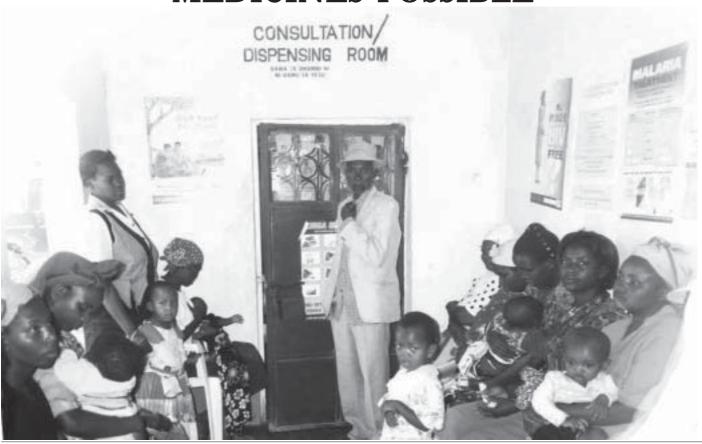


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MAKING ACCESS TO ESSENTIAL MEDICINES POSSIBLE



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Stacking of shelves with essential medicines

MAKING ACCESS TO ESSENTIAL MEDICINES POSSIBLE

It is likely that everyone reading this knows of the welcome relief that medicines can provide to relieve a headache, a toothache or some other pain that they have suffered from. Furthermore, anyone who has observed a child suffer from the ravages of malaria, or seen a non-immunized child crippled by the effect of polio, or helplessly watched as the condition of AIDS patients deteriorate rapidly due to lack of antiretroviral drugs, will attest to the crucial need to make essential medicines available and accessible to all

In a world that has adequate resources

to provide for the basic needs of all its inhabitants, it is estimated that over a third of the global population and over half of those living in Africa and Asia. lack access to essential medicines, a resource that can make the difference 3 on the quality of life or even between life and death. Why is this so? Is there anything that can be done to address this situation?

There are no easy answers to these questions. This issue of

Contact highlights some of the underlying causes of lack of access to essential medicines and recounts some examples of the innovative work being done to overcome some of the obstacles.

When considering access to medicines, one must start first with ensuring that the drug is available. That means the drug must be manufactured and

formulated in usable form and made available in the market. Pharmaceutical companies invest in research, development, formulation subsequent sale of drugs. They make a profit on their investment through patents which confer monopoly to the company for some years. At the end of patent period, other companies can reproduce the drug making it available in cheaper generic forms. Dr Srinivasan's article looks at the impact of global trade agreements on the availability the drugs. He highlights India which had become one of the leading countries supplying generic drugs in the world. As India changes its regulations in order to comply with the WTO rules,

the country's ability to remain a principal source of generics may be limited.

Pricing and affordability also have huge impact on the accessibility of drugs. Preliminary findings from pricing surveys conducted by WHO and HAI show the impact of the pricing mechanism on the final cost to the user. Price, overstretched health systems, lack of financing mechanisms, and inadequate man resources are some of a factors that lead to dicines being unaffordable to be proportions of population.

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Unless the drugs are within the reach of bunts some the people who need them, availability work being and affordable prices will have little or no

the people who need them, availability and affordable prices will have little or no impact on access. Drug supply and distribution are therefore key functions in addressing access. The article by Donna Kusemererwa highlights the factors that hinder supply and distribution and suggests what can be done to get it

Cover photo:

Treatment of patients includes access to essential medicines Credit:: CHAK

right. Commitment to address the limitations and a willingness to learn from each other and to promote best practices are crucial for moving forward.

Getting essential medicines to where they need to be requires an engine to move things forward; the engine is an adequately trained and skilled human resources! Unfortunately, there is a worldwide deficit of skilled professional staff within the health care systems. Chipupu Kandeke of Zambia and Eva Ombaka of EPN discuss the problem of human resources which is experienced by both developed and developing countries. The brain drain of skilled manpower from developing countries is one of the main contributive factors to the human resource deficit in low-income countries. The solution requires a global effort.

However, it is not all gloom. Even in these difficult circumstances, innovative and encouraging work is going on, proving that something can be done. The experience of CFWshops in Kenya demonstrates how SHEF has addressed the issue of geographical access by establishing franchise model that balances profit and service. Alternative models such as the CAREshops in Ghana implemented through MSH's Strategies for Enhancing Access to Medicine (SEAM) project also exist, From Central African Republic, we learn of how communities have taken up the responsibility to provide and support primary health care services including supply of essential medicines.

However, even in these encouraging experiences we are made aware of the fragility of these efforts in the face of economic or, political hardship and other external forces that are obstacles to the development and empowerment of communities in their work.

These articles have been written by members and friends of the Ecumenical Pharmaceutical Network (EPN). These are people on the ground, who, on a daily basis, work and deal with efforts towards making access to



Health personnel sorting out drugs

essential medicines possible. They are motivated and committed to the cause and believe "it can be done". Although more needs to be done, we hope that this issue of *Contact* will encourage everyone to play their part in contributing towards the dream of making it possible for every living person to have access to essential medicines.

Eva Ombaka is the coordinator of the Ecumenical Pharmaceutical Network (EPN). This is an International organization with its secretariat in Nairobi, Kenya that brings together church-related health services to address pharmaceutical issues.

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TRADE IN MEDICINES AFTER WTO/TRIPS: DOES IT SUPPORT OR HINDER AVAILABILITY?

Trade is a necessary part of a human's life. One of the great debates of our times is the question of how free should trade be in the light of globalization. Does free trade necessarily mean free capital flows? Does it imply free migration of labour or free exchange of information? Is free trade always fair to the poor? Under a framework of free trade, patents and intellectual property rights are anomalies which act as hindrances to development. The amendments to India's patent laws may affect global availability of affordable generic medicines.

Patent as a monopoly device

A patent is a means for creating a monopoly. Since many popular drugs are developed as a result of discovery through a publicly funded research centre or university there is something akin to claiming too much of property rights than justified. When these so-called intellectual property rights conflict with the health of nations, the tragedy and the absurdity are even starker.

TRIPS and WTO

Debate on the World Trade Organization (WTO), patents and Trade Related Intellectual Property Measures (TRIPS) usually reflects on at least three broad positions:

- WTO/TRIPS are part of a country's international commitments and obligations
- 2 Making the best of a bad bargain that is WTO/TRIPS using the flexibilities in TRIPS Agreement and the Doha Declaration.
- 3 The TRIPS and WTO go against the fundamental grain of openness, creativity and what is at stake is the survival, welfare and development of all human beings.

The introduction of TRIPS has been as a result of fear among multi-national companies (MNCs) that countries like India, Brazil, Argentina and China will sell drugs cheaply and dominate the world market. The sale of quality drugs at lower prices would rob MNCs of their justification for pricing branded drugs at very high prices. Big pharmaceutical



Medicine is depensed to a patient at a clinic in Dili, India

companies and governments of developed countries – chiefly the USA – introduced the notion of intellectual property rights to protect the idea of free trade. Ironically, this has turned out to be a major trade barrier. (For more information on why this is a trade barrier, see Bhagwati, Jagdish: *In defense of Globalization*, OUP, New Delhi,pp.182ff)

Patents and TRIPS: case of India and its implications for other importing countries

Most drugs in India in the pre-1970 era were expensive. Even the Kefauver Committee of the US Senate had observed that the prices of antibiotics and other medicines were the highest in India before 1970. About 85 percent of the medicines at the time were manufactured and marketed by MNCs. Given the poor price control at the time, many dugs were expensive even for a lower middle class person, let alone a

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labourer on low wages. Irrational and unscientific prescription practices, corporatization of health care and poor public health services in India, also made drugs less accessible for the poor person. This was indicative of a larger crisis in access to health services globally.

After independence in 1947, the government of India was keen to build up the pharmaceutical sector. The government appointed two committees to examine the 1911 patents act. The 1970 patents act was an outcome of the recommendations of these committees. This act was groundbreaking both as a model for other developing countries and for helping to unleash a revolution in the Indian pharmaceutical sector.

The 1970 Act did not allow *product* patents for pharmaceuticals, food, insecticides and chemicals. According to the act only *processes* could be patented for "substances intended for use, or capable of being used, as food or as medicine or drug". The patents for *processes* were held for a maximum of seven years.

As a result, the post-1970 period saw an explosion in the manufacture of formulations and active pharmaceutical ingredients (APIs) or bulk drugs. By 2003, the Indian pharmaceutical industry was supplying 20 percent of the world's drugs (by volume). India currently has one of the largest pharmaceutical industries in the world. At least 60 manufacturing plants in India have US Federal Drug Administration (FDA) approval, second only to the United States. In 2004, India's drug prices were among the lowest in the world (dollar terms and even in purchasing power parity terms) with China as the only country able to offer even lower prices.

