Commentary

Narrowing the gap
Anne Bayley Previously Professor of Surgery, University of Zambia

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 6 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 Organi-
sations (ICASO) in 1999, sets out the meaning
of “compulsory licensing” and “parallel importing”,
both possible strategies for improving access to
drugs. 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 pen-
tamidine. 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 stand-
ards of health care. Priorities are viewed differ-
ently by different organisations. Moreover, many
decisions are made and implemented by persons
who will not be affected by the consequences of
does, 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 implica-
tions of this — and to provide funds for essential
equipment, to the considerable benefit of every-
one, 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 com-
   mitment 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, educa-
   tion 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 ill-
nesses, 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 indus-
try 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:
the infrastructural support truly appropriate? In
countries where more local manufacture of intra-
venous fluids or standard antibiotics and im-
proved 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 treat-
ments? 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 re-
sources 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 adminis-
tration of antiretroviral drugs during labour and
after birth, one certain consequence will be to
increase the already large number of children fac-
ing life without one or both parents. In resource-
poor societies, how should responsibility for cop-
ing 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.

The Revd Dr Anne Bayley was previously Professor of Surgery at the University of Zambia.

References
Narrowing the gap

Anne Bayley

J Med Ethics 2000 26: 51-53
doi: 10.1136/jme.26.1.51

Updated information and services can be found at:
http://jme.bmj.com/content/26/1/51

These include:

References
This article cites 3 articles, 1 of which you can access for free at:
http://jme.bmj.com/content/26/1/51#BIBL

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections
Articles on similar topics can be found in the following collections

HIV/AIDS (116)
Sexual health (150)
Health economics (45)
Health policy (125)
Health service research (103)
Research and publication ethics (490)

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/