

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

MISSION FOR ESSENTIAL DRUGS AND SUPPLIES, KENYA

CASE STUDY



World Health Organization



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INTRODUCTION

This case study examines the innovations and experiences of a faith-based supplier of essential drugs and other health commodities, working to ensure the safe delivery of competitively priced antiretroviral (ARV) drugs to patients in need. The Mission for Essential Drugs and Supplies (MEDS) has built on its existing service infrastructure to include the provision of ARV drugs to its client base, which consist primarily of mission hospitals. It is hoped that these experiences will encourage managers of facilities who are concerned with procurement and supply of ARVs, to consider ways of enhancing the security and reliability of service delivery.

BACKGROUND

MEDS is a Christian not-for-profit organization based in Nairobi, Kenya. The organization was founded in 1986 as an ecumenical partnership for improving access to good quality health care. It is a joint service of the Kenya Episcopal Conference (KEC) and the Christian Health Association of Kenya (CHAK). CHAK, which was established in the 1930s, provides nearly 20% of the faith-based health services in Kenya. It is an umbrella organization for a network of 20 hospitals, 45 health centres, 44 churches or church health programmes and 253 dispensaries, all owned by either missionary groups or Christian denominations.* KEC has nearly twice the membership of CHAK, almost 400 of which are MEDS clients.

Kenya has a population of nearly 30 million people. Among adults the prevalence of HIV is approximately 15%,⁽¹⁾ and about 700 people are estimated to die every day from HIV-related disease. In 2003 Kenya was ranked 146 out of 175 countries according to the human development indicators ranking of the United Nations Development Programme.⁽²⁾ Although the Ministry of Health (MOH) estimates that approximately 200 000 people urgently need ARV drugs, under 20 000 people receive such treatment.⁽³⁾ The use of antiretroviral therapy (ART) in Kenya has, for the most part, been limited to the private sector, church health facilities, research institutions, and nongovernmental organizations (NGOs) providing treatment to limited numbers of people.

At least 40% of the health services in Kenya are provided by church health facilities, which have received no subsidies from the government since 1998,⁽⁴⁾ although some have benefited from the secondment of staff from state institutions.

Most patients receiving ART pay for it themselves. This situation may continue even when the government begins to stock ARV drugs in district hospitals. Patients may be required to contribute to the cost of treatment under a cost-sharing system.⁽⁵⁾

Facilitating legislation

In December 2002 the second edition of the *Guidelines to antiretroviral drug therapy in Kenya* was published by the MOH. These guidelines give the recommended ARV drug combination for each category of patients. The Industrial Properties Act of 2002 removed all legal barriers to the importation of generic products, some of which have been registered by the Pharmacy and Poisons Board. This body has been hampered by insufficient capacity and financing, with the result that delays have affected the process of registration. However, a special authorization waiver was introduced in that year allowing non-profit organizations to import generic ARV drugs

OBJECTIVES

MEDS seeks to promote health for all through the provision of essential drugs, medical supplies, training and other pharmaceutical services, guided by ethical and professional Christian values.** In pursuit of this mission, MEDS has two broad objectives:

- to provide a reliable supply of essential drugs and medical supplies of good quality at affordable prices;
- to improve the quality of patient care through training in all aspects of health and general management, with specific emphasis on the essential drugs concept and the rational use of drugs.

* <http://www.chak.or.ke/membership.php>

** MEDS promotional leaflet (2003).

NATIONAL POLICY ON ANTIRETROVIRAL TREATMENT

The MOH published the *Guidelines to antiretroviral drug therapy in Kenya* in February 2001, and a second edition was released in December 2002. The guidelines include reference to nucleoside analogue reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors (Table 1), which are included on Kenya's essential

drugs list. Along with the WHO list of prequalified ARV drugs, the guidelines are used during the purchase and standardization of ART in facilities obtaining ARV drugs from MEDS. The guidelines were released almost simultaneously with the purchase of MEDS first stock of ARV drugs, and consequently were helpful in the preparation of training courses on ART.

Table 1: Drugs included in the *Guidelines to antiretroviral drug therapy in Kenya*: recommended first-line and second-line regimens

Nucleoside analogue reverse transcriptase inhibitors*

- ▶ zidovudine (ZDV)
- ▶ didanosine (ddI)
- ▶ lamivudine (3TC)
- ▶ stavudine (d4T)
- ▶ combination ZDV/3TC

Non-nucleoside reverse transcriptase inhibitors*

- ▶ nevirapine (NVP)
- ▶ efavirenz (EFZ)

Protease inhibitors*

- ▶ indinavir (IDV)
- ▶ nelfinavir (NFV)
- ▶ lopinavir/ritonavir (LPV/r)

Recommended first-line regimen

D4T/3TC and either EFZ or NVP, depending on whether the patient presents with tuberculosis coinfection.

Recommended second-line regimen

ZDV+ ddI + lopinavir/r or NFV

* Paediatric preparations are available for all except EFZ.

HISTORY OF MEDS

MEDS began operations in 1986 after a feasibility study by WHO demonstrated that there was an opportunity to provide drugs for people who needed them but could not afford them.⁽⁸⁾ Previously, the church health facilities had bought their pharmaceutical and other supplies from the government-run central medical stores. However, whenever a stockout was imminent the government health facilities were given priority for the delivery of supplies. Consequently, the church facilities found these supply services to be less than satisfactory.

MEDS was set up as a revolving drug fund with funding mainly from church donors abroad. Contributions also came from local churches. From its office base, MEDS requested suppliers to deliver directly to the health facilities and received bills on their behalf. In 1989, MEDS started operations at its current site in Nairobi's industrial area. At this location it was possible to maintain buffer stocks, thus ensuring a continuous supply to the organization's health centres and avoiding stock outs (which had also occurred with commercial suppliers). MEDS now has complete autonomy and does not have to rely on outside funding for its routine operations.

ORGANIZATION AND MANAGEMENT SYSTEMS

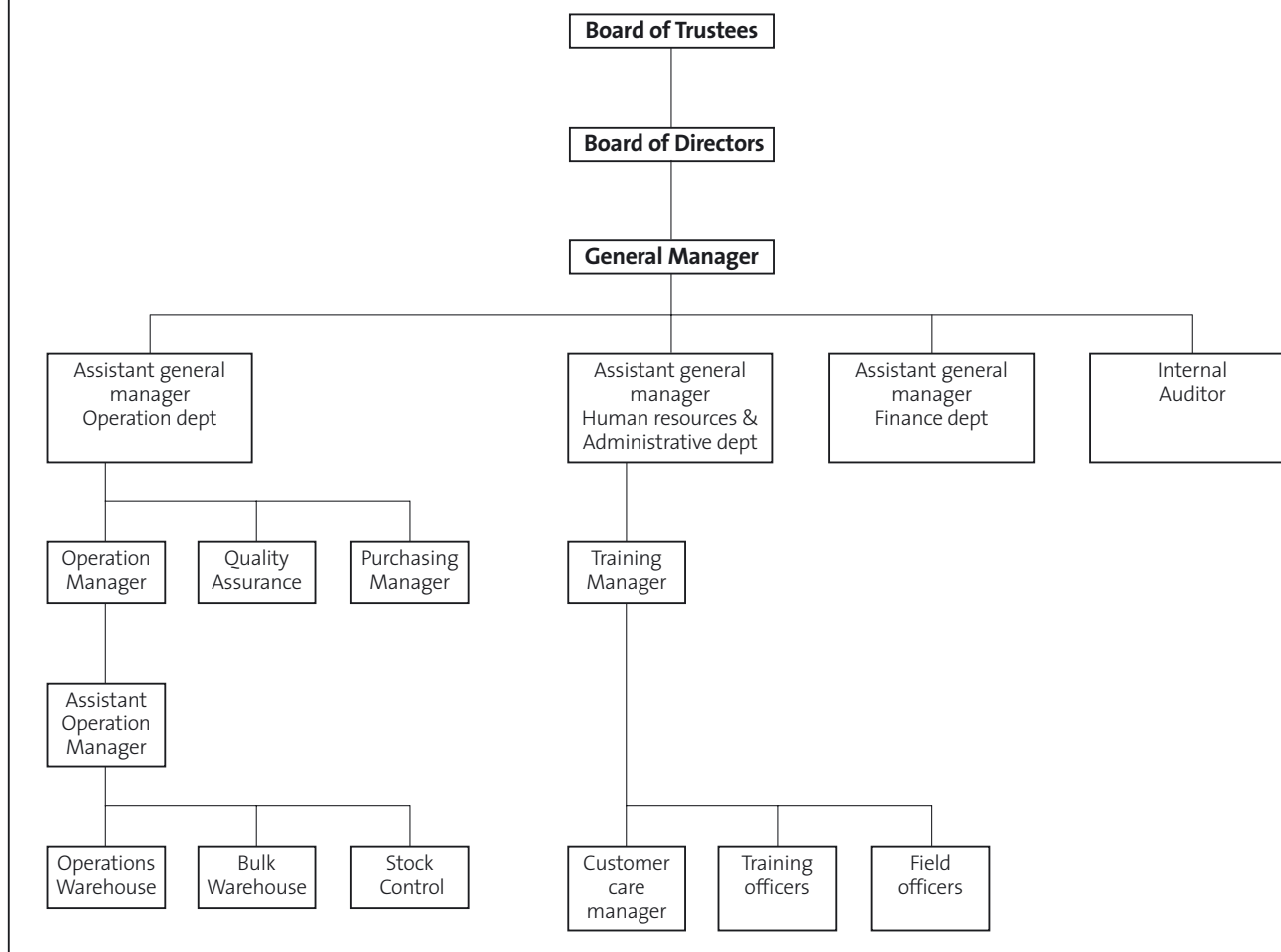
The organizational structure of MEDS consists of three levels of management.

1. The Board of Trustees, whose members are drawn from the church leadership of CHAK and KEC. They are not involved directly in either management or strategic planning.
2. The Board of Directors, whose members are appointed by the two church secretariats. They do not participate in day-to-day management but are involved in policy issues such as the constitution of the MEDS tender board and the determination of terms of employment.
3. The General Manager is the link between the Board of Directors and the daily operations.

The Management Committee consists of four heads of department (operations, human resources and administration, finance, and marketing). It meets once a month and at other times as necessary. A management team of 12 people from different sections within the departments meets every month. Staff meetings are held after Wednesday morning prayers, and staff can meet informally with section heads at prearranged times to discuss any issue that arises. Annual MEDS days provide opportunities for employees to have further interaction with each other and their clients.

MEDS has not had to increase its complement of personnel in order to handle the addition of ARV drugs to its stock. Indeed, staff numbers have decreased in recent years because of normal attrition and a policy of limited staff replacement accompanied by increasing efficiency through computerization.⁽⁷⁾ Thus in 2001 there were 112 staff whereas there are only 104 currently. Fig. 1 illustrates the present organizational structure of MEDS.

