Despite decades of effort by communities and governments to improve access to health care, and despite the help of WHO and other institutions, the health sector deficiencies in the developing world appear to be growing instead of shrinking. Even before the epidemic, the health care system did not get a fair share of the national budget. Typically, health centres and hospitals were short-staffed, facilities for diagnosis were inadequate and drug supplies erratic, and training for health care providers was uneven and often poor. These deficiencies have worsened with the arrival of the HIV epidemic, which has increased the demands for health care and simultaneously reduced the health system's capacity to respond (see page 31). In the poorer developing countries, local health centres and small hospitals lack adequate facilities to diagnose the opportunistic diseases of people with HIV. They repeatedly run out of supplies of essential drugs, including the ones needed to alleviate distressing symptoms and to manage opportunistic infections. For example, oral thrush – a fungal disease which causes pain on swallowing – could be treated relatively easily, but millions of patients continue to suffer for lack of a simple anti-fungal drug. Tuberculosis, which can be cured, often goes untreated for the same reason. In Zambia, for example, where the tuberculosis case-load increased sixfold between 1992 and 1998, proper treatment became increasingly problematic because health facilities kept running out of TB drugs.

Even big teaching hospitals affiliated with urban medical schools – supposedly the best-supplied part of the health system – have serious problems, to judge from a UNAIDS survey of 22 university teaching hospitals in 19 African and 3 Asian cities completed in 1997. The hospitals surveyed had suitable diagnostic facilities and the right drugs to treat three conditions – pneumonia, pulmonary tuberculosis and oral thrush. These are the only HIV-related conditions that are easy to diagnose and inexpensive to treat. For any other HIV-related illness, diagnostic capacity (X-ray and laboratory facilities) and drug supplies were so inadequate that a patient would have less than a 50% chance of being correctly diagnosed and treated. This was true, for instance, of Kaposi sarcoma (a frequent HIV-related cancer), serious fungal infections such as cryptococcal meningitis, and viral infections affecting the brain. Relief for difficulty in breathing was unavailable in half the hospitals. Strong painkillers were available in only two-fifths, despite the fact that most people with advanced HIV infection require pain control at some point.

The high costs of antiretroviral drugs, and the sophisticated medical facilities required to track patients' progress and monitor side-effects, have been major stumbling blocks to access for the vast majority of people with HIV in the developing world.

Enormous variations in access to antiretrovirals exist in middle-income countries. In most of Asia, people with HIV have limited access. In Thailand, for instance, the Government subsidizes the cost of antiretroviral drugs for patients enrolled in clinical trials in a few centres of excellence, but this currently ensures access for only around 2000 of the approximately 70 000 new AIDS cases occurring annually.

A few projects in sub-Saharan Africa aim to promote the rational use of treatment for people with HIV, including antiretrovirals (see Box 19, page 103). Even within the projects it has repeatedly been problematic for patients with opportunistic

Automated Records Management System
Hex-Dump Conversion

infections to have access to the essential drugs they need. Outside these projects, antiretrovirals can only be purchased from a poorly regulated private sector where concerns about inefficiency and the potential for counterfeit loom large.

There are some Latin American and Caribbean countries where even treatment for opportunistic infections is problematic. However, other countries in the region have responded to demands from groups of patients, doctors and human rights organizations and now lead the developing world in providing access to antiretrovirals. Argentina, Brazil, Colombia, Costa Rica and Uruguay provide a legal right to some form of antiretroviral therapy, though the application of the law is somewhat patchy. Coverage of eligible patients has been reported to be 100% in Brazil, 70% in Argentina, 65% in Chile and Uruguay, 40% in Panama and 20% in Ecuador. Some countries operate with a lottery system or limit antiretroviral drug access to those with social security or private health insurance. Experience in Brazil shows that the costs of such therapy, although high, are offset to some extent by savings on treatment for opportunistic infections and on hospital stays (see Box 18, page 101).

Nevertheless, some concern has been voiced over the risk that HIV prevention activities may suffer if too much effort and money is devoted to providing treatment.