When India became a signatory to the WTO/TRIPS Agreement in 1995 it was given a 10-year transition period to comply with WTO requirements. The period came to an end on 1st January 2005. In order to comply with the requirements, the Indian government

The effect of India's new bill on global availability of generics

India is recognized globally as a country that provides generic brands of medicines at an affordable cost. This is mainly due to the 1970 patents act which allowed Indian manufacturers to legally produce generic versions of medicines patented in other countries. In 2004, India's drug prices were among the lowest in the world. This has ensured that poor countries have access to quality, affordable medicines.

However, this situation could change due to the amendment of the 1970 patents act. The amendment gives MNCs monopoly on the drugs and medicines they develop for a minimum of 20 years making the medicines expensive and therefore not accessible to the poor. The situation could revert to what it was prior to the enactment of the act with the odds balanced heavily in favour of multinational companies and against developing countries.

Unless measures are taken to bring down the cost of life-saving drugs, those to bear the brunt of this amendment are many poor countries that depend on India as a source of medicines. The most affected area will be HIV/AIDS since fifty percent of low-cost generic ARV drugs are manufactured in India.

Over the last several years, the production of affordable quality ARV drugs has seen an estimated 700,000 people in developing countries get access to treatment in developing countries. Although this number is below the intended target, it is a step forward in curbing the deadly effects of HIV/AIDS on the global population. It is imperative that India allows the continued production and export of generic versions of new medicines so that this progress is not negated.

amended 1970 patents act in 1994 by an ordinance (which subsequently lapsed); then a bill introduced in 1999 and revised and passed in 2002; and finally a third amendment was made through a presidential ordinance on 26th December 2004. The last ordinance had to be ratified by Parliament within six months for it to become an act. The Government of India subsequently passed the patents amendment bill in March 2005 with the President giving his assent in April 2005. The April 2005 bill tried to address some of the criticisms against the December 2004 ordinance from health activists and peopleoriented groups.

Reversing the gains of the 1970 act? Some of the major issues emerging from the recent amendments made to India's 1970 patents act with respect to medicines include:

- Protection for product patents on drugs introduced for a period of 20 years.
- Mailbox facility for product patent applications introduced with provision of Exclusive Marketing Rights (EMRs) in the period between 1st January 1995 to 1st January 2005. One of the biggest concerns after passing the ordinance was that drugs produced by Indian companies for which patent applications were pending in the mailbox would go off the market once the patents were granted. It was also feared that MNCs would use their patent monopoly to hike up the prices of drugs. Fortunately the March 2005 amendments clarifies that there is no question of patent violation of drugs already in the public domain during this 10-year period.

Compulsory license procedures can override product patents but the procedures for applying for these licenses are cumbersome and difficult even after the March 2005 amendments. Compulsory license procedures would have been automatic in cases of diseases like AIDS and drugs for major problems like malaria, TB, diabetes, and for vaccines. The Indian law provides a number of grounds for the granting of such licenses such as high prices, nonavailability and promotion commercial activity. For the compulsory licensing system to be effective, procedures for granting such licenses need to be simple and effective.

An earlier December 2004 ordinance required that to export a patented product to Least Developed Countries (LDC), one would need to have a compulsory license in India as well as in the importing country. However it would have been difficult for a

country with weak patent regulation and no requirements to give patent protection till 2016 to avail a compulsory license to an Indian exporter. This clause had attracted widespread criticism, as many developing countries would have been unable to import medicines from India if retained. The March 2005 amendments now clarifies that an LDC can import from India if "by notification or otherwise allowed importation of the patented pharmaceutical product from India."

"Inventive step", "novelty" and "product" were less clearly defined in the earlier amendments leading to fear of evergreening of patents. Evergreening is the perpetuation of patents monopoly beyond the stipulated 20 years by repeated patent grants based on small changes made to the original molecules.

The March 2005 amendments to the Ordinance have now restricted the scope for the granting of patents on frivolous claims. It clarifies that an "inventive step" means a feature of an invention that "involves technical advances as compared to the existing knowledge or having economic significance or both." The amendments contain a new definition for "new invention" in order to strengthen the provision of denying patents on frivolous claims and on the new use of a known substance.

To minimize evergreening, the amendments clarify that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy" is not patentable. Further explanations are that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isopmers, complexes, combinations and other derivations of known substances shall be considered to be the same substance, unless the differ significantly in properties with regard to efficacy."

Compulsory license procedures could have been automatic in cases of diseases like AIDS and drugs for major problems like malaria, TB, diabetes, and for vaccines

In summary: According to India's amended patents law, medicines patented before 1st January 1995, irrespective of the date of launch by Indian companies, can be freely marketed without any arrangement with the innovator company irrespective of the expiry date of the patent.

Drugs patented subsequently up to 1st January 2005 when the new patent law came into force, can be launched by manufacturers in India with approval from the innovators only. If the drug has already been launched prior to 1st January 2005, the Indian manufacturer is required to make arrangements with the patent holder for continued manufacture and marketing.

However no compensation can be claimed by the patent holder for the preceding period when the drug was being manufactured and sold without consent of the patent holder. What is important in Indian law is not the date of launch of a medicine or the expiry date of the molecule but the effective date of start of patent².

Not taking Doha Agreement to the fullest and other issues

The Doha Agreement has clarified TRIPS flexibilities and clearly states that a country's public health needs to be given primacy above all. Unfortunately this interpretation has not been used either in the provisions of the recent amendments of India's Patents Act regarding more liberal grounds for compulsory license or for defining what drugs can and cannot be patented. The amendments to the 1970 Act could have stated that drugs of a certain therapeutic class important for certain crucial disease situations prevalent in India are not patentable.

The amendments are not clear on whether the patent holder needs to manufacture the drug within India as proof of having worked on the patent. However, as no compulsory license can be granted under the amended provisions for the first three years, the government of India cannot control the price of newly patented drugs as it would



Branded antiretroviral drugs at the Coptic Hospital in Nairobi, Kenya

need data of costs of manufacture. Pending knowledge of these, the landed cost will have to be accepted as the cost of the drug over which a margin of 50 percent is allowed. Patenting new essential drugs without an automatic procedure for compulsory license in case of overpricing, supplemented by India's ineffective price control regime, is guaranteed to make the situation worse.

The Indian government needed to amend only section 5 of the 1970s patents act to provide for product patents; instead there are more than 70 amendments. India has not thought it fit to use the flexibilities afforded by TRIPS Agreement and the 2001 Doha Declaration. Primacy has been given to concerns of MNCs than the needs of the people of India. India is now a major source of good quality, low-priced APIs

According to India's amended patents law, medicines patented before 1st January 1995, irrespective of the date of launch by Indian companies, can be freely marketed without any arrangement with the innovator company irrespective of the expiry date of the patent

and formulations for many third world countries. This position will be affected especially with respect to new drugs, which would enjoy a patent protection of 20 years, unless the Government of India issues a compulsory license in the interest of public health.

The March 2005 amendments to India's patent laws have restricted the ability of India to produce generic copies of *new* drugs that will be granted patents in India after January 1, 2005. However, according to WHO sources, 90 percent of the medicines on the Essential Drug List are out of patent and therefore LDCs can still import medicines from India. This overrides existing patents obligations to innovator companies until 2016 after which they can invoke the principle of parallel imports, if they have not signed Free Trade Agreements (FTAs).

To leave it to market forces to find a cure for AIDS or drug resistant TB is being too callous about our collective fate

TRIPS Plus, Free Trade Agreements

Many developing countries, including Kenya, Malawi and India, have enacted stronger laws than the minimum required by TRIPS. Many developing countries have signed free trade agreements with the US and/or the EU which has given pharmaceutical majors an advantage through these bilateral free trade agreements.

Presently 13 countries have signed free trade agreements with the USA and 47 others have begun, or are due to begin, negotiations on trade agreements, which are likely to contain TRIPS plus provisions.

Business and research: no end in themselves

Business, trade and discovery is for overall human development, and not the other way around. Unfortunately the TRIPS/WTO thinking endorses the latter. To leave it to market forces to find a cure for AIDS or drug resistant TB is being too callous about our collective fate. A new paradigm for funding and doing research for public purposes is required.³

There have been discussions on nonpatent led drug discovery with suggestions including:

- Government funded drug research (such as the CSIR in India and NIH in the US);
- Public-private partnerships driven by the needs and disease profile of a country;
- What could be classified as 'open source' biotechnology Research and Development;
- The idea of a patent pool where individuals and groups develop drugs and put it in the public domain for a reasonable remuneration;
- The proposed global biomedical R&D treaty which would permit each country to adopt its own form of R&D.

Other important strategies would include South-South technology transfer and trade collaboration in the matter of research, production and availability of medicines. It is also important to resist the tendency of professionals in WHO and international bodies to go overboard and mystify technology of drug production and formulations to harmonize standards. Such tendencies serve as trade and production barriers even as the need of the hour is demystification of production technologies of pharmaceuticals.

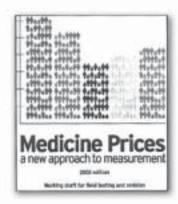
Dr S. Srinivasan has been associated with LOCOST (Low Cost Standard Therapeutics), Baroda, India. LOCOST (www.locostindia.com) has been making quality essential generic medicines which it markets at low prices for the NGO sector since 1983. The author (locost@satyam.net.in) and LOCOST have been involved in India, with policy issues of pricing, availability and rationality of drugs nationally.

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- See for instance: The Truth About the Drug Companies: How they deceive us and what to do about it. Marcia Angell. Random House, 2004.
- ² Dr Gulhati, Editor, MIMS India (Monthly Index of Medical Specialties.
 ³ For one suggested model see: http://www.cptech.org/ip/health/rndtf/
 or http://www.cptech.org/workingdrafts/24feb05WHOen.pdf

EFFECTS OF PRICING ON ACCESS

WHAT THE WHO/HAI MEDICINES PRICING SURVEYS TELL US



Around half of the population in poorly developed areas of Africa and Asia lacks access to essential medicines. The poorest people often pay the greatest out-of-pocket expenses for medicines. The World Health Organization (WHO) and a number of non governmental and civil society organizations that support countries in their efforts to improve access to health care, have drawn attention to the unacceptably low numbers of people who are able to access essential medicines. They point to unaffordable prices, overstretched health systems, and lack of financing mechanisms and human resources to manage pharmaceuticals as the major factors contributing to limited access to essential medicines^{1,2}.

A ccording to the World Health Organization (WHO), there are four key factors affecting access to essential medicines namely: rational selection and use of medicines, affordable prices, sustainable financing, and reliable health and supply systems.



There is limited knowledge about the prices of medicines, or how these prices are set between the manufacturers' selling price and the price that the patient pays. Reliable information and price transparency are needed to ensure that favourable purchasing agreements are negotiated and relevant policies introduced.

To tackle the challenges of availability and affordability of medicines, WHO and Health Action International (HAI) conducted pricing surveys in several countries. So far pricing surveys have been carried out in around 40 countries globally, including 12 sub-Saharan African countries³.

The surveys sought to answer the following questions:

- What prices do people pay for key medicines?
- Do the prices and availability of the same medicines vary in different sectors?
- Do the prices and availability of the same medicines vary in different sectors in a country and across countries?
- What is the difference in prices of branded and generic equivalent medicines?
- How do procurement prices compare with international prices and with local retail prices?
- What taxes and duties are levied on medicines and what is the level of the various mark-ups which contribute to retail prices?
- How affordable are medicines for the public?

The process

The surveys in the 12 African countries involved multi-stakeholder participation by all the Ministries of Health, as well as WHO and in several countries Civil Society Organizations – including the Ghana Catholic Health Service, the Kenyan branch of the International Network for Rational Use of Drugs

There is limited knowledge about the prices of medicines or how these prices are set



A patient receives treatment at a rural treatment centre

The overall purpose of
the WHO/HAI
medicines pricing survey
methodology is to
systematically collect data
and analyze affordability
of medicines, price
differences within
countries, and pricing
structure - including retail
prices to the consumer

(INRUD) and Health Promotion and Social Development (HEPS) in Uganda – played a key role in the work, through the HAI Africa network.

WHO and HAI Africa are involved in developing follow-up recommendations and in contributing to analysis at country, regional and global level. This coherence has been possible because the pricing surveys are part of a wider collaborative programme between WHO and HAI Africa. The collaboration programme aims at facilitating improved access to medicines in Africa and is funded by the United Kingdom Department for International Development (DFID). DFID also co-funded the global dimension of the pricing survey that has included development of the methodology.

The collaboration has enabled WHO to appoint National Professional Officers (NPOs) in 14 countries in Africa, as of July 2005. The NPOs are pharmaceutical specialists whose work is to support Ministries of Health on a wide range of medicines' access, safety and rational use issues, defined in the WHO (2004-2007) medicines strategy.

Summary of findings from eight African countries

Preliminary findings of the pricing surveys conducted in Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda and Zimbabwe in 2005 are as follows: Public sector procurement prices: Overall, fair prices were observed in public sector procurement; however there was generally poor availability in the public facilities. Five countries reported their procurement prices as being less than the international reference price (MSH 2003) (n=6 countries).

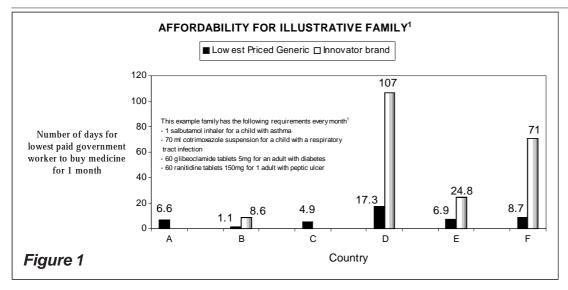
Private sector prices: Medicine prices were considerably higher in the private sector. The median patient prices for the lowest price generic were twice as high when bought from dispensing doctors as compared to private pharmacies (n=2 countries).

Prices of branded and generic medicines: Prices of originator brands were considerably higher than the prices of their lowest priced generic equivalents. In private pharmacies, branded medicines were found to be on average four times more expensive than the lowest priced generic equivalent. This however varied from around twice to almost seven times between countries (n=8 countries).

Variations in prices within and between countries: There was a lack of consistency in the pricing of medicines within countries as well as large price variations for the same brand or generic entity within and between sectors. In some countries, there were significant variations in medicine price between public sector facilities. In one country prices varied, on average, by three times for the same branded or generic entity within the same sector for quite a number of items this variation was greater than ten times. There were large variations in prices between countries for the same medicine; the price of branded medicines varied on average by 220% between countries, and by 217% for the lowest priced generic available (n=8 countries).

Affordability: Medicines were generally unaffordable for a large proportion of the population – particularly for chronic diseases.

Figure 1 illustrates the affordability of medicines for a family across six countries. In the family, there is an



asthmatic child with a respiratory infection, an adult with diabetes and an adult with a peptic ulcer.

In country "D", a lowest paid government worker would need to work 107 days or 17.3 days for branded or generic medicines respectively to pay for a month's treatment and the course of antibiotics. In five of the six countries, it would take an average five or more days salary to pay for the medicines.

It should be noted that many families' incomes are lower than that of the lowest paid government worker and hence these medicines are probably unaffordable to the majority of the population. The level of implementing practices of generic prescribing and dispensing therefore has a major impact on the proportion of income that patients have to pay for their medicines.

The out-of-pocket affordability of malaria treatments is critical in malaria endemic countries. The affordability of a course of sulphadoxine-pyrimethamine tablets was found to be as little as 0.1 days and as much as 1.3 days salary for the lowest paid government worker depending on whether branded or generic medicine were purchased. The variation between countries in affordability was 820% for the branded and 1400% for the available lowest priced generic.

For most sections of the population, there is often a trade-off between, food, housing, and children's education, or the purchase of essential medicines.

Next steps

The strategic approaches identified at country level that need to be addressed to make medicine prices more accessible and affordable are: improving availability in the public sector; improving availability and appropriate use of generic medicines including generic substitution; providing reliable price information; continuous monitoring of procurement and retail prices; improving efficiency of supply and distribution systems; regulating mark-ups, and removing import taxes and levies on essential medicines.

Having identified these areas in need of improvement, Ministries of Health can begin to work with WHO, HAI Africa, and HAI Africa partners on the steps that need to be taken at regional and at global level in order to make medicines more accessible and affordable.

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Philippa Saunders is the consultant responsible for support to the WHO/HAI Africa Collaboration Programme, working on behalf of DFID.

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- 1 Pharmaceutical Sector Surveys carried out in 11 African countries by Ministries of Health in collaboration with WHO, and in some countries HAI-Africa partners, between 2001 and 2003
- 2 Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines http://ww.unmillenniumproject.org/reports/tf_essentialmedecines.htm
- 3 Chad, Cameroon, Ethiopia, Ghana, Kenya, Mali, Nigeria, Senegal, South Africa, Tanzania, Uganda, Zimbabwe

For most sections of the population, there is often a trade-off between, food, housing, and children's education, or the purchase of essential medicines



A patient purchases medicines at the Mulanje Hospital Pharmacy in Malawi

GETTING MEDICINES TO THE PEOPLE

Without continuous availability of good quality medicines and medical supplies it is not possible for any health system to provide appropriate care for the people it serves. The existence of a reliable drug supply systems is one of the essential elements for access to medicines.

To determine whether or not a group of people have access to medicines one has to consider how readily they can avail themselves with the most basic essential medicines. This evaluation has to take into account cost, physical proximity to the source of the medicines and presence of the medicines at the time they are needed. Other factors such as the effectiveness and quality of the medicines as well as the information required to use the medicines properly should also be taken into account for a more comprehensive appreciation of access.

For populations with low levels of literacy and limited access to information the situation may be even worse since there is a general conviction that every ailment has a corresponding capsule, tablet, or injection for its resolution. In such cases people's perception of the effectiveness of the health system depends largely on the availability of medicines. Any effort to strengthen health care delivery therefore must take into account the issue of improving access to medicines.

Unfortunately it is estimated that nearly one third of the world's population have no access to the medicines that they critically need for a decent quality of life. The worst affected are the poor in Africa and India. Sadly, this situation exists and persists even though it is known that if the world's resources were harnessed in the right way it would be possible to provide the entire global population with at least the basic essential medicines.

Supply systems

Access to essential medicines depends on a nucleus of key factors including rational selection, affordable pricing, sustainable financing and reliable supply systems. A medicine supply system, encompasses the procurement component, warehousing and logistics management, the transportation, and human resources throughout the whole supply chain. Any good medicine supply system should aim at ensuring continuous availability of good quality, low cost, essential drugs with limited stockouts and low service delivery costs.

Supply systems serving government health facilities are often based on one of five approaches: a government owned central medical store, an autonomous supply agency, a direct delivery system, a prime vendor system or a fully private supply system.

The supply systems in developing countries are varied but in many countries are said to be 'inefficient and poorly attuned to current needs. Even in a country like Namibia, which by African standards spends a significant amount per capita on health, the public drug supply system is inefficient. Although the Namibian government is often able to get supplies to facility level, lack of personnel and poor inventory management among others mean the system is not reliable.

The absence of an effective government supply system often means a lot of other players have to come in to fill the gaps creating, in some cases a complex multifaceted medicine supply system. In Uganda, for example, there is a government supply system that primarily serves government facilities, a church owned store that supplies mainly Faith-Based Organisations (FBO's) and Non Governmental Organizations (NGOs), as well as a lot of privately owned wholesalers and distributors who target whoever is willing and able to buy their products. However, none of these channels of supply are exclusive and there is a lot of overlap (see figure 1).

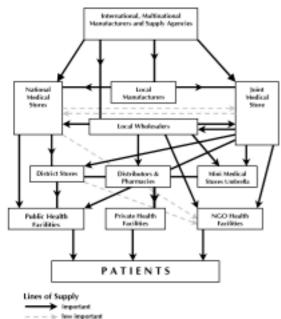
Despite the fact that there are so many largely independent players in the system on many occasions one finds

Effective distribution depends on good communication, cost containement and a well designed, well managed system.



that suddenly an important medicine cannot be availed in adequate quantities from any of the major suppliers.

Responsiveness of supply systems



Responsiveness of supply systems in poor countries is rather limited in the sense that they are not able to keep up with the changes in the dynamics of the population with respect to numbers. morbidity patterns, population movements and demographic profiles. Furthermore, because of inadequate funds available for health in general and medicines, in particular the supply systems often focus on only providing medicines for which there are sufficient numbers within the population to make it economically justifiable. This means that medicines for rare conditions are hardly ever availed, or if they are, then only for those who can afford to pay.

One of the critical inputs for a supply system is a clear and timely indication of what you need to supply. Having adopted the Essential Drugs Concept promoted by WHO, many countries have Essential Drug Lists that are supposed to provide the basis for national procurement of medicines. However, Essential Drugs Lists are not updated frequently enough to keep up with the product development and changes in morbidity patterns.

Another problem that plagues supply systems in developing countries is

corruption. At the procurement level, flawed processes lead to misappropriation of resources, purchase of substandard products or even complete failure to avail much needed products.

Good procurement procedures are important for access. Poorly executed procurement leads to drug shortages, poor quality products and high prices. In most developing countries there are many players involved in procurement including government drug supply agencies, NGOs, donor agencies individuals as well as private providers. This complex mix can lead to wastage and inefficiency. In addition, drug leakages at various levels in the national supply chain are common and greatly compromise the quality of care provided by the system.

The development of reliable and effective supply systems is further hampered by the lack of adequate human resources. There are not enough people with the skills and knowledge that are needed to move the right medicines in the right quantities at the right time to the people who need them the most.

Various strategies have been tried out in different situations to try and ensure effective and efficient supply of medicines. In El Salvador, a single commercial wholesaler was contracted to take care of the country's supply system after tenders were awarded by the Government. The vendor is responsible for managing purchase orders, storage and distribution. This model was developed to increase effectiveness and efficiency in inventory management of which cost-savings would be translated into broader coverage to reach the poor and rural segments of the population.

Distribution

For players in the medicine supply systems in poor countries, getting medicines and supplies out to where they are needed is an unending challenge. Poor road infrastructure, even poorer communication, vast distances and insecurity are among the many factors that have to be taken into

There just are not enough people with the skills and knowledge that are needed to move the right medicines in the right quantities at the right time to the people who need them the most



Offloading medical supplies for distribution

Effective distribution depends on good communication, cost containment and a well designed, well managed system account. While it is often possible to get supplies into the urban centres, supply to rural and remote areas is often haphazard and unreliable. The fact that people in these areas are on the whole often too poor to support commercial medicine supply enterprises means that even in the cases where people could pay for their medicines the medicines are just not available. Effective distribution depends on good communication, cost containment and a well designed, well managed system.

An international perspective

In 1999 it was estimated that NGOs distributed 20% of the global supply of medicines. The World Health Organization (WHO) has been working on mechanisms to collaborate with NGOs in medicine supply and distribution since the early 1990's. WHO found themselves in a unique position where they could link with or to Ministries of Health, NGOs and National Drug Programmes, links which proved beneficial in furthering the work of improving access to medicines.

The 3 x 5 initiative of WHO has ensuring 'an effective and reliable supply of medicines and diagnostics' as one of its areas of focus. In this regard, the Global AIDS Medicines and Diagnostic Service was set up to ensure that poor countries have access to quality medicines and

diagnostic tools at the best prices. The service was intended to help countries manage and supply products for the treatment and follow-up of those who are undergoing care. The WHO prequalification scheme takes the responsibility for evaluating medicines, manufacturers, laboratories, procurement agencies and making sure that they comply with international quality safety and efficacy standards.

The usefulness of collaboration in supply and distribution is demonstrated in the programme set up by the pharmaceutical company Merck for the donation of Mectizan® (Ivermectin) to help patients suffering from river blindness. The success of this global donation programme is attributed in part to the evolution of a reliable and effective distribution system. The programme, which was set up in 1988, has benefited poor patients in over 30 countries. The programme was built on the premise of enabling communities to manage their own distribution system for the medicines needed to control and eradicate a disease that was causing ill health and loss of economic productivity.

Getting things right

Ensuring effectiveness in the supply chain is not an issue for developing countries alone. Developed nations which provide developing countries with technical and financial assistance for health care must ensure that part of this support is channelled to building effective, efficient and sustainable systems.

New global initiatives such as the Global Fund to fight AIDS, TB and Malaria and the US government PEPFAR initiative provide opportunities for developing countries to improve their health systems by availing much needed additional resources. However, it remains to be seen whether things will really take a turn for the better after implementation of these programmes.

Translating opportunities into concrete benefits, not only for today but for the far future, has always been a challenge for many countries in Africa. Human resource development, for example, is one area that governments could ensure benefits from these global initiatives. Transfer of skills and expertise from the North to the South is vital to ensure sustainability of health programmes and prevention of further decline of the people's health status. Every effort should be made to build the capacity of health personnel not just from the narrow perspective of AIDS care but in a way that can make them useful to the health system as a whole. Governments need to ensure that these initiatives are implemented in such a way that existing systems are strengthened or at the very least safeguarded.

Another recommendation made for improving supply systems is the development of best practices that can be shared among countries that need to improve their systems. An example of a first step in this direction is the guidelines for Drug Supply Organizations developed by the members of the Ecumenical Pharmaceutical Network (EPN). These guidelines highlight a number of area which are important in maintaining a good drug supply organization.

A public private mix is also recommended in order to realize an efficient and effective supply of medicines. Closer interaction between the different players involved in supply would ensure that essential medicines are available. However, public-private partnership is not easy to put in practice as it seems on paper. Getting governments to commit to real partnerships and not marriages of convenience remains a considerable challenge. The private sector must continue to lobby for recognition as crucial players in the provision of care and demand for their efforts to be supported.

Conclusion

The battle for universal access to medicines appears to be one that has only started. The state of the supply and distribution systems in poor countries is intimately linked to poverty, corruption, low levels of human development and a



MEDS warehouse in Nairobi, Kenya

host of other ills that continue to confound politicians, economists and scientists. Commitment is required from leaders at the highest level if real progress is to be achieved. Countries that still have to grapple with issues of access must learn from each other and use existing best practices to move their systems forward to a level that can ensure that national health goals are realized and that people enjoy the dignity that is their right.

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Countries that still have to grapple with issues of access must learn from each other and use existing best practices to move their systems forward to a level that can ensure that national health goals are realised and that people enjoy the dignity that is their right

HUMAN RESOURCES: THE ENGINE THAT DRIVES IT ALL

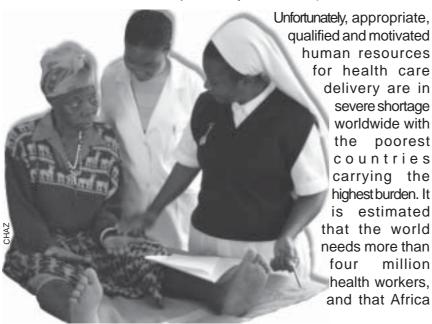
Availability of appropriately qualified and motivated human resources in any health care delivery system increases the quality of services. It usually also results in appropriate or optimal use of resources within the system including medicines. However, there is currently a crisis in human resources for health with low-income countries bearing the brunt of the problem.

> uman resources are undoubtedly the most important factor in effective health care. It is people who work to prevent diseases, administer the drugs and vaccines, perform the operations, take care of the invalids and provide the necessary services for cures. Availability of adequate and qualified and motivated personnel is therefore key to ensuring quality services.

> A health care delivery system without consistent supply of essential medicines lacks credibility and frustrates preventive and promotive programmes. With specific regard to the effect of human resource on access to essential medicines, what springs to mind immediately is pharmacy staff. However, access and appropriate use of drugs involves other health workers. Drug treatment involves prescribers (doctors, clinical officers), laboratory personnel, nurses and dispensers (pharmacists, pharmacy technologists, pharmacy assistants).

appropriate, qualified and motivated human resources for health care delivery are in severe shortage worldwide with the poorest countries carrying the highest burden

A Clinical officer and a nurse attend to a patient at a mission hospital in Zambia



human resources for health care delivery are in severe shortage worldwide with the poorest countries carrying the highest burden. It estimated that the world needs more than million four health workers. and that Africa alone requires one million additional health workers to ensure the staffing levels required to deliver basic health interventions. Currently, there are only 750,000 health workers in Africa (0.8 health worker for every 1000 people) against a world median density of 5 per 1,000 people.

Causes of the human resources deficit

Many factors contribute to the shortage of health workers:

Absolute shortage in numbers

Insufficient training opportunities mean that very few people are joining the health field. For example, 24 out of 47 countries in Sub-Saharan Africa have only one medical school and 11 countries have no medical school at all. This is compounded by the fact that many highly trained and experienced health professionals from low-income countries, are lured to work in highincome countries. Paradoxically the rich countries to which health wo rkers migrate to possess well developed education systems. For example a country like Zambia, which has only one School of Pharmacy and one School of Medicine is losing its doctors and pharmacists to countries like the United Kingdom which has several medical schools.

HIV/AIDS is the second major factor contributing to shortage in numbers of health workers. In addition to increased workload and the stress on their morale. many health workers are dying from AIDS-related illnesses. There is also loss of man-hours as when workers are either sick themselves or absent from work in order to look after sick spouses or kin. In some countries between 18 percent and 41 percent of the health workforce are already infected with the virus.

Skills imbalance

In many countries skills imbalance create huge inefficiencies. Often, health care systems depend too much on doctors and specialists leading to the neglect of community-based public health. This leads to the neglect on the training and deployment of health workers with skills appropriate to the level of care needed such as auxiliary and community workers.

Urban/rural mal-distribution

Mal-distribution within the country includes urban concentration of workers, a common problem in many countries. For example in Tanzania, the city of Dar es Salaam alone has nearly 30 times as many medical officers and medical specialist as other rural districts. Unequal distribution of staff between public and private sectors is also common. A growing trend in this area is the movement of qualified staff to international organizations and NGOs, sometimes to carry out duties that do not fully utilize their health skills.

Brain drain

International migration is an issue that seriously affects the sustainability of health systems in developing countries. The effects are most severe in English speaking countries of sub Saharan Africa. It is estimated that 60 percent of doctors trained in Ghana in the 1980s have left the country. In 2003, the UK alone had 5880 health and medical personnel from South Africa, 2825 from Zimbabwe, 1510 from Nigeria and 850 from Ghana.

It is estimated that each migrating health professional represents a loss of US\$ 184,000 and five years training investment to Africa. The idea that repatriated overseas earnings could make up for the deficiency is unrealistic, as the income does not necessarily find its way into health care improvements. Furthermore, the loss of well trained, experienced personnel who would serve

Building human resource capacity in drug management

The Churches Health Association of Zambia (CHAZ) supports the training of Pharmacists and Pharmacy Technologists who upon completion are posted to member institutions. In addition, CHAZ conducts in service training in Drug Management and Appropriate Use. The programme has been going on for the past eight years.

To evaluate the effect of posting trained pharmacy staff, CHAZ conducts drug indicator studies to compare drug management and availability of essential drugs in institutions with trained pharmacy staff and those without. In these studies, managers of the health institutions are interviewed about their perceptions of drug management and availability of essential medicines before and after the posting of trained pharmaceutical staff.

So far, results show that institutions with trained pharmaceutical staff manage drug supply better than those without. In addition, institutions where the doctors in charge have attended in-service training in Drug Management and Rational Use support programmes to improve appropriate use of medicines; and have a higher score in terms of availability of indicator drugs.

as role models and teachers of younger health personnel cannot be compensated by monetary terms. Since very few health personnel move to the developing countries, the developing countries experience all drain but no gain.

Poor work environments

One of the main issues that makes health workers look for opportunities abroad is the low level of compensation. For example the average monthly salary for a doctor in Ghana and Zambia is just over \$400 while a nurse in the UK National Health Service earns about \$2576!

Given the macroeconomic and fiscal reality of the African countries and other developing countries, large scale increases in salaries of health workers is difficult. The poor emoluments are further complicated by lack of adequate working tools such as supplies, facilities, and other non-financial incentives such as training and career advancement opportunities, housing, education facilities for children, governance and management shortcomings and political or personal security.



The loss of well-trained, experienced personnel who would serve as role models and teachers of younger health personnel cannot be compensated by monetary terms

Weak knowledge base

Data and research on human resources are underdeveloped, sparse and fragmented. This hampers planning, policy development and programming and makes it difficult to set up workforce norms, standards and documenting of best practices.

Addressing the health workforce crisis

The need to address the health workforce crisis has been receiving attention with several meetings and consultations taking place to contribute towards an action agenda. Among these are the High level Forum (HLF) and the Joint Learning initiative (JLI) that have proposed ways to mobilize and strengthen the human resources for health.

In summary, strategies are proposed to address three core objectives: coverage strategies to promote

numeric adequacy, appropriate worker skills mix and outreach to vulnerable populations; motivation strategies to focus on adequate remunerations, positive work and career environments and supportive health systems; and strategies

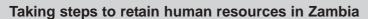
focusing on advancing competencies through educating for appropriate attitudes and skills, training for continuous learning and cultivating leadership, entrepreneurship and innovation.

Implementing these strategies will need country-led action, political commitment and resource allocation. It will also mean a multi-sectoral approach involving the ministries of labour, finance and education, and other stakeholders including the private for profit and notfor-profit organizations, academia and professional associations. The response must also include the international community as technical support and external resources will be needed to overcome macroeconomic constraint of the poor countries, and for educational programmes. The establishment of a special global education fund open to application from individual countries for its education investment plans has been proposed. The plans are there, the challenge is making it happen.

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A health worker conducts an inventory of tablets



The health workers' migration crisis has put many developing countries on the alert. Zambia is no exception. As a low-income country, the government finds it difficult to retain health workers due to the poor working environment. This has led to the massive brain drain of nurses, doctors, clinical officers, pharmacists and other health workers.

The Zambian government, with support from the Netherlands embassy has developed a scheme aimed at retaining medical doctors within the public health care system. The scheme provides for the doctors' salaries, rural hardship allowances, education allowances as well as postgraduate training for the doctors after completion of a three-year contract. The doctors also have access to loan facilities. The scheme has so far retained 68 doctors who are serving in rural areas.

This scheme does have its limitations; as it only targets doctors, its impact is inadequate. Nurses and clinical officers who in most cases are the only staff serving at the health centre level are not part of the scheme. This means that they are most likely to migrate though they are the most needed particularly in rural settings. Another limitation is that since the scheme only targets doctors in the rural setting, those in urban centres do not have incentives to work in government facilities and therefore prefer to work for non governmental organizations or to venture into private practice which is more lucrative than working for the government.

This scheme, though a step forward towards retaining human resource in healthcare, needs to be developed and implemented on a wider scale to accommodate all cadres of health workers.

BALANCING SERVICE AND PROFIT USING FRANCHISE MODELS

Child and family Wellness Shops in Kenya

ew would argue that a single mother living in the Kenyan interior, or a widowed father of seven surviving on the shores of Lake Victoria should have "access" to essential medicines that keep their children alive and healthy. Many people in rural areas do not have access to basic medicine for the most common and easily cured diseases.

Marcy is a mother of three who lives in a farming village near Mt. Kenya. In the past, Marcy had to trek one and a half hours to the government dispensary to get medicine for herself and her family. After waiting for several hours, she often found that the clinic did not have the drugs she needed. She either had to do without treatment and medication or travel another 20 kilometres using a Public Service Vehicle, which would cost her additional time and money.