Fig 1: Organizational structure (only relevant departments shown)



MEDS recently embarked on a strategic plan for the period 2003–2007, one of the issues in which is the management of debt. MEDS has to manage debt arising largely from a previous policy of extending credit to its clients for the products ordered. As of the end of 2002, an amount equalling about 8% of annual sales was owed to MEDS by health facilities for drugs and medical supplies.⁽⁸⁾ The credit policy has been changed and new customers' payment practices are observed for a year before a credit line can be opened for them. MEDS is working closely with the two church secretariats to improve this situation. Debt recovery measures are being strengthened.

CLIENT BASE

The client base of MEDS comprises nearly 1000 health care providers in various categories. These include 723 church

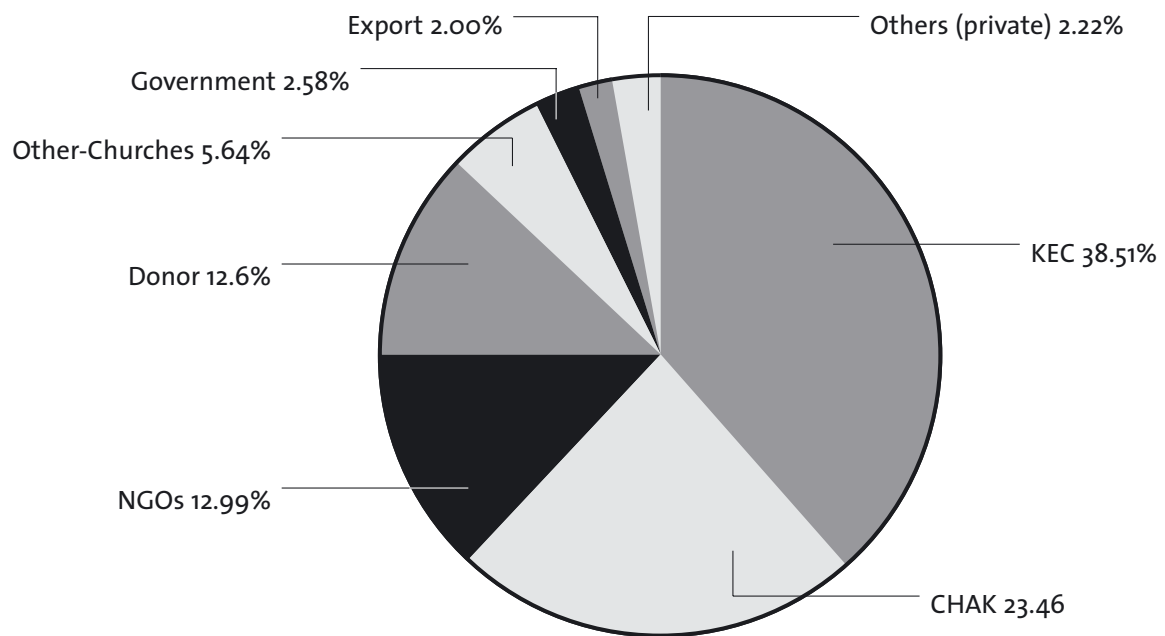
health facilities (CHAK and KEC) to which it makes its primary commitment, 150 NGOs (mainly relief agencies serving in areas ravaged by war and/or famine, in Kenya, the Horn of Africa and the Great Lakes region), the Bamako Initiative, donor-funded public health care projects, government health facilities, community-based health care initiatives and health institutions run by other religious groups. The clients that are private health facilities include clinics of companies providing health services for employees, their families and surrounding communities.

The health professionals in government-run health facilities tend to be more experienced and better represented than those in mission hospitals. This difference seems to have increased since the recent rise in doctors' salaries.⁽⁹⁾ However, the mission hospitals have tended to hold better stocks of medications because of their affiliation with MEDS.⁽¹⁰⁾

Government institutions accounted for 20% of MEDS sales during 2003, an increase of 4% from 2001. This contributed significantly to the increase in sales between 2001 and 2002 (Fig. 2). The growth was attributed to the support of public health institutions in various districts by the Swedish

International Development Agency, the Danish International Development Agency and Belgium Technical Cooperation through the MOH, and the creation of revolving drug funds for those districts.

Fig 2. Sales by market segment, January to November 2003



COMPETITION WITH OTHER SUPPLIERS

MEDS enjoys a dominant role in providing a range of drugs and medical supplies to church-run health facilities. In addition, because of its reputation and long working relationship with suppliers, MEDS is able to offer competitive prices comparable to those of international procuring agencies. The church facilities can benefit from special deals on drugs occasionally offered by MEDS. These conditions have made it possible to negotiate favourable prices for ARV drugs. Moreover, in Kenya there is no value-added tax or import duty on medicines.

The government-appointed institution for procurement and logistics management, the Kenya Medical Supplies Agency (KEMSA), has been undergoing a process of restructuring and capacity improvement. A project backed by the United States Government is working with KEMSA to provide some logistics, capacity-building and distribution support. The project manages and distributes drugs against sexually transmitted infections and tuberculosis, HIV test kits, and family planning supplies including condoms, through a system parallel to KEMSA.⁽¹¹⁾ Since early 2004 no ARV drugs have been handled through any system in the public sector, although the government has announced the availability of approximately US\$ 2.3 million for purchasing such drugs.⁽¹²⁾

CLIENT SERVICES AND COLLABORATION WITH GOVERNMENT

MEDS stocks 580 products chosen from a list that is regularly reviewed by a committee of experts from church health facilities, the MOH, MEDS, WHO and elsewhere.* Over 90% of the products in stock are sourced locally and 70% of the stock comes from Kenyan manufacturers. Other products are sourced from local distributors and 5% are purchased from overseas suppliers.