Box 16. Strengthening "horizontal" collaboration on HIV and sexually transmitted infections in Latin America and the Caribbean

Building on a long tradition of joint collaboration in the region, and the desire for more self-reliance and less dependency on donors, the Directors of national AIDS programmes from 12 countries agreed in 1996 to set up a new process for "horizontal" interregional technical cooperation. As part of the reciprocal process of exchanging experience, information and technology on equal terms, for example, the Horizontal Technical Collaboration Group (HTCG) has encouraged intercountry visits so that members can see first-hand how to improve drug management and distribution in rural areas. Through a multicountry survey conducted by the Group on the prices being paid for HIV-related drugs and commodities, countries became aware of major price differences and were in a better position to negotiate price reductions with pharmaceutical companies. Argentina, for instance, was able to reduce the cost of measuring viral load from US$ 250 to US$ 70. The HTCG also provided the initial impetus for establishing a revolving fund for HIV-related drugs under the auspices of the Pan American Health Organization, WHO's Regional Office for the Americas. The fund is now in its initial trial phase.

As of May 1999, 21 countries belonged to the HTCG* and efforts are now under way to incorporate national AIDS programme Directors from Central America and from the English-, Dutch- and French-speaking countries in the Caribbean.

** Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela.*

Comprehensive care and support strategy needed

In the early 1990s, WHO's Global Programme on AIDS advocated that care and support for people living with HIV or AIDS should be comprehensive – embracing

tomated Records Management System
-Dump Conversion

the psychological/spiritual, social and medical dimensions – and integrated, with the various providers offering a "continuum of care" centred on the clients' needs. This vision remains relevant today. As discussed earlier (see page 85), people with HIV infection need a range of measures to support them (and their families) in coping with their situation and to enable them to live healthy, productive lives for as long as possible. Counsellors, religious communities and family members should provide vital care and support at home and in the community. For diagnosis and therapy, patients and their carers must in turn be able to rely on the support of health services, such as home and community care programmes, private practitioners, local health centres, and clinics and hospitals.

Since this vision was formulated, UNAIDS has identified new opportunities for prioritizing action and accelerating progress. UNAIDS proposes to target action along five strategic axes. Two are dealt with elsewhere in this report, while the others are discussed in separate sections below:

- creating political will and mobilizing resources (see pages 107-115)
- increasing access to voluntary HIV counselling and testing: over and above the benefits for prevention, discussed earlier (see page 78), individuals who learn they have HIV can gain access to support at an earlier stage and, with new preventive regimens, may live longer and healthier lives (see pages 105–106)
- increasing access to psychosocial support and impact alleviation
- improving health service delivery
- increasing access to drugs of special interest to people living with HIV infection.

When possible, it is best for countries to develop plans for care and support as part of their strategic planning on HIV/AIDS, whether at national or district level. Health system reform can offer an opportunity to look at the range of care and support needs in a comprehensive manner (see Box 17).

Box 17. Health reforms and HIV: experience from Phayao Province, northern Thailand

The Phayao Health Office undertook a review of its efforts to reform the health sector in the light of the lessons learnt from reducing the spread of HIV and caring for people with AIDS in this badly affected province of the country. The Office posed a number of questions to see whether the reform was really improving the health sector's capacity to tackle the epidemic effectively.

Quality of life and autonomy are important concerns of people with HIV and their families.

- Does the health reform aim only to reduce rates of sickness and death?
- Or is the reform also geared to better quality of life, less dependence and greater autonomy?

People with HIV require comprehensive support, and not just medicines.

- Does the health reform aim mainly at better provision of health care?
- Or does it also enable the health sector to catalyse community action and put health issues on the agenda of society and its decision-makers?

Care for people with HIV involves the health system at several levels.

- Does the reform respect the three principles of health-care organization:

– integrated care achieved through teamwork by care providers of different disciplines?
– continuity of care throughout the levels of the health system?
– a focus by the care provider on the client's priorities?