Bringing services closer to the people

Child and Family Wellness Shops (CFWshops) is a franchised network of clinics and drug shops that aims to provide access to inexpensive essential medicine to children and families in rural Kenya, to mothers like Marcy. In August 2004, CFWshops opened a clinic two hundred metres from Marcy's home. As a result, when her five-year old daughter Caro came down with malaria in late March, Marcy did not have to walk to the government clinic or worry whether the medicine would be available.

"Since the [CFWshop] clinic opened we are very happy because before we had to travel a long way [to the government health centre]. There we had to wait in a long line and many times they didn't even have medicine," explains Marcy. Now she has access to inexpensive, quality medicine a few footsteps away from her home.

Marcy's story is similar to the stories of many other CFWshops' patients who in the past have had to travel long distances to health facilities that often lacked essential drugs. The Sustainable Healthcare Enterprise Foundation (SHEF) created the CFWshops network to help solve this problem by developing a sustainable and reliable model for the distribution of essential medicine. Instead of relying solely on donor support or government sponsorship, SHEF uses a micro-franchise model.

To start off, SHEF gives the CFWShops franchisee a loan, an initial stock of medicine, a month-long training course on basic medical treatment and business management, furniture, and other materials needed to start the business. Once the outlet is open SHEF's fieldwork staff visits the franchisee regularly. The staff provide a consistent supply of medicine and work with franchisees to ensure compliance with franchise regulations. The fieldworkers also assist franchisees to develop their businesses through



Many people in rural areas do not have access to basic medicine for the most common and easily cured diseases.

A healthworker consults with a patient



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A major difference between SHEF and for-profit franchises is that CFWshops targets communities that are inhospitable business environments



A mother holds her child and an insecticide treated net (ITN). The ITN was provided by a SHEF franchise shop

targeted marketing strategies and community awareness. Franchisees pay back the loans for the initial stock of drugs in small monthly instalments that are paid over a three-year period. Ideally, after this period the franchisees should be able to maintain enough profit to restock the outlets while retaining a salary for themselves and any employees.

Franchise with a difference

Unlike many social franchising organizations that are "fractional franchises" and target a portion of existing operators' businesses, CFWshops are stand-alone franchises. SHEF serves as a franchiser, overseeing the entire outlet from branding to procurement and the treatment of patients. The benefits of this system include the guarantee of quality service through standard regulations for the treatment of patients, as well as a mass procurement system that keeps costs low for the franchisees and the patients.

The CFWshops mission is similar to that of many international franchises: to provide a quality product with efficient service that is standardized across the organization. However, unlike most franchise operations, SHEF is not looking to make a profit at the franchiser level. Instead, the relatively small "franchise fees" are built into the cost of the medicine that the franchisees buy. Currently, these fees support only a small portion of SHEF's operational costs, with the rest being subsidized by external funding; however, as the network grows this gap will decrease and less outside funding will be needed to support the franchise.

A major difference between SHEF and for-profit franchises is that CFWshops targets communities that are inhospitable business environments. Since the goal is to provide access to medicine for people who may otherwise not have it, most outlets are located in rural areas where the primary source of income is small scale farming. In these communities, irregular cash flow means that people may not have money to pay for medicine. Even though the

medicine at CFWshops is generally less expensive than at other private clinics or pharmacies, extreme poverty, especially among the elderly and single mothers, still makes it impossible for them to afford it.

Given these circumstances, most franchisees have developed credit systems. John Kimenyi, owner of Ena CFWclinic near Embu has established credit facilities for those who have no cash at hand. However, on a daily basis he receives at least two impoverished patients who can barely even afford food. In such situations he gives the patients the medicine they need, accepting the loss rather than trying to give credit that will most likely never be paid.

Despite this less than ideal business environment, SHEF realizes that the profitability of individual outlets is vital for their sustainability. Furthermore, measurable impact increases with the profitability of the individual outlet. Hence the more the franchisees sell, the more patients they can see and help, and the more motivated they become.

Creating trust and demand

Franchising has proved a successful model in assisting individual outlets become profitable. One reason is that franchising requires standardization and a link to a larger network. This in turn creates something invaluable for the franchisees: trust.

"When the community sees the CFWshop vehicle outside my clinic," says Rosemary who owns Huruma CFWclinic, "they see that I have support and I am a part of something bigger, then they begin to trust me and my product."

Even though government health centres have long been known for their inefficiency and lack of stock, the people trust the government to give them good medicine at a fair price (usually about \$13) for diagnosis and treatment. Even those who have given up on the government system are reluctant to go to a private clinic or chemist who might sacrifice quality for making a profit. Therefore, as Rosemary observes, seeing that the individual outlets are

"overseen" by an umbrella organization creates trust.

Prevention rather than cure

Once trust is established and the outlet earns a favourable reputation in the community, the next step is to create awareness in the community on the importance of prevention. This increases demand for preventative products rather than curative drugs. SHEF recently rolled out a new marketing plan for the outlets focusing on health education. The result was improved sales and patient numbers, creating substantial impact in the communities.

In February-April 2005 the outlets ran a WaterGuard Promotion. WaterGuard is an inexpensive chemical that kills bacteria and prevents most waterborne diseases. One bottle of WaterGuard costs about \$0.6 and can treat water for a family for six months. For the promotion, franchisees gave out free treated drinking water in their outlets and were provided with WaterGuard to demonstrate how to treat water. The demonstrations were conducted in schools. churches and homes. They also taught about the importance of prevention and how buying WaterGuard is less expensive in the long run than treating diseases caused by drinking contaminated water. By the end of March the sale of WaterGuard in the network had increased by over two hundred percent. At Karaba clinic in Mbeere district, franchisee Jane Kiswali sold twenty bottles of WaterGuard in just one and a half weeks, and says that the promotion has had a substantial impact on the number of cases of Typhoid and worms in her community.

Since March, SHEF has subsidized the cost of Insecticide Treated Nets (ITNs) and Amodiaquine (a malaria treatment) by fifty percent. Franchisees were provided with posters and pamphlets on prevention and treatment of Malaria. The response was overwhelming; the outlets sold 6,000 nets in the first week of the promotion. These promotions are the beginning of marketing plans that will encourage the sale of preventative products.

Growing network



Clean water for school children

Once the rural consumers realize the quality and consistency of the service offered at each CFWshop outlet, the demand is overwhelming. Magombe CFWshop in Bunyala district near Lake Victoria is one example. Margaret, the shop owner and Community Health Worker (CHW), opened her shop only six months ago, and already the community is urging her to hire a nurse so that she can stock and dispense a wider range of drugs. Although there is a chemist and a government health centre within five hundred metres of her shop, the chemist is more expensive and less reliable, while the government centre is almost always out of medicine.

In the past few months, SHEF has made a concerted effort to upgrade shops like Margaret's to clinics. The shops are run by CHWs who have been trained only in basic medical care. For the shops to be upgraded to clinics, the CHW must employ a nurse. The clinics can then stock a wider range of medicine, including antibiotics and injectable drugs. Furthermore, with a nurse at the outlet, the CHW has more time to make home and school visits and attend community events. This coupled with the ability to provide a wider range of services and products has increased sales and patient numbers of outlets that are converted to clinics.

With a recent focus on marketing and improving performance at the outlet level, the SHEF staff is learning exactly what it takes to have a successful shop/clinic. These lessons are translated into system-wide improvements; as the model is refined new outlets that are opened can be more successful right away. The advantage of franchising therefore is not only standardization, but also the replication of a successful business model across a wide range of locations.

SHEF will continue to grow and improve its network in Kenya. The goal is to reach as many people as possible. Being a pioneer in this model has meant that the SHEF staff has had to work and re-work the CFWshop system. The ultimate hope is that people in other countries can learn from the experience of CFWshops and will be inspired by the success of the SHEF model to create their own networks to improve access to medicines for people marginalized areas all over the world.

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CAREshops in Ghana

The CAREshops model is also having impact on local pharmaceutical industry through assured sales and credit management.

n Ghana, as in many developing countries, pharmaceutical services are characterized by comparatively high drug prices, inadequate availability of quality essential drugs and poor quality of services. Most of the wholesale and retail pharmacies are located in the capital city Accra and other urban areas. There are however, over 8,000 licensed chemical sellers (LCS) who provide the first line of pharmaceutical services and are widely distributed in the peri-urban and rural areas. The LCS however have to spend 30 percent of their time travelling long distances to obtain medicines and other supplies. In addition they have to visit multiple sources to obtain the range of products they require. This process adds significantly to their costs.

To address these problems an innovative franchise model called CAREshops was created in 2002. The franchise is a collaboration programme between GMSF Entreprises Limited and Management Sciences for Health (MSH) with funding from the Gates Foundation and DFID. The aim of the CAREShops model is to improve the level of pharmaceutical care and services and the availability of affordable good quality medicines in the underserved areas. The programme works with LCS who have established businesses and are willing to add a package of services to their business.

A patient visits a rural pharmacy



Participating LCS undergo a training programme covering management and entrepreneurial skills, drug management and rational drug use and the management of simple

ailments of common occurrence in their communities. They are also trained in data collection and to recognize and refer clients whose needs are beyond their capacities. On their part, GSMF Ltd, acting as the franchiser, procures drugs and supplies centrally and provides doorto-door delivery to the LCS. Thus the LCS outlets benefit through gaining skills to run their business, upgrading of their outlets and improved visibility through the use of CAREshop logo and colours.

The CAREshop franchise has been successfully implemented in 20 districts in three regions of Ghana. Starting with 41 LCS in 2003, the number has grown to 221 by mid 2005. The participating LCS report increase in sales and growth of their businesses and the community is provided with much needed services. The CAREshops model is also having an impact on local pharmaceutical industry through assured sales and credit management. The data collected by the CAREshop franchisees is used in assisting management decisions, in identifying training needs, in policy formulations on drug consumptions and for other public health issues by the Ministry of Health. The success of the franchise has stimulated participating LCS to emulate the CAREshops.

Even so, the model does have its challenges. The rapid growth in the number of participating LCS presents a challenge in managing, supervising and providing logistical support. Training, a crucial component of the model, is expensive. Furthermore, changing behaviour needs time and perseverance. However the end result of providing good quality pharmaceutical care to all who need it irrespective of where they live is well worth the effort!

From a presentation by **D. E. Mensah**, at Strategies for Enhancing Access to Medicine (SEAM) Conference, 2005.

COMMUNITY ACTION TO IMPROVE ACCESS

n 1983, the sub-prefecture of Bocaranga and a population of 100,000 inhabitants was served by a small rural hospital. Consequently, four dispensaries ran by the Evangelical Church of Brothers (Eglise Evangélique des Frères, EEF) were started to provide medical care to this population. EEF was supported by an American project, which for years used a small plane for the supervision of the dispensaries and the evacuation of critically ill patients to its missionary hospital at Boguila, 200 kms away from Bocaranga. With the completion of the American project, access to health care for the majority of the communities dispersed in the rural villages became difficult, if not impossible.

With the example of EEF in mind, the Catholic Church, which had established itself in Ngaoundaye, decided to commit itself more in the field of health. A project of Primary Health Care (PHC) was born and developed gradually in accordance with the strategy recommended by WHO to sensitize and mobilize the population towards an active community participation.

A small rural hospital was built in Ngaoundaye to become a centre of reference for the northern sector. A team made up of a doctor, a midwife, three graduate nurses, a social worker and a hygiene assistant, shared the tasks to build the "minimum package" of activities in accordance with the national PHC programme.

At the same time, coordination efforts with all the stakeholders present in the subprefecture made it possible to create alliances and synergistic partnerships around the same project. Thus the German Organisation GTZ provided the financial assistance and the Lutheran Church, which had agreed to return to the area after 10 years of absence, provided the technical skills for construction of the buildings. The Catholic Church ensured the training of health staff, and the village communities began to implement their management committees, to choose

their health agents and to provide work forces for the constructions.

The work developed well thanks to a process of "self-promotion through imitation": new health posts became operational each year. The first essential drugs store was inaugurated in Ngaoundaye, but soon, because of the distances, the two sectors, one in the north and one in the South were seperated, and each one developed an autononmous hospital and drug store.

Two different development models were tested, that of Bocaranga under supervision of GTZ, and that of Ngaoundaye under community leadership, with the team of the Catholic Church as technical adviser.



The Community's involvement

The community gradually developed and structured itself in an empirical manner. With the experience gained over the years and the prevailing circumstances, it has evolved into a form that nobody had initially imagined: simple, original, and daring.

In the beginning, the village communities were hesitant to take charge of their health posts since GTZ had always offered financial support. After four years of awareness campaigns, meetings and training courses, each management committee assumed the responsibility for its health post,

The work developed well thanks to a process of "self-promotion through imitation": new health posts became operational each year

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for the hall sector

A pharmacist dispenses medicines at a pharmacy in Central Africa Republic

This rural community
pharmacy has the
potential to become the
financial pillar of any
medical development in
the area it covers

even if reluctant to do so.

Governing body

The health posts formed association namely "Rural Community Pharmacy" ("Pharmacie Rurale Communautaire". PRC). Its legislative body is the general assembly of the posts health management committees :its executive is a board of directors made uр of elected and legitimate members, representing the following institutions: the hospital, the town hall, the education sector, the social services, waste collecting services, and the religous

communities. Being of rural origin each elected member benefits from the technical support of a legitimate member, when in function. Two technical staff and a supervisor ensure the daily management of the PRC and the regular supervision of the health posts. They are recruited through a competitive process and are paid regularly. The other members work voluntarily except for small incentives, which they receive for specific services.

Drug Procurement

Initially, with the assistance of the Catholic Church, the PRC imported drugs directly from Europe via Assomesca (Association of the Medical Charities of the Church in Central African Republic). However, this system soon became complicated and unsustainable in the absence of expatriate personnel and was therefore set aside. The alternative was to support the creation of intermediate depots between the periphery and the central

level. Thus two intermediate depots were created in two large cities: the one of Bossangoa where the Catholic Church is one of the founder members, and the diocesan depot of Bouar. These depots, being members of Assomesca and having a more significant capital and a higher technical level, can get their supplies from either the capital Bangui, or directly from Europe. The peripheral depot, namely the PRC, benefits from a tiny profit margin, but which is sufficient for its functioning, in particular the procurement for the hospital and the health posts. There are currently 25 health posts which manage to ensure a medical cover of 93% of the population. The area in which the PRC operates is approximately 60 km, a distance which can be covered in a day or two by a health agent using a bicycle. To go there and back, it takes one or two days except if there are small bicycle failures due to the bad roads.

Challenges

The PRC remained undamaged during the last civil war in 2001, because its capital was hidden and safeguarded. Thus it could compensate the other health posts that had been ransacked and recently it also funded the construction of a new building for a health post which was damaged during the war.

In the future, this rural community pharmacy has the potential to become the financial pillar of any medical development in the area it covers.

The rural community is proud of their achievements and of the results obtained. The PRC is officially recognized, according to its duly approved statutes, as a self-managed community depot and an associate member of Assomesca, because the Catholic mission, being a legitimate member of its board of directors, continues to play the role of technical adviser.

If the war did not destroy the achievements of these rural communities, two serious dangers currently threaten the efforts and darken the future of PRC.

The first one is the government which always calls upon the denominational private sector for a synergistic and active partnership, while it does not respect its own commitments. As the government no longer has the financial means to support the regions and the health districts, the prefectoral depots have been created in the large cities in spite of already existing depots. The prices of drugs were increased to make it possible to have a profit margin of 40% intended for the functioning of the regions and the health districts. All health facilities, not only the denominational ones, are forced to get their supplies in the new depots. As retail drug prices are fixed, no profit margin is available for the peripheral depots. As retail drug prices are fixed, no profit margin is available for the peripheral depots. As the small health posts do not have a sufficient drug revolving fund and cannot ask their health agents to cover a distance of 300 km by bicycle, they will gradually be excluded from the health system and the posts will become dormant.

The second danger is the irrational interference of certain organisations because they have significant financial means. They seek to impose their humanitarian aid projects without taking into account existing systems. An example is an international NGO which conducted health missions in villages of the Ngaoundaye district to consult and treat for free those aggrieved by war: an action of charity towards the poor. Missions such as these render the PRC dormant. The health agents will return to work on the fields, because they will no longer have their small monthly incentives and the health posts will close their doors. At the end of the project, when the NGO will have achieved its humanitarian mission, the poor will be poorer.

The poor refuse to be taken as hostages. They are free to choose their supplies from wherever they can and want to. They propose other forms of support: training courses to improve the quality of health care and the use of drugs; the

creation of a budget line for health facilities to enable them to give free treatment to the ones in need; the free offer of emergency surgical interventions at hospital level, and of antenatal consultations and labour services at health centre level. There are no shortages of ideas, but so far, the voices of the poor do not have any echoes.

Conclusion

Reflections are imperative for all those who commit themselves in humanitarian aid projects. What is true charity? Assistance or development? Even the Catholic Church via the voice of the Pope, this great master of charity for many decades, has recently called upon all people of goodwill for "A new imagination of charity" (Message for the 13th World Day of the Patient). "A charity which suggests the right approach in various situations making it possible to perceive the particular character of each one and to answer it". A charity which is not a humiliating gift but which brings support to our brothers and sisters to help them to stand up on our sides with the idea of sharing and true solidarity. Charity and development cannot be separated from each other. It is urgent to engage ourselves resolutely with this point of view in mind.

For those who "do not recognize the face of Christ in the features of any person who suffers, and are motivated only by reasons of philanthropic compassion towards the people in need", below is an old Chinese proverb to illustrate the best strategy for PHC:

Go to the people
Live with them
Like them
Start with what they have.
But remember:
The best teacher is the one who,
when the work is completed,
hears the people say:
We did it ourselves!

lone Bertocchi is a medical doctor, who was in charge of a rural hospital in the Central African Republic for 25 years. Currently, she is the health coordinator of the Diocese of Bouar and president of ASSOMESCA, an ecumenical association of Christian medical services, whose main objective is to help its members carry out Primary Health Care activities.

Charity and development cannot be seperated from each other. It is urgent to engage ourselves resolutely with this point of view in mind

UNIVERSAL ACCESS TO MEDICINES: IS THERE A VISION?

EZEKIEL 47: 12 (b)

The following reflection has been prepared by **Moses Manohar** of Inter-Church Services Association (ICSA)

f all the basic needs, one of the most difficult to get especially for impoverished communities is affordable, efficient and effective healthcare and services. Health care is affected by factors among them: affordability/cost/pricing, geographical setting/locality (rural and urban) and accessibility/ availability.

These difficulties make healthcare a luxury more than a necessity for many communities especially those in developing countries. Should this be the case? It is time for the vision of many to become a reality where health care services are available and accessible to all regardless of economic status.

Read Ezekiel 47:12

Prophet Ezekiel was one among eight thousand Jewish captives taken to Babylon after the fall of Jerusalem to Nebuchadnezzar in 598 BC. While in Babylon, the present Iraq, the prophet saw a vision from God depicting Jerusalem's reconstruction. In his vision there is a long river with trees on either side of its banks.

The trees are referred to as being of "all kinds," to symbolize their variety and "very many," symbolizing their abundance in number. Their leaves do not wither nor their fruits fail - they are not restricted by seasons. The leaves do not involve any commercial activity; they are freely available and are meant for healing. According to Ezekiel's vision, healing is not restricted to a few rare herbs; this emphasizes the ease of which medicines should be accessed.

Our reality

In comparing Ezekiel's vision with our present reality, we realize that there are many differences

that have been brought about over the years by the transformation of society. Patent laws have been developed and are now implemented on food and plants. In most of these cases, the laws are applied in countries far from the products' original countries. Patent laws give a 20-year period for the patent holder to have exclusive marketing rights making prices prohibitive. Pricing

> policies allow profit for traders and medical professionals while those in dire need of the medicines do not receive them due to the high cost of the medicines.

> > The situation has been

worsened by the pharmaceutical organizations' financial influence. They are in positions to fund national elections and influence policies of govern-ments. Essential medicines that save lives and that are not expensive have been replaced with expensive combinations making them inaccessible to those who need them the

Questions for reflection

most.

- 1. Do we have visions? Our world needs visionaries with prophetic zeal to announce and act on having life-saving medicines accessible universally.
- 2. What is our vision for health and healing? Do we identify health and healing with patent rights, brands and exclusive hospitals that only offer specialized treatment? or with food, sanitation and essential medicines?
- 3. Can we realize the vision of Prophet Ezekiel where medicines shall be available as easily as leaves? If so how soon?

Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law

This book provides an analysis of the differences between the WTO's focus to make it possible for countries with insufficient or no manufacturing capacity of pharmaceuticals to have effective use of compulsory licensing and, the EC's regulation to promote differential pricing for needed medicines.

Author: Kathreen Gamharter

Published in 2004 ISBN 3-211-22670-2

Access to essential drugs in poor countries: a lost battle?

This article by B. Pecoul, P. Chirac, P. Trouiller and J. Pinel, focuses on the problems of access to quality drugs for the treatment of diseases that predominantly affect the developing world including poor-quality and counterfeit drugs and; lack of availability of essential drugs due to fluctuating production or prohibitive cost.

Available at:www.dndi.org/cms/public_html/images/article/229/JAMA.pdf

Progress on Global access to HIV Anti-retroviral Therapy – An update on 3 by 5 (June 2005)

This interim report focuses on understanding the reasons for the successes and failures for scaling up HIV/AIDS interventions under the 3by5 initiative. The report makes recommendations concerning the approaches needed to overcome major bottlenecks, the need for sustainable financing mechanisms and greater harmonization of effort by technical and financing partners.

Available online at www.who.int/3by5/Fullreport.June2005.pdf

Global health challenge: Essays on AIDS

This book highlights how developing countries can be organized and motivated to combat HIV/AIDS. It examines blood vaccine research, government strategies to contain the pandemic and media influence over the public in relation to HIV/AIDS.

Available at: www.selectbooks.com.sg/titles/32346.htm

Access to medicines in under-served markets: what are the implications of changes in intellectual property rights, trade and drug registration policy

This is report summarizes studies that examine policy implications of changes in intellectual property protections and drug registration requirements as well as how strengthened intellectual property protections and heightened registration standards may or may not improve access in under-served markets.

Available online at www.unmillenniumproject.org/documents/ TF5-medicines-NotesReferences.pdf

Millennium Development Report: Prescription for healthy development: increasing access to medicines

This report presents an authoritative and in depth look at strategies for increasing the availability, affordability and appropriate use of medicines in developing countries.

Lead Authors: Paula Munderi, Coordinator, Beryl Leach, Joan E. Paluzzi. Published in 2005.

www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf

Drugs and Money – Prices, Affordability and Cost Containment (7th Edition) (WHO, 2003; 158 pages)

This report aims to provide policy makers and regulators with a compact and practical review of the various approaches that have been developed and tested in an effort to contain the overall costs of pharmaceutical services and drug treatment. It devotes considerable attention to the special problems of developing countries and those where the economy is currently in transition.

Available at: www.who.it/InformationSources/Publications/Catalogue/20030429_1

HIV/AIDS: Standard Operating Procedures for Pharmaceutical and Laboratory Services

The Rational Pharmaceutical Management (RPM) Plus Program manual points to several pilot and small scale programs which demonstrate the feasibility of safely, effective use, affordability, geographical accessibility and availability at facility level of ART in resource-poor settings in sub-Saharan Africa and Haiti.

Available online at www.msh.org/projects/rpmplus

Moving Mountains: The Race to Treat Global AIDS

This book reports on the discrimination experienced by people with HIV infection, the risks that women face when they cannot negotiate for safe sex and the challenges faced by primary healthcare systems that serve for many as the only source for treatment.

http://content.nejm.org/cgi/content/short/352/10/1052

Cost-containment mechanisms for essential medicines, including anti-retrovirals, in China – health economics and drugs (EDM Series No. 13)

(WHO; 2002; 30 pages. In English, French and Spanish)
This report tackles the issues of pricing and licensing of medicines in China as well as lessons from other countries experiences in negotiating price discounts.

Available at www.who.int/medicines/library/par/who-edm-par-2003-6/CostContainmentEnglish.pdf

The Global Health Situation and the Mission of the Church in the 21st Century: International and Ecumenical Study Consultation

Forty three health workers, clergy and theologians from 38 churches and related organizations representing a spectrum of Christian traditions came together for this Consultation held in Breklum, Germany from September 25 to 30, 2005.

The consultation was organised by the World Council of Churches (WCC), the Northelbian Centre for World Mission and World Service.

The main objective of the Consultation was to consider important new and foreseeable developments in the global health situation and the consequences these could have for the mission of the Church. The participants engaged in study, dialogue, discussion and prayer in order to better understand the factors that

affect global health and healing. As the state of the world's health worsens, the participants made an urgent call for churches, congregations and individuals to take up the healing ministry in all its dimensions more seriously.

Further details are available on http://www.vehnanjyva.org/breklum/

ECUMENICAL PHARMACEUTICAL NETWORK (EPN)

Increasing positive health outcomes through church-related pharmaceutical services

EPN is an independent, apolitical non-profit Christian organization that works in a context of increasing poverty and need for health services.

Our goal is to increase positive health outcomes through church-related pharmaceutical services and our purpose is to increase the capacity of church-related pharmaceutical activities to provide effective and efficient services. EPN's ultimate beneficiaries are in line with the 'Health for All' ideal; however there is a specific emphasis on the poor and marginalized. The Network's intermediate beneficiaries are its

members—church-related health services and their representatives.

The Network currently has three main programmes: development of an active network with increased pact; maximizing access to essential medicines for church health services and their clients and increasing the capacity of church leaders and church-related health services to respond to the massive challenge of HIV/AIDS treatment.

As part of their efforts to increase access to essential medicines, the Network members have developed a set of 25 factors (guidelines) and an implementation strategy that will expose the practitioner, the

consumer and the institution to the critical issues of access. These guidelines include factors necessary for the institution to access the drugs and others to ensure access for the customer of the institution.

Other access activities include the strengthening of the church-related drug supply organizations so as to ensure appropriate selection, supply, distribution, use and management of the

medicines and capacity building to address the human resource limitations.

Contact deals with various aspects of the churches' and community's involvement in health, and seeks to report topical innovative and courageous approaches to the promotions of health and healing.

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