In the early 1990s, on behalf of the Kenyan Government, MEDS distributed free HIV test kits to church mission hospitals with facilities for screening blood donations. The use of HIV tests for testing and counselling services was included in 2003, when distribution to all health facilities through the state's district health facilities was established. Often the tests sent out for distribution are not enough to cover both safe blood supply and testing and counselling. This means that the health facilities have to purchase test kits on the market at their own expense, at prices of up to \$250

for 100 tests. MEDS currently does not stock HIV tests, reagents or diagnostics for CD4 counts and viral load testing. While HIV tests are obtained through government distribution, CD4 and viral load tests and reagents are not stocked because MEDS customers do not have the facilities necessary for conducting these tests. Patients requiring them are directed to other health facilities.

MEDS management participates in the ARV Task Force of the MOH, whose members include the Pharmaceutical Society of Kenya, Liverpool VCT, WHO, the Kenya Medical Research Institute, Family Health International, Médecins Sans Frontières, Crystal Hill (private sector), the United States Agency for International Development, the Department of Defence, the Kenya Medical Association, the Kenya Paediatric Association, the Pharmacy and Poisons Board, the United Kingdom Department for International Development, the Kenya NGO Consortium (KANCO), Kijabe Hospital, the National Laboratory Association and the Kenyatta National Hospital.⁽¹³⁾

PROCUREMENT OF ARV DRUGS

Tendering for the stock of MEDS drugs and supplies is performed three times a year under a restricted system. There is a lower mark-up for high-cost items and vice versa. The mark-up ranges from 10% to 22%. In June 2002, MEDS procured the first consignment of ARV drugs consisting of single and dual-combination products from a research and development company. Because of increasing market demand and the lifting of legal restrictions, MEDS gradually built up stocks of WHO-prequalified generic combinations from manufacturers based in India. Three times more generic products than branded products are now being procured. The initial investment to start procuring ARV drugs came from the MEDS revolving fund, and the costs have since been recovered.

MEDS includes a 2% mark-up in its prices of ARV drugs to cover distribution costs, and strongly recommends to its clients that the price to patients should not exceed an additional 5% of the price to the health facility. No deviation from this recommendation has been reported. Consignments are either collected by clients or delivered by MEDS van within a certain radius of Nairobi or by commercial transport or courier services. Transportation charges are included in the price of the products.

* MEDS promotional leaflet (2003).

LOBBYING FOR PRICE REDUCTIONS

Before 2001, MEDS routinely stocked treatments for opportunistic infections in AIDS patients but was not involved in the distribution of ARV drugs. Members of MEDS management joined pressure groups to lobby for increased access to these drugs. They began to negotiate with research-based pharmaceutical companies early in 2001 with a view to obtaining more affordable prices. (Fig.3.)

A few months before the Industrial Property Act of 2001 became law, the research and development companies reduced the price of their combination therapy (D4T/3TC/EFV) from \$769 to \$77 per month. A second reduction occurred after the enactment of Section 58(2) of the Act, whereby "The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country, or imported into Kenya",* under which the importation of generic ARV drugs is allowed. Regulation 37 of the Industrial Property Regulations 2002 elucidates further that "the limitation on the rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market". As a non-profit organization, MEDS was able to obtain permission to import generic ARVs through a waiver system. In July 2002, when the Act was enforced, the prices of treatment dropped further. Generic products were made available to MEDS clients at \$38 a month. By July 2003 the cost of treatment per patient was \$25 a month

In May 2003 the single-tablet fixed-dose combination triple therapy (D4T/3TC/NVP) was added to the inventory. MEDS has found it a challenge to forecast its inventory requirements accurately as the availability of ARV drugs becomes more widely known and increasing numbers of clients place orders. Some three months after first stocking the triple therapy combination drug, MEDS had to place an emergency order with suppliers so as to meet growing client demand.



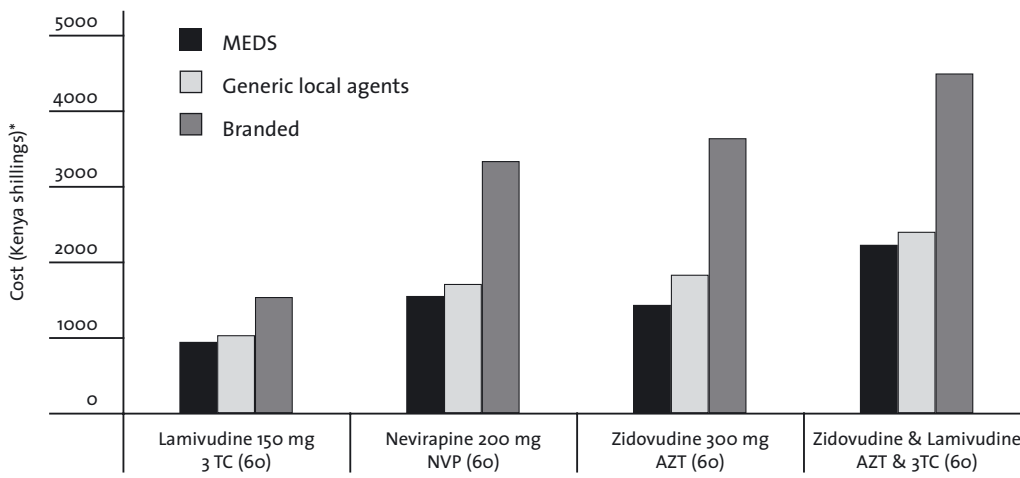
Members of MEDS, Médecins Sans Frontières and Ecumenical Pharmaceutical Network lobby parliament on the Industrial Property Act, May 2001.

Data from patient tracking forms indicate that by August 2003 there had been over 4000 patients on ARV drugs at the church health facilities supplied by MEDS clients since distribution began in 2001. It is estimated that 10 000 patients are on ARV drugs in the private sector and mission hospitals through self-pay or employment health insurance.⁽¹⁴⁾

Overall ARV drug sales have risen rapidly (Fig. 4). However, formulations of single-tablet ZDV have been used very slowly since MEDS began stocking the combination formulations. Customers invariably prefer the fixed-dose combination drug. MEDS is considering phasing out ZDV because much of the stock is expiring on their shelves.

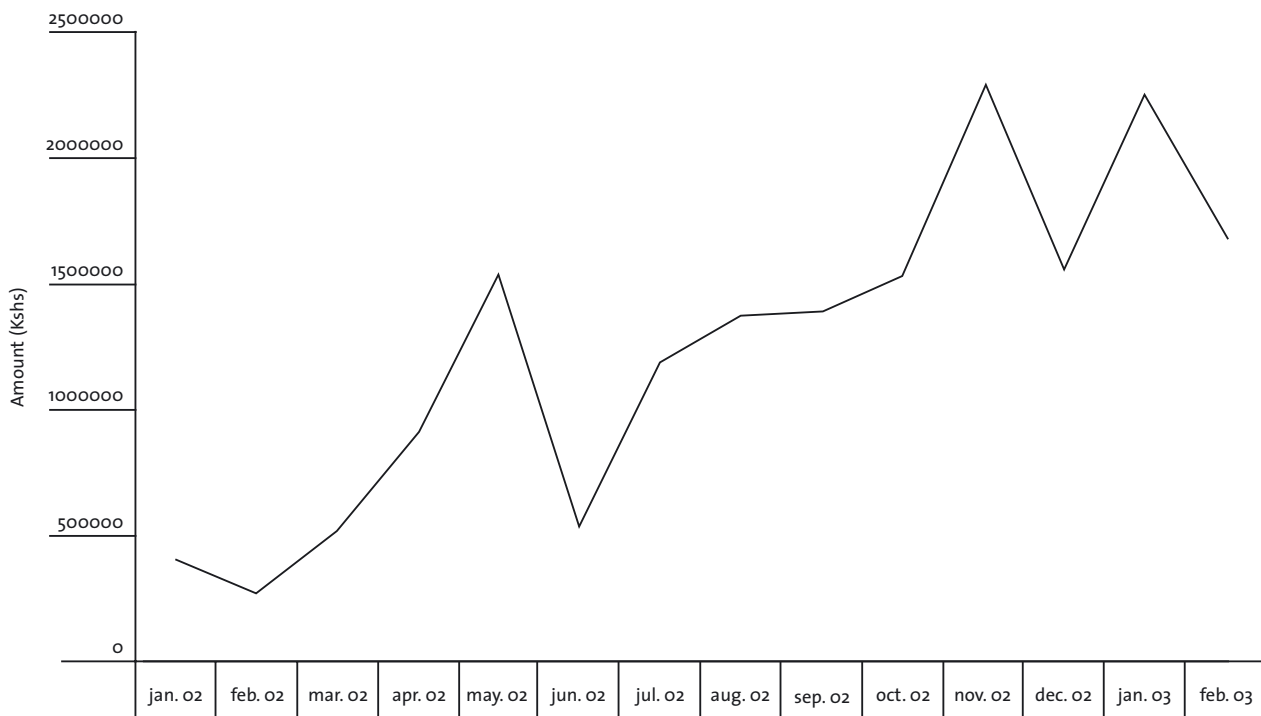
* <http://www.msf.org/content/page.cfm?articleid=065B1FFF-8E15-434F-811E96F301113191> on 12 October 2003

Fig. 3: Comparison of prices of ARV drugs, January 2003



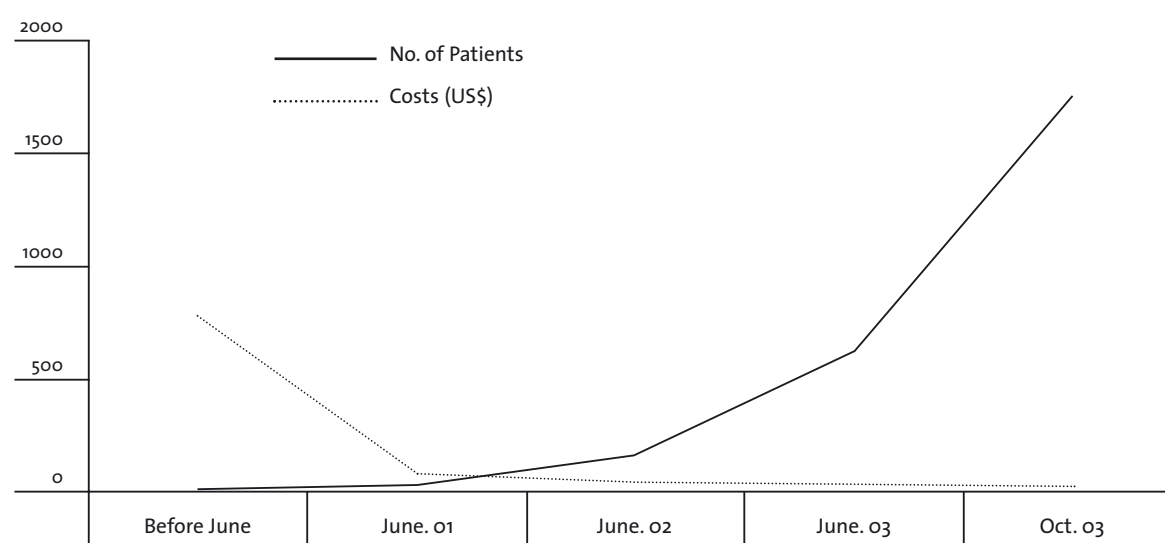
* Per pack of 60 tablets per patient month.
 Source: PowerPoint presentation, *Anti-Retroviral Drugs* by Jane Masiga, Assistant General Manager for Operations, MEDS, 18 June 2003.