Automated Records Management System
Hex-Dump Conversion

Inclusion of HIV-positive people in society starts at the health centre and the hospital.

- *Does the health reform focus on the personal development of health personnel?*
- *Does it enable them to feel more comfortable about HIV/AIDS issues in their private life?*
- *Does it help them avoid discriminatory and judgemental attitudes when caring for HIV-infected patients?*

People with HIV have a great deal to contribute to the organization of the health care system.

- *Do key clients have a say in the design and implementation of health reforms?*

Psychological and social support and other measures to alleviate the impact of HIV/AIDS

People living with or affected by HIV need support in confronting the multiple challenges of a chronic, incurable and generally fatal condition that can result in social ostracism (see page 38) and economic disaster (see page 27).

Psychosocial support – an essential element of the care and support package (see Table 1, page 98) – ranges from purely psychological support to the social measures needed to create an environment in which those affected can cope and thrive. Some types of support straddle the line.

Family members, representatives of religious communities, health-care providers and counsellors are important sources of psychological and spiritual support for coping with HIV infection in oneself or the family. However, they are often in need of support themselves. There is growing evidence of the great stress associated with care-giving, particularly in relatives who form the majority of front-line carers in developing countries. While ways of managing this stress are becoming better understood, it is unclear how these coping mechanisms can be financed.

An important goal of social support is inclusion – enabling affected people to live without fear and to continue functioning as normal members of society. Among the wide-ranging measures needed to bring this about are public statements by community and religious leaders urging solidarity with those affected, and legal and other mechanisms for protecting HIV-affected individuals and survivors from discrimination, loss of inheritance and property-grabbing.

Psychological and social support can help reduce stigma and other negative consequences of being HIV-positive and in this way make people less reluctant to seek HIV counselling and testing. In turn, the staff of counselling and testing facilities can contribute to psychological support, for example, by assisting individuals to share the news of their test result with their spouse or a trusted relative. Their contribution could be even greater if voluntary counselling and testing services were more widely accessible and more welcoming to certain categories of clients. In particular, these services need to be better geared to attracting young people, couples and men.

Another challenge is time. In busy community health settings, where staff have too much to do, it is important to find ethically acceptable ways of reducing the time required for counselling.

Associations of people living with HIV are a good example of community mechanisms that provide both psychological and social support. Formed to counter the social isolation often experienced by HIV-positive people and to allow

Automated Records Management System
Hex-Dump Conversion

them to share and discuss their experiences and problems openly and safely, these mutual support mechanisms provide peer support and help members cope with discrimination and stigma. One such group, at an antenatal clinic in South Africa, was described by the women members as the only place where they could relax and be themselves.

However, support groups are generally unable to meet one of the most important challenges facing people in developing countries: lack of income. Most people with HIV or AIDS are or become unemployed, and the stark reality is that unless they can rely on broader support from government and society there is little a community group can *do to alleviate this impact.*

Alleviating economic impact

Many support organizations have discovered the pitfalls of trying to alleviate the economic hardship of their members. The AIDS Support Organization (TASO) of Uganda, which runs support groups for people living with HIV, asked members of= one group how their home support could be improved. Three-fifths said they needed capital to start an income-generating activity and close to half asked for increased assistance of the kind already being provided, such as staple foodstuffs and cash for school fees, uniforms and books to enable their children to go to school.

In one scheme, selected TASO centres received funds to be given as revolving loans for income-generating projects. While 75% of the projects were later assessed as having been successful enough for the clients to repay their loans, only 12% did so. It emerged that while some people understood the concept of a revolving loan, others perceived it as a grant that did not have to be repaid. The scheme soon collapsed. Avenues for tackling the economic impact of the epidemic range from loans or grants to individuals with HIV, at one end, to complex societal measures for averting and alleviating the epidemic's impact on agriculture, the educational system and the private sector, for example (see pages 26–36). Alleviation measures may be directed at a well-defined problem, such as the increase in orphans, or may be more general in nature. In some cases the project's beneficiaries may be restricted to people living with HIV or AIDS.

There is no perfect or universally applicable solution. For example, restricting grants to people affected by AIDS may help channel severely limited resources to where they are badly needed, but it can also have negative consequences. Organizations bringing support to AIDS orphans learned early on that it was better to target all orphans as a group so that the project would not create resentment among those excluded or attach an AIDS stigma to specific children.

Micro-credit, also known as micro-finance, is an effective poverty-alleviation instrument promoted by the United Nations Development Programme (UNDP). These group lending schemes grant small loans to individuals who want to start up a small business and who seem likely to be able to repay. Communities with HIV-positive people generally meet the criteria for these schemes, including the presence of many poor people, the existence of market opportunities and infrastructure facilities, high population density, approval of local authorities, and the ability to build trust in the community. Experience has already shown that the schemes can work very successfully in high HIV-prevalence areas of Africa. In

Malawi and Uganda, for example, the Foundation for International Community Assistance (FINCA) has achieved 100% recovery of its loans.

While some micro-finance organizations are closing their eyes to the AIDS epidemic or even excluding sick members, some are helping their clients to accumulate savings by serving as a bank or banking intermediary, assisting them to carry on their business when they fall ill, and providing survivors with advice on inheritance and legal protection. Some have even joined the front-line fight against the epidemic. For instance, FINCA in Uganda is working with organizations such as TASO to promote condoms and educate its clients about safer sex, while the Zimbabwe Opportunities Industrialization Centre (ZOIC), operating in small towns and rural communities affected by the epidemic, is organizing community-based orphan care programmes.

These practical examples of an integrated response to AIDS illustrate why it can be artificial to make a distinction between prevention, care, support and impact alleviation.

UNDP estimates that micro-finance at present covers only 1% of the potential market, affording great potential for expansion. It has been suggested that proxy indicators of possible HIV spread – such as military conflict and population migration – could be used to identify priority areas for expanding the coverage of micro-finance institutions.

In parallel, since the micro-credit approach will not be feasible everywhere, governments and other institutions should step up direct humanitarian aid to families in need through outright grants of food or cash. The two approaches must remain separate, however, if micro-credit schemes are to maintain their credibility.

Finally, in high-prevalence countries where the epidemic risks destroying the very fabric of society, the impact of AIDS has to be mitigated through intensified development strategies. Teachers, extension workers and other human resources who are crucial to development are falling ill and dying, sometimes at even higher rates than the general population. To minimize this impact, countries need urgently to establish human resource policies on absenteeism and recruitment while stepping up AIDS prevention and care programmes at the workplace. The coverage of social assistance programmes must be expanded to a wider group of households, defined by both poverty and AIDS indicators. And existing mechanisms for improving access to land, capital, education and other limited resources must be intensified and applied more widely. AIDS is a development problem.

Improve health service delivery

The inadequacy of health service delivery to people living with HIV can be redressed by rationally selecting the services to be offered, upgrading the human resources of the health system, improving its infrastructure (e.g. buildings and laboratory equipment), and ensuring the availability of HIV test kits, drugs and other essential commodities.

These things have a cost, and therefore a prime consideration is to secure financing for the health system.

Automated Records Management System
Hex-Dump Conversion

An in-depth study of total spending on AIDS – both public and private – in four countries and São Paulo State, Brazil, found that expenditure ranged from 60% of per capita gross domestic product in Tanzania to 300% in São Paulo, with average expenditure being about 150% of per capita GDP.
In Thailand, a policy of making zidovudine and didanosine (an antiretroviral regimen now recognized as suboptimal) available to patients free of charge would require a public subsidy amounting to six times that country's entire AIDS budget, and would therefore be unaffordable for the Government. Even with this subsidy patients would have to pay just under US$ 500 a year for the related health care required – a sum that only around half of them could afford.
An analysis presented at a WHO/UNAIDS workshop concluded that, in most developing countries, antiretroviral treatment programmes aiming at universal coverage would not be affordable. For example, based on 1997 prices, the provision of triple combination therapy to all people with HIV in sub-Saharan Africa could consume between 9% and 67% of total GDP.
As these examples make clear, the ability to secure financing for health care, particularly for advanced care options such as antiretroviral therapy, is very limited in developing countries. Determining the best buy within the prevailing resource constraints
– a recurring challenge for health system decision-makers – must go hand in hand with efforts to make health service delivery more efficient and to mobilize additional resources for the sector.
One of the critical factors for service delivery is the availability of people to deliver services. As mentioned earlier, AIDS increases the demand on the health sector (see page 31), and at the same time reduces the human resources available to it by causing illness and death in the sector's workforce. With fewer health care providers available to carry an ever-increasing workload, it is easy to understand why the remaining staff may experience burn-out, which results in a lower quality of service and further attrition in the workforce. It is urgent for governments to establish human resource policies aimed at mitigating these impacts on the health sector (see pages 94-96). The desirable response would be to increase the number of health care workers so as to maintain the sector's ability to deliver services. This requires decisions about the kinds and numbers of health care workers that will be needed, and a clear idea of how the cost of the mitigation efforts will be shouldered.

Care and support packages

The kind of care and support "package" made available to people living with HIV or AIDS will thus depend on the ability to mobilize human, infrastructure and financial resources. Where the ability to mobilize resources is extremely limited (such as in most of rural sub-Saharan Africa) or somewhat limited (as in northern Thailand), the package will necessarily be more limited than where resource availability is relatively unrestricted.
Examples of what the essential, intermediate and advanced packages could comprise are given in the Table 1, page 98.
It is important to emphasize that progress in improving health service delivery need not be strictly linear. For example, planners may discover an opportunity for expanding access to treatment for multiresistant tuberculosis (an option in the advanced package) in a region where people with HIV are receiving mainly the

Automated Records Management System
Hex-Dump Conversion

intermediate package. If so, they should not hesitate to push ahead with this option, in particular when the prospect for improving delivery of some of the less advanced options is poor.

In these examples of care and support packages, no consideration is given to improving health service delivery through greater efficiency and coverage. For instance, possible expansion of community-based care and home care is not taken into account, nor are considerations of more efficient referral patterns. A further limitation is that they omit health sector activities that are not specific to "care and support".

In addition, even when resource constraints are very serious, health services everywhere should provide care for sexually transmitted infections, family planning services, HIV testing of blood for transfusion, and the promotion of universal precautions to be taken by health workers in the handling of body fluids. Other imperatives come under the general heading of health policy, such as the licensing of nurses or other practitioners to prescribe morphine, and the regulation of the supply of drugs (including antiretrovirals) in order to minimize the risk of drug resistance and counterfeiting.

Table 1. Care and support packages, according to resource availability

The essential package	• voluntary HIV counselling and testing • psychosocial support for HIV-positive people and their families • palliative care and treatment for pneumonia, oral thrush, vaginal candidiasis and pulmonary tuberculosis (DOTS) • prevention of infections with cotrimoxazole prophylaxis for symptomatic HIV-positive people • official recognition and facilitation of community activities that reduce the impact of HIV infection
The intermediate package	**All of the above PLUS one or more of the following:** • active case-finding (and treatment) of tuberculosis among HIV-positive people • preventive therapy for tuberculosis for HIV-positive people • systemic antifungals for systemic fungal infections (such as cryptococcosis) • treatment of Kaposi sarcoma with essential drugs • surgical treatment of cervical cancer • treatment of extensive herpes with acyclovir • funding for community activities that reduce the impact of HIV infection
The advanced package	**All of the above PLUS:** • triple antiretroviral therapy • diagnosis and treatment of opportunistic infections that are difficult to diagnose and/or expensive to treat, such as atypical mycobacterial infections, cytomegalovirus infection, multiresistant

Automated Records Management System
Hex-Dump Conversion

	tuberculosis, toxoplasmosis, and HIV-associated cancers • specific public services that reduce the economic and social impacts of HIV, to supplement community efforts that reduce the impact of HIV infection.

Where an intermediate care and support package is feasible, one would expect that prevention activities requiring intermediate levels of technical and human resources would also be available. These include measures aimed at reducing mother-to-childtransmission of HIV, and antiretroviral treatment to prevent HIV infection in health care workers who have been exposed occupationally to the virus (post-exposure prophylaxis).

Improve access to drugs

Improving access to drugs of special interest to people living with HIV infection is a priority strategy for UNAIDS, and is currently mobilizing much interest worldwide.

Making drugs more accessible requires a broad look at the underlying reasons for poor access. One factor is the cost of drugs. Another is inadequate information about the drugs needed to manage HIV-related illnesses. Finally, drug access is hampered by the poor capacity of health systems in developing countries to select and use drugs in a rational manner, to monitor patients' progress and side-effects, and to manage their drug supply. This is linked in turn to inadequate financing of the health system in general and of the drug supply in particular.

In the current context, attention has mainly focused on drug prices, and in particular= the price of antiretroviral drugs still under patent in high-income countries, which makes them financially inaccessible to most people with HIV. However, for the reasons mentioned above, people with HIV also have inadequate access to the "essential drugs" for treating HIV-related illness, including drugs that are no longer under patent. The poor availability of drugs for pain relief or respiratory distress and for the treatment of many HIV-related diseases found in a survey of university teaching hospitals shows how inadequate this access is, even at the highest echelon of the health system (see page 89). Another indicator of inadequate drug access is the limited coverage of tuberculosis programmes, which, according to WHO, manage to diagnose and treat only around 40% of TB cases. Overall, WHO estimates that access to essential drugs for health conditions of all kinds is guaranteed for only 50% of the population in developing countries.

Through collaboration between the UNAIDS Secretariat, WHO and UNICEF, some of the obstacles to essential drug access are being tackled. First, beginning in 1997, 15 new drugs of interest to people with HIV were included in the WHO Model List of Essential Drugs. The next step was to pinpoint the reason why most wholesalers of generic drugs were not distributing the newly included drugs, and why even several important older drugs were rarely on offer. Working with WHO and UNICEF, the Secretariat identified manufacturers and prices for 44 essential drugs whose procurement was being hampered by insufficient information on cost and availability.

Automated Records Management System
Hex-Dump Conversion

This information has been posted on the UNAIDS, UNICEF and WHO websites along with an offer to assist countries in locating generic drug suppliers and organizing drug procurement. Information of this kind is also used to help convince planners that it is feasible to include HIV care and support in national strategic plans on HIV/AIDS.

Strategies for cost and price reduction

One of the lessons learnt from the UNAIDS Drug Access Initiative in Côte d'Ivoire and Uganda (see Box 19, page 103) is that, with determination and good will, it is possible to negotiate a significant reduction in drug prices and improve the delivery of health care. End-user prices of antiretroviral drugs in both Côte d'Ivoire and Uganda decreased after negotiation with the pharmaceutical companies holding the patents on those drugs. The companies that participated in the initiative either donated a percentage of the drugs or agreed to sell them at a reduced price. Similar decreases in drug prices were achieved through a national drug access initiative conducted in Senegal.

Price reductions can be achieved through avenues other than negotiation with patent holders. One strategy is to produce or import generic alternatives to proprietary drugs. UNAIDS' analysis of the patent situation of HIV-related drugs with WHO and UNICEF has shown that most proprietary drugs used in the treatment of people with HIV are not patent-protected in the majority of developing countries.

Table 2 shows the prices of proprietary antiretrovirals in the USA, Côte d'Ivoire and Uganda, and some generic equivalents in Brazil and Thailand. The lower price of generic products is partly explained by the lack, or low level, of investment in research and development by the manufacturers.

Table 2. Price (US$) of a defined daily dose of selected antiretrovirals in five countries

Drug	*Defined daily dose*	*USA [1]*	*Côte d'Ivoire [2]*	*Uganda [3]*	*Brazil*	*Thailand [6]*
zidovudine 100 mg	*600 mg*	*10.12*	*2.43*	*4.34*	*1.08 [4]*	*1.74*
didanosine 100 mg	*400 mg*	*7.25*	*3.48*	*5.26*	*2.04 [4]*	*2.73 [7]*
stavudine 40 mg	*80 mg*	*9.07*	*4.10*	*6.19*	*0.56 [4]*	*0.84*
indinavir 400 mg	*2400 mg*	*14.93*	*9.07*	*12.79*	*10.32 [5]*	*NA*
saquinavir 200 mg	*1200 mg*	*6.50*	*4.82*	*7.37*	*6.24 [5]*	*NA*
efavirenz 200 mg	*600 mg*	*13.13*	*6.41*	*NA*	*6.96 [5]*	*NA*

(1) Prices, 2 April 2000, from www.globalrx.com, a US mail-order pharmacy that offers proprietary antiretrovirals with a minimum mark-up (shipping not included).
(2) End-user prices, UNAIDS Drug Access Initiative, Côte d'Ivoire, March 2000.
(3) End-user prices, UNAIDS Drug Access Initiative, Uganda, March 2000.
(4) Generic drugs produced in Brazil (US$1 = R$ 1.8).
(5) January 2000 cost to the Brazilian Government of imported drugs (US$ 1= R$ 1.8).
(6) Generic drugs produced by Government Pharmaceutical Organization, Thailand (US$ 1 = 38 baht).
(7) 115 mg powder formulation, equivalent to 100 mg tablet.

Automated Records Management System
Hex-Dump Conversion

Box 18. Experience in Brazil with generic alternatives to proprietary antiretrovirals

The Government of Brazil has a policy of universal access to antiretroviral drugs that currently benefits nearly all AIDS patients in the country (about 85 000). The introduction of combination antiretroviral therapy nearly halved the annual number of AIDS deaths between 1996 and 1999 and reduced the incidence of opportunistic infections by 60-80% over the same period.

The universal access programme would not have been possible without significant decreases in the cost of antiretroviral drugs. The Government decided to start local manufacture of drugs that were not patent-protected, and for which it had the know-how and infrastructure. Local production, combined with bulk purchases of imported antiretrovirals, led to significant decreases in the programme's drug costs. The annual cost of double therapy with nucleoside analogues decreased on average by 80% between 1996 and 2000, from US$ 3812 to US$ 763. For triple therapy with two nucleosides and one protease inhibitor, the cost reduction was 36% over the same period (from US$ 7342 to US$ 4717) and for triple therapy with two nucleosides and one non-nucleoside it was 34% (from US$ 4584 to US$ 3009).

The programme's annual drug costs were approximately R$ 611 million (US$ 339 million) in 1999, and are expected to rise to R$ 831 million (US$ 462 million) for the year 2000, taking into account both a higher proportion of patients on triple therapy and a larger overall number of patients. Between 1997 and 1999, approximately 146 000 AIDS-related hospitalizations were averted, resulting in savings of approximately R$ 521 million (US$ 289 million); this has partly offset the high cost of antiretroviral therapy. At the same time, condom sales increased by nearly half (from 216 million to 320 million pieces) between 1996 and 1999, and demand for voluntary HIV counselling and testing rose 35% between 1996 and 1998.

Yet another approach is to utilize a safeguard incorporated into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international treaty that protects patent rights, including those for drugs. Patent protection provides an important incentive for innovative research and development of new HIV/AIDS drugs and, hopefully, the discovery of HIV vaccines, in particular, vaccines suitable for use in developing countries (see Box 14, page 68).

The TRIPS agreement sets out minimum standards in relation to intellectual property for Member States of the World Trade Organization (WTO). Countries that wish to be members of WTO must comply with the TRIPS standards, where necessary by changing their national laws and regulations. In practice, for many developing countries, this will mean giving patent protection for the first time to pharmaceutical inventions (both products and processes). Under TRIPS, patent protection must be available for a minimum period of 20 years. However, the TRIPS agreement also foresees that in certain circumstances, such as national emergencies, governments may grant third parties the right to produce and sell a patented product even without the consent of the patent holder, according to carefully prescribed conditions.

This safeguard, known as "compulsory licensing", was incorporated into the TRIPS agreement through negotiations by developing countries. Its maintenance

utomated Records Management System

lcx-Dump Conversion

as part of TRIPS has been vigorously defended by nongovernmental organizations and activist groups, such as Act Up, the Consumer Project on Technology and Médecins Sans Frontières, who have conducted international campaigns for improved drug access.

These organizations have also sought to obtain compulsory licences on drugs of interest to people with HIV/AIDS in South Africa and Thailand. The campaigns did not result in the issuing of compulsory licences. However, access to the target drugs improved when the pharmaceutical companies involved donated the drug free of charge to some patients (as was the case for fluconazole in South Africa), or agreed to a significant price reduction around the same time that non-patented alternative formulations were put on the market (as was the case for didanosine in Thailand). The fact that pharmaceutical companies have not yet decreased their prices enough to make their products affordable to the majority of people in developing countries does not preclude future progress. To achieve prices even lower than those available from small suppliers of generic drugs, it will be necessary to pursue discussion and collaboration with the pharmaceutical companies that developed the products.

"Differential pricing" of HIV/AIDS drugs and other pharmaceutical products is gaining increasing acceptance in industry and should help in making these products affordable in countries with limited local purchasing power.

At the same time, governments should increase access to drugs by reducing import duties, customs and taxes on HIV-related goods and lowering their cost, and by removing unduly restrictive regulations that impede drug availability. More broadly, at a time when the epidemic is increasing the demand for health services, governments and donor agencies should improve the affordability of drugs by giving higher priority and greater financial support to the health sector.

Box 19. Lessons from the UNAIDS Drug Access Initiative

The Drug Access Initiative enrolled its first patients in Uganda and Côte d'Ivoire in

1998. In Chile and Viet Nam, the initiative became operational in early 2000. The initiative aims to evaluate ways of overcoming obstacles to the provision of drugs, using access to antiretrovirals as an entry point for wider access to a comprehensive package of HIV care in developing countries.

Some important lessons have already been learnt about the operational aspects of the initiative from the experience of Côte d'Ivoire and Uganda, where currently about 600 and 900 patients respectively are receiving antiretroviral therapy.

Rational drug selection and drug use

Advisory boards in both countries defined treatment policy, and training efforts were successful in ensuring physician compliance with the proposed treatment guidelines in the referral centres participating in the initiative. The guidelines and training took a comprehensive approach to the management of patients with HIV, including their opportunistic infections and diseases. However, the procurement guidelines focused almost exclusively on antiretroviral therapy until 1999. Since then, at the insistence of UNAIDS, both countries have shown a greater interest in the management of opportunistic diseases. Anticipating the March 2000 consultation on cotrimoxazole prophylaxis (see Box 20, page 106), Côte d'Ivoire and Uganda adopted guidelines on using this drug combination for the

Automated Records Management System
Hex-Dump Conversion

prevention of opportunistic infections in people with HIV. The increased emphasis on drugs for opportunistic infections will make the Drug Access Initiative more relevant to clients who cannot afford antiretroviral drugs, and to follow-up centres where antiretrovirals are not prescribed.

Efforts to increase drug affordability

Drug price negotiations led to a significant decrease in the price of antiretroviral drugs in the region, both within the Drug Access Initiative and beyond. However, a comparison of these prices with those obtained by Brazil or Thailand (see Table 2) makes it clear that further price reductions should be possible to achieve, if need be through the introduction of generic competition. Uganda, a relatively poor country, opted not to use any public funds to subsidize antiretrovirals supplied through the initiative (the cost being borne by the patients). In Côte d'Ivoire, a richer country, the Government committed itself to shoulder part of the cost for selected patients; however, the allocation of treatment subsidies was very slow. While an in-depth analysis of the use of antiretrovirