient, the lack of resources preventing the full application of a comprehensive system of drug quality assurance. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce consequently finds wide application. Kenya recently became a signatory to this certification scheme.

24. The authority to monitor and control the quality of drugs in our pharmaceutical supply system is vested in the Drugs Inspectorate Control Section of the Pharmacy Department of the Ministry of Health. The administrative and regulatory procedures for the control of pharmaceuticals, such as notification, authorization, or registration, are carried out by the Pharmacy and Poisons Board.

Inspection, sampling, and analysis of pharmaceutical products on the market, supplemented by information from other sources (manufacturers, distributors, other regulatory agencies and advisers, investigations of reported defects) provide the basis for action to minimize the health hazards due to poor-quality products. These functions are performed by the Drugs Inspectorate Control Section.

25. Verification by inspection includes assessment of manufacturing and distributing firms as well as of retail and dispensing outlets such as pharmacies and hospitals. Drug quality surveillance should be supported by inspection and laboratory services, but in Kenya a government central analytical quality control laboratory is lacking.

The right to distribute

26. The regulations require that distributors should be authorized sellers of poisons or licensed wholesale dealers, with the business under the control of a registered pharmacist. A licence for this purpose is issued by the Pharmacy and Poisons Board. The distribution must be carried out from approved and registered premises.

The right to prescribe

27. National legal duties are imposed on such key persons as the pharmacist and the prescriber, who are involved in the final steps of the distribution of pharmaceutical products. These persons have statutory responsibilities concerning product quality. The pharmacist and prescriber also have the responsibilities placed on them by their professional standards and professional codes in relation to defective products.

28. There are no regulations or legislation obliging the prescriber to prefer a brand product to a generic equivalent or vice versa. Brands and generic products are given the same preference in regard to registration, quality control, trade, and use. In the public sector, however, more encouragement has recently been given to generic prescribing as a result of the essential drugs list mentioned above, in which the drugs are identified by generic or international nonproprietary names.

29. The right to prescribe drugs is vested by the appropriate legal and professional authorities in duly qualified and registered practitioners (medical practitioners, dentists, veterinary surgeons) or people approved or otherwise authorized by the Director of Medical Services.

Drug promotional activities

30. The importation, manufacture, distribution, and sale of drugs and other pharmaceutical preparations are controlled by the acts mentioned above. Under those acts the Pharmacy and Poisons Board licenses the various activities and persons or establishments concerned with pharmaceuticals and vets all advertising of drugs. It does not allow advertisement in the media of drugs for certain diseases and medical conditions listed in the schedule to the Pharmacy and Poisons Act or of certain psychotropic and narcotic drugs.

31. There are no standard regulations or format that must be satisfied before drug promotional activities may be allowed.

Pricing

32. The pricing of pharmaceutical products is not controlled in the same way as that of general commodity items. Normally the price of any drug is negotiated at a figure acceptable both to the supplier and to the Price Controller in the Ministry

of Finance. Neither the Pharmacy and Poisons Board nor the competent authority in the Ministry of Health has any influence in the pricing of pharmaceuticals. Once it has been determined, however, the price remains the same for all parts of the country.

Symposia

33. It is open to any establishment wishing to promote a new product or disseminate new or additional information on its own product to hold symposia. The only requirement is that the target groups for such symposia must be clearly defined. Such target groups are usually practising medical professionals or medical students. In this case the provisions concerning advertisement must be strictly followed. This does not preclude the provision of information to prescribers and other users in the form of texts and other information aids. Such technical information is disseminated by medical (sales) representatives, who are themselves required to be licensed as such for the purpose of possessing medical samples. The question of giving samples has been debated widely in the meetings of the Pharmacy and Poisons Board. Normally sales representatives are drawn from people who have been trained in the biomedical professions, such as pharmacists, pharmaceutical technologists, or nurses.

34. Thus the control the Ministry of Health exerts on the promotional activities and distribution of drugs by pharmaceutical manufacturers is as follows:

- the products manufactured are registered and licensed by the Ministry of Health
- the manufacture and distribution are carried out in and from registered and approved premises
- the manufacturer is under the supervision of approved persons who are technically qualified
- the distribution is effected under the supervision of a registered pharmacist
- the dissemination of technical information and the supply of medical samples are carried out by licensed medical representatives
- any advertisement complies strictly with the provisions of the Act.

Distribution

35. A major problem under the old system was losses on the way from the Central Medical Stores to rural health facilities, due to breakages, pilferage, careless handling, exposure to the weather, etc. Whatever drugs arrived at district hospitals, were usually retained by them for their own use.

36. Under the new management system drugs are packed at the site of manufacture in strong sealed kits so designed as to withstand rough handling, transport hazards, and the most inclement weather. The drug kits are sent to the district hospitals, where they are stored in clean dry conditions before onward transportation under the supervision of district health teams to the rural health facilities. At no time may the kits be unsealed or opened before they reach the rural health facilities.

37. Excess stocks are collected once every three months by district supervisors, returned to the district hospitals, and redistributed to other health facilities that may have a greater need for them.

38. Drug kits are sent to the district every three months and to the rural health facilities every month, depending on the patient workload.

Control

39. Control of the essential drug supplies is carried out by the Ministry's Management Unit of Drug Supplies, working in close coordination with district and provincial health teams. A simple but effective bin card system is in use in the health facilities to give all parties a better check on supplies and use. This can easily be correlated with patient workloads and diagnoses/treatments, which have to be recorded accurately by health workers.

Organization and administration

40. At the start of the new management system a new unit was established in the Ministry of Health in Nairobi, whose task was to coordinate the implementation and running of the new system. This Management Unit of Drug Supplies to Rural Health Facilities (MDS), working as a staff unit in the Rural Health Project in the Ministry, has the following main functions:

- to review and update at regular intervals the lists of essential drugs, standard treatment schedules, and guidelines for clinical diagnosis
- to evaluate the adequacy of clinical diagnosis and management of patients in rural health facilities
- in liaison with the Central Medical Stores, to manage the procurement, storage, quality control, and distribution of essential drugs in accordance with the budget allocated
- to promote the training of district and provincial health teams and rural health facility staff in clinical diagnosis and patient management
- in consultation with district health teams, to determine drug requirements for rural health facilities.

The cost

41. It is important to note that the new management system in Kenya does not necessarily mean a vast growth in expenditure on drugs. The system is based on the concept of rationing, that is, on a drug supply tailored to the patient workload and to morbidity, on the training of health workers to diagnose more effectively and treat more efficiently, and on the procuring of essential drugs as generics at world market prices; and it is expected that the rural health facilities will be able to provide a vastly improved service within budgetary constraints.

42. However, more important than cost is the benefit in terms of human wellbeing that the new management system will bring. Apart from the purely therapeutic benefits, an adequate supply of drugs increases the utilization of health services as a whole, fosters staff motivation and morale, and significantly improves the health care delivery system.

43. Although considerable savings are already apparent in drug procurement under the new system, as well as savings due to better packaging, distribution, and use, it is not to be expected that the new system will cost less than was spent on rural health facility needs previously. However, at that time the rural health facilities were seriously undersupplied. It is certain that the new management system will enable all Kenya's rural health facilities to be supplied with

essential drugs adequately at much less cost than under the old system. Moreover, applying the same principles to the hospital service will no doubt have similar if not greater effects. The Ministry of Health is about to embark on this initiative.

Results

44. The new management system has been in operation for three years and covers all districts. The public is now using the rural health services much more than before, thus relieving the district hospitals of a heavy burden. Health workers are much more motivated in their work, having the drugs necessary to cope with the main diseases and conditions seen in rural health facilities. Transport, storage, and distribution have been simplified. Losses due to breakages, pilferage, and wastage have been eliminated.

45. Apart from health workers and patient satisfaction with and enthusiasm for the new system, another more objective benefit from the new system is already evident. Outpatient attendances at district hospitals are down by 30-40%. Patients are now returning to their rural health facilities, leaving district hospitals breathing space to attend to more serious or referral cases. Important socioeconomic and family benefits will ensue from this return to the local health facilities.

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