Fig. 4: Increase in ARV drug sales, January 2002 to February 2003



Source: Presentation by Jane Masiga, Assistant General Manager for Operations, MEDS.

Fig . 5: Reduced cost of ARV drugs leads to significantly increased numbers of patients receiving ART in church health facilities



Source: Background discussion paper for the WHO/EDM meeting on fixed-dose combination drugs for HIV/AIDS, tuberculosis and malaria, November 2003.⁽¹⁵⁾

In order to stock ARV drugs manufactured by the research and development companies, MEDS had to agree to:

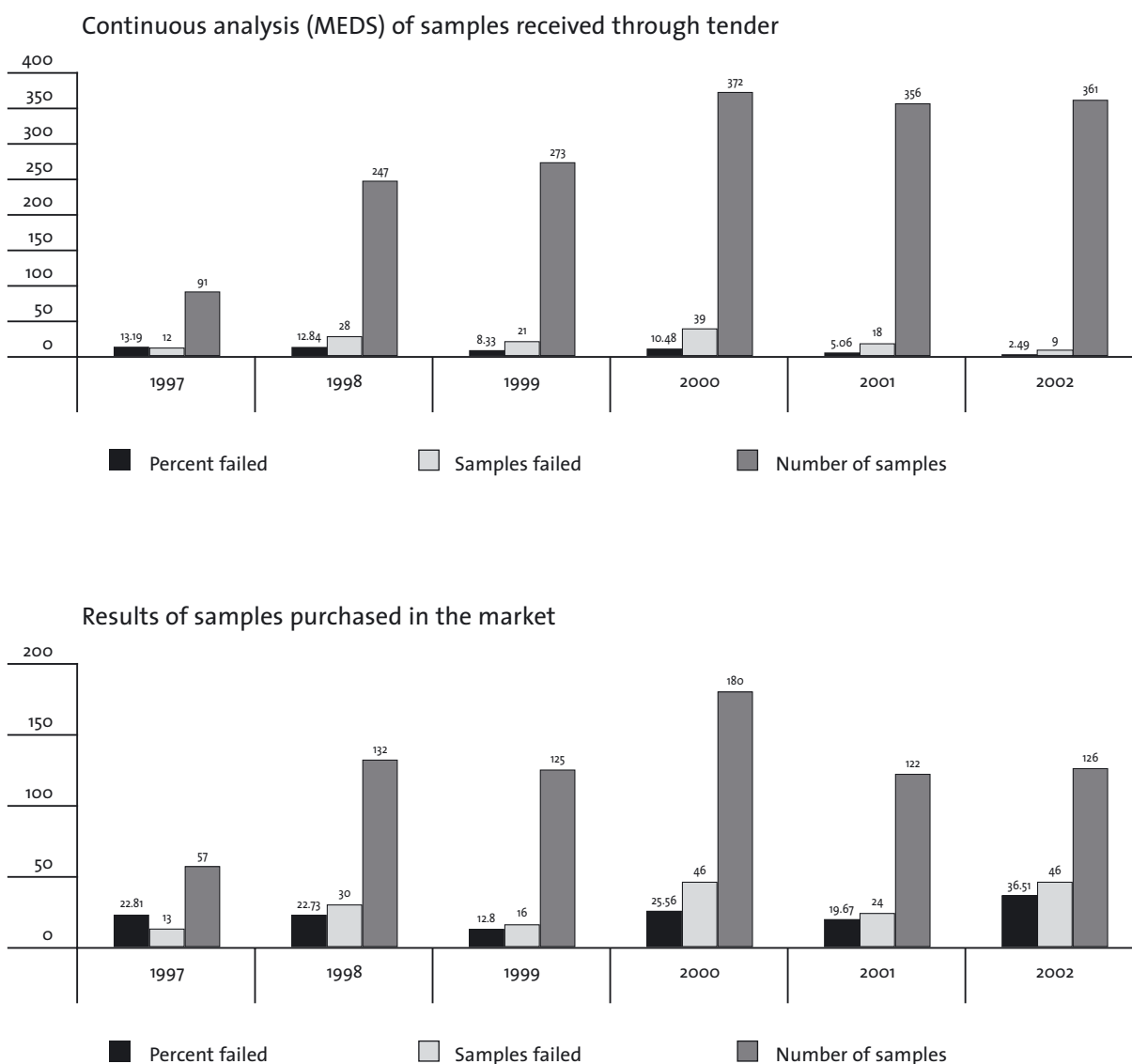
- ▶ ensure that patient-tracking systems were established in order to prevent the misuse of drugs;
- ▶ refrain from providing the combination drugs to any profit-making health care institution;
- ▶ supply ARV drugs to patients at no profit;
- ▶ refrain from reselling to other organizations other than the church missions and its customer NGOs;
- ▶ refrain from selling outside Kenya.

Under this agreement, MEDS was unable to supply ARV drugs to its customers in neighbouring countries which otherwise relied on MEDS for medical supplies.

QUALITY ASSURANCE

MEDS has a functioning quality assurance system which guarantees that its stocks meet international quality standards. Regular visits are made to manufacturing plants of local suppliers in order to verify adherence to good manufacturing practices. Furthermore, customer feedback is routinely sought. A pharmaceutical technical committee, comprising a quality control analyst who is a chemist, and a purchasing manager, the operations manager and a quality assurance manager, who are all pharmacists, screen all products at tendering and at delivery. Stored products are randomly sampled for chemical analysis as a matter of routine in order to verify their continuing good quality. As a result of these efforts, MEDS has observed a drop in the failure rate from 20% to 3% in stock received by tender, whereas the failure rate for the same products on the market has remained above 20%. As the box charts show, of the 126 external samples tested at MEDS in 2002, 37% failed, whereas only 3% of the 361 samples from MEDS stocks failed.

Fig . 6: Results of laboratory analysis of drug samples at MEDS



MEDS has a limited capacity to audit suppliers and manufacturers abroad. In the case of ARV drugs the prequalification list of manufacturers compiled by WHO has made it easy for MEDS to make decisions on selection. In July 2003 it became compulsory to obtain an import declaration form, requiring the inspection of drugs in the source countries of the manufacturers and ensuring more stringent inspections of medicines. The form costs 2.75% of the total invoice value and necessitates an inspection by a government-appointed inspector in the country of origin of the drugs before shipment to Kenya. Unauthorized products cannot be added to a

consignment if they do not appear on the import permit licence. The lead time for receiving new stock has increased from about a month to three months as a consequence of this new requirement.

At present, MEDS cannot undertake quality testing of ARV drugs because the testing methods have not been published and reference standards are not available. MEDS is considering collaboration with other organizations that conduct such audits, e.g. the International Committee of the Red Cross and Pharmaciens Sans Frontières.

TRAINING AND CLIENT SUPPORT PROGRAMME

The programme for training and supporting client health facilities started in 1988, well before the need to train staff on ART was recognized. MEDS training normally involves residential seminars, facility-based training and, recently, consultancy services, for all cadres of health care workers. Courses are offered every year for all levels of hospital staff, ranging from programme coordinators, matrons, board members and administrators to patient attendants and store managers. The courses, which can include coverage of the etiology and clinical management of HIV/AIDS, end with discussion of the services that MEDS provides. MEDS acts as a facilitator, and its training and client support team have training, expertise and credibility in facilitation.⁽¹⁶⁾ The training team is supported by experts from other departments of MEDS, the MOH and the University of Nairobi. The registration fee is about \$47 per participant. Some 2280 health workers have been trained since 1999.

Field officers visit clients individually to identify areas of need, to share information on health-related matters with staff in the facilities, and to set up customized training, particularly for small units. They aim to visit approximately three-quarters of the facilities in a year. The training and field service departments have been highly dependent on external funding. Because income for training grants has been decreasing in recent years, both departments are engaging in income-generating consultancy services. These have yielded about \$13 000 at time of writing.

MEDS hosts the secretariat for the Pharmaceutical Assistant Training Programme for the church secretariats of Kenya, Tanzania, and Uganda. This two-year certificate course in pharmacy for staff from church health facilities is accredited by the University of Western Cape, South Africa, and aims to provide skilled personnel for implementation of the essential drugs schemes. The management of MEDS runs the programme, which produces an average of 25 pharmaceutical assistants a year. Review and evaluation of the programme has been supported by the WHO Essential Drugs and Medicines Policy Department.

Funding and technical support

The support of donors has been vital because the training needs in the health facilities have always been greater than MEDS can meet through its operational budget. Funding has been received from ActionAid of the United Kingdom, the Interchurch Organization for Development Cooperation of the Netherlands, and Cordaid (formed by Roman

Catholic development organizations in the Netherlands). Technical support is received from the Ecumenical Pharmaceutical Network.

Training on ARV drugs

MEDS made ARV drugs available to clients in June 2001, as soon they were in stock. It was soon realized that prescribers at the client facilities were not familiar with the use of these drugs in the management of AIDS. The field officers found that clinicians were prescribing monotherapy or dual therapy, that diagnosis was not always made correctly and that there was no monitoring of side-effects. MEDS therefore decided to add the use and storage of ARV drugs to its training on commonly known diseases and their treatment.

- In August 2001, MEDS conducted its first three-day training course for doctors in the management of HIV/AIDS and the use of ARV drugs, with a view to them becoming trainers so that there would be a team of clinicians capable of providing these drugs in each facility. The course was funded by donor organizations when it became clear that the costs would exceed that which could be met within the MEDS budget.
- In 2003, nurses were offered a five-day training seminar on skills for managing patients on ARV drugs.
- Physicians and clinical officers participated in a four day training course on the epidemiological and clinical aspects of HIV infection, drug procurement and the reduction of stigma affecting HIV-positive patients.
- A five-day training course is available for coordinators of home-based and community-based care programmes, who, in general, are already affiliated to hospital facilities.
- The MEDS training programme for 2003 included a three-day course on store management for storekeepers, purchasing/supplies officers, pharmacy assistants and other pharmacy staff. The participants were trained in record-keeping, correct methods of dispensing ARV drugs to patients, stock-keeping, forecasting and budget preparation.

At least one person has been trained in each of nearly 70 health facilities. The training is being extended to other cadres of health care workers so that each facility has a complete team, consisting of a physician/clinical officer, a nurse, a laboratory technologist and a counsellor, for the

management of HIV/AIDS patients. Between August 2001 and August 2003, MEDS organized training for 151 doctors, 94 clinical officers, 74 nurses and 41 laboratory staff. Because there are only five pharmacists in the church-run health facilities, much of the work involving drugs is done by nurses or pharmacy assistants where present.

The impact of MEDS training for clinicians at the mission facilities was described by its Assistant General Manager for Operations at a satellite meeting before the International Conference on Sexually Transmitted Infections and AIDS in Africa, held in Nairobi in September 2003.⁽¹⁷⁾ The evaluation of a pretraining survey that was conducted among participants before the course is summarized in Table 2. Extrapolation of the responses to question 4 suggests that over 70% of course participants had received no training on the handling of ARV drugs before they received MEDS training.

Impact of training

Table 2: Results of a pretraining survey

Questions	Responses (% of all respondents)	
	Yes	No
1. Did you stock ARV drugs in your facility?	15	85
2. Have you ever used ARV drugs in the management of HIV/AIDS?	26	74
3. Why has your facility not introduced ARV drugs?		
▶ Cost (assumed prohibitive price of ARV drugs)	74	–
▶ Non-availability	45	–
▶ Lack of information	36	–
4. Have you been trained in the use of ARV drugs?		
▶ Formal training	5	–
▶ Informal training	18*	–

* Based mostly on courses provided by the pharmaceutical industry, Internet or outdated literature.

Table 3: Results of follow-up survey

Type of test ordered	% of respondents ordered tests	First-line ARV combination prescribed	% of respondents who prescribed ARV drugs
Full haemogram	61	3TC, D4T, NVP	39
Liver function tests	44	ddI, D4T, EFV	23
CD4 count	44	3TC, D4T, EFV	15
Urea/electrolytes	26	ddI, D4T, NVP	6
Viral load	11	ZDV, 3TC, EFV	6

A follow-up face-to-face survey was conducted in 18 of the 66 mission health facilities whose personnel received training between August 2001 and August 2003 on the clinical management of HIV/AIDS, related illnesses and ART. Five clinicians managing HIV patients were interviewed in each selected facility. As part of the survey they recorded the tests they requested for patients before ART was initiated (Table 3). The study revealed that 16 providers were prescribing without having had any formal training on ARV drugs. Clearly, therefore, providers needed more opportunities to learn about the correct use of these drugs.

THE FUTURE OF MEDS

The grants awarded to Kenya by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) are among funds earmarked for making ARV drugs available in public health facilities. Over the next two years, Kenya could have access to approximately \$52 million for scaling up prevention, treatment and care in this field. In preparation for scaling up ART the Government has ordered CD4 monitoring equipment for each of the eight provincial hospitals in the country.

MEDS maintains that it could serve twice the present number of clients and it has been suggested that it could assist the Government with the management of ARV procurement and supply. However, MEDS' storage space is limited thereby, restricting the inventory. The Board of Directors and the Board of Trustees have considered moving to other sites but are concerned that this might disrupt operations.⁽¹⁸⁾

MEDS has been asked by a generic ARV drug manufacturer to consider opening a retail outlet. Since a number of prescriptions written at private facilities remain unfilled because patients cannot afford ARV drugs at the prices offered by private pharmacies, a low-cost provider like MEDS would potentially increase access to the drugs for the people concerned.

As part of its quality assurance, MEDS could conceivably introduce a process for the laboratory assessment of the ARV drugs that it purchases. This would allow a broadening of the sources from which selection could be made. Facilities such as the WHO Bulk Procurement Scheme Facility might permit institutions like MEDS to purchase HIV test kits jointly with other distributors, giving access to competitively priced sources of the kits if supplies from the government agency became insufficient.

LESSONS LEARNT

The experience of MEDS illustrates the potential for building on competencies and skills that can be used to scale up access to treatment for HIV/AIDS.

- In response to an immediately recognized need, MEDS modified its training scheme for health workers so as to include training on the clinical management of HIV/AIDS and related illnesses, as well as on the use of ARV drugs.
- The existence of a sound training system has made MEDS a competitive candidate for receiving further grants from donors such as GFATM. This is an important consideration at a time when training funds are dwindling.
- MEDS could potentially expand training by supplementing government-provided training and/or increasing the number of graduates from the pharmacy assistant training scheme in order to benefit the entire region.
- Organizations that provide similar training to that of MEDS should work with the authorities in the ministries concerned in order to develop guidelines on the essential elements of a training package.
- The existence of the quality control laboratory provides an opportunity to reduce the risk of counterfeit and expired drugs being sold on the market. However, MEDS needs support in expanding the testing of a range of ARV drugs submitted for tender and supply. This requirement can be expected to grow as with increased treatment availability, providers seek to substitute drugs because of greater numbers of adverse reactions and treatment failure.
- Various factors have helped MEDS to import ARV drugs into Kenya and have consequently contributed to faster and wider access:
 - the removal of taxes and import duties on ARV drugs;
 - the waiver allowing non-profit organizations to import ARV drugs that are not yet registered;
 - the selection of ARV drugs for purchase from the WHO prequalification list of manufacturers and the new inspection requirements of the Government of Kenya provide a further shield against the risk of importing drugs of questionable quality.

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

- ▶ MEDS found itself in a good position to manage data as it was in the final phases of upgrading its information systems in order to streamline operations between March and December 2003. It has software that allows the direct exchange of information with suppliers and clients (there are approximately 110 core business clients) via automatically generated individualized email messages. It can harness this facility to plan inventory needs with customers and to monitor patient numbers at a time of rapidly increasing demand.

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