
Commentary

Narrowing the gap

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Since 1981 AIDS has illuminated, like a roving searchlight, a series of ethical questions, which extend far beyond the apparently narrow limits of one disease. It has revealed, one by one, human attitudes and behaviours that were previously unquestioned, or unobserved - based on unidentified but shaky pre-suppositions.

This commentary offers two contrasting perspectives on the problems facing developing countries. In the first part, I comment on the preceding article, from the perspective of a clinician who has worked for many years in Africa, and who witnessed the emergence of AIDS in the early 1980s and its medical, social, political and economic consequences.¹ In the second, I comment on a conference in Lusaka in September 1999 that addressed many of the issues.

Narrowing the gap?

"Narrowing the gap" raises questions about truth or transparency in the activities of multinational companies, the ethics and economics of health care in global society and the distribution of responsibility for unwanted side effects of new treatments. The scale of HIV infection in developing countries draws attention to weaknesses or instability in theoretical and practical structures, which serve - or should serve - human wellbeing, whenever it is disturbed by disease.

Truth and transparency

During the last 60 years, combined with improved standards of living, the products of pharmaceutical effort and ingenuity have resulted in large gains in life expectancy. These were most marked in rich northern societies, but even poor southern countries had seen it extended by 15 to 20 years, until recently.

However, "the costs of drug development are not small".² A detailed study of costs of clinical trials found that the total cost of new drug development can be as high as \$500 million per drug.³ Patent laws allow a temporary monopoly for the production and sale for a number of years. During this "protected" time companies aim to recoup the

large costs of research and development (R&D). The initially high cost falls, often dramatically, when the patent expires and a generic drug can be manufactured by companies, near to points of use.

Patent protection is the subject of a treaty that is binding upon member countries of the World Trade Organisation (WTO). "The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) sets out minimum standards. WTO member countries have to comply by changing their national regulations to follow the provisions of the agreement. TRIPS requires countries to grant patent protection to pharmaceutical products for a minimum period of 20 years".² The duration of patent protection is not mentioned in "Narrowing the gap" even though "the price of our products is heavily influenced by their R&D costs of \$350-500 million a product".¹

Greater transparency is needed about other "influences" which determine the final price of antiretroviral drugs:

- * What is the actual cost of manufacture, quality control, packaging and distribution?
- * What proportion of total cost to the consumer represents recovery of R&D costs, and what proportion is profit?

However, "with respect to HIV-related drug therapies, it has usually been governments (rather than drug companies) that have paid for initial development, pre-clinical research and clinical research. For the pharmaceutical companies, this significantly lowers the cost of bringing these products to market. For example, the costs of securing Food and Drug Administration approval in the United States for HIV/AIDS drugs has been estimated to be only about \$25 million per drug".^{2,4} This lower estimate of R&D costs for antiretrovirals is withheld.

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) argues that compulsory licensing of drugs (to permit local manufacture of generic versions) would slow down the search for new drugs. Initiatives outlined

in “Narrowing the gap” could be interpreted as evidence for social responsibility – or as reluctant concessions to increasing public pressure from an articulate and economically significant consumer-group: Western users of antiretroviral drugs.

An important background paper, prepared for the International Council of AIDS Service Organisations (ICASO) in 1999, sets out the meaning of “compulsory licensing” and “parallel importing”, both possible strategies for improving access to drugs.² It notes: “Some support for the position that drug prices are not related to replacement of R&D costs is provided by the current price for pentamidine. Pentamidine was a cheap treatment developed to treat sleeping sickness. However, when it was found to be effective in the treatment of AIDS-related *Pneumocystis carinii* pneumonia, the price of pentamidine increased by 500%”.²

Ethics and economics of health care

The late Jonathan Mann’s visionary outlook on HIV/AIDS included the perception that “we do not yet have a global health policy”. (Jonathan Mann was the first Director of WHO’s Global Programme on AIDS.)

In theory WHO, UNAIDS, the World Bank and governments, working in cooperation, have the authority to agree upon a global health policy. In practice health policies (like party politics in some democracies), seem to function on a response-to-the-most-recent-crisis basis, rather than gradually approaching, step by step, agreed universal standards of health care. Priorities are viewed differently by different organisations. Moreover, many decisions are made and implemented by persons who will not be affected by the consequences of those decisions, because they themselves can afford alternative Western-standard medical care when necessary. The practical abolition of double standards in health care might have a dramatic and rapid effect on the quality of care available in developing countries.

Bitter effect

In Lusaka, for example, long before structural adjustment programmes had taken bitter effect, the clinician in charge of an intensive therapy unit pointed out that a few diseases demand immediate local treatment and prove fatal if expertise or equipment are missing. Officers in charge of embassies and non-government organisations (NGOs) were quick to see the personal implications of this — and to provide funds for essential equipment, to the considerable benefit of everyone, rich or poor.

There is an absolute need to increase health budgets in developing countries: health budgets of

less than 10 US\$ per person per annum cannot deliver adequate care, however prudently used. Three strategies are needed:

1. Re-assessment of priorities to redistribute funds away from prestige activities towards health;
2. Cancellation of unrepayable debts, with commitment of funds so released to stepwise improvement of health care for all, in local applications of global policies and
3. Long term investment in agriculture, education and appropriate industrial development, in order to raise gross domestic product (GDP) – for further re-investment in these areas.

“Narrowing the gap” describes planned pilot studies which aim to make patented drugs for prevention and treatment of AIDS-related illnesses, as well as antiretroviral drugs, more widely available. These studies require governments to provide “all the elements of a proper treatment programme, including monitoring for resistance, counselling, and laboratory testing of viral load and CD4 T cell numbers. For its part, the industry partners are subsidising some of the necessary infrastructure costs, including reduced prices for the drugs”. Later an important question is raised: “Are reduced prices any more affordable than full price with a health budget as small as those of many governments?”

A second pertinent question needs to be asked: is the infrastructural support truly appropriate? In countries where more local manufacture of intravenous fluids or standard antibiotics and improved salaries for doctors and nurses (to retain trained staff) are urgently needed, is it ethical to divert laboratory space and scarce personnel to determine viral loads and count CD4 T cells? The answer to both questions may be “No”.

Who is responsible for side effects of new treatments? The side effects of new treatments are not limited to adverse symptoms but also include wider social consequences. For example, over the last 30 years successful vaccination programmes have contributed to “demographic entrapment”, a short-hand term for an imbalance between a country’s population and the agricultural resources needed to feed it, which cannot be relieved by migration or by imports.

In the case of programmes designed to reduce mother-to-child transmission of HIV by administration of antiretroviral drugs during labour and after birth, one certain consequence will be to increase the already large number of children facing life without one or both parents. In resource-poor societies, how should responsibility for coping with this be divided?

Ethics of using scarce resources for doomed patients?

The International Council of AIDS Service Organisations (ICASO) and Zambia recently hosted an international conference in Lusaka of over 6,300 delegates. I greatly respected their achievement in organising the meeting, and its style and content. One innovation was a “Village Programme”. These less formal workshops, discussions and skills-building sessions allowed the general public to join in fora with delegates around themes of People living with AIDS, Women’s issues, Non-governmental organisations, Community and Youth.

Budgets for annual health care are as low as six to 12 US\$ per capita in many heavily HIV-affected countries of Sub-Saharan Africa. What criteria should determine use of funds in these circumstances? The “greatest good for the greatest number” principle suggests that interventions should be highly cost-effective, especially in impact on public health, with minimal add-on costs for infrastructure. In previous decades concentration on safe water, nutrition, vaccinations and treatment for curable common conditions (pneumonia, malaria, gastroenteritis, tuberculosis) was cost-effective, leading to falling infant mortality rates and rising life expectancy in most Sub-Saharan countries—until about ten years ago.

Absolute priority

Since then, as speaker after speaker emphasised, infant mortality is rising again, GDP is falling and losses of ten to 17 years of life expectancy at birth have already been recorded. Regional governments were warned that for reasons of economic, social and political stability—and even security—HIV/AIDS should now take absolute priority over other issues. Debt relief is urgently needed to fund attempts to reduce transmission and impact of HIV infection. Heads of state were bluntly and repeatedly reproved for not being present to attend to detailed warnings and comments, such as: “We can’t afford an army, or a diplomatic presence in so many countries”.

There was general agreement on the most urgent “best buys” for a real impact:

1. Breaking parent-to-child transmission, at a cost of US\$4 per course, using nevirapine;
2. Universally available voluntary counselling and testing (VCT) facilities—because knowing about infection *does* change behaviour;
3. Improved control of sexually transmitted infections, which may require regular treatment of high-risk groups, already shown to be acceptable and effective in pilot studies;

4. Increased per capita specific budgets for HIV/AIDS (Uganda spends US\$1.81 per annum, contrasted with Zambia’s US\$0.73, and is the only country in Africa to show a falling incidence of HIV in the 15-19 age group);
5. Serious investment in *appropriate* reconstruction of health services devastated by years of under-funding and the consequences of “structural adjustment programmes”, followed by long term increases in the proportion of GDP devoted to health promotion and care.
6. Urgent work on a vaccine *for* Africa, using non-B subtypes which are common *in* Africa, (where infection is at least 100-fold higher than in Western Europe), for “even a poor vaccine giving only 30 to 60% protection would save millions of lives” (personal communication: Max Essex, a Harvard-based scientist).

To these priorities I would add: massive investment to improve education and employment prospects for youth. At present, the replacement generation of young people seemed willing to accept and to promote abstinence before marriage and fidelity within it and were constructively critical of the parenting they had received. At the forum entitled Looking to the future, young people did just that—with energy, commitment and sparkle. There were some startling poster messages: “VIRGIN! Teach your kids that it’s not a dirty word!” and “Youth arise, to believe in love. Youth arise, to cherish life. Youth arise, to believe in abstinence!” “Abstinence”, “fidelity”, “good parenting” and “spirituality” were concepts freely and seriously discussed amongst young people.

The positive idealism shown by these young people needs to be encouraged by serious attention to their legitimate demands for dignity and work. They were sadly disappointed that no government officers were present to hear their speakers, many of whom (in my opinion) rivalled international delegates in clarity and quality of strategic thinking.

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References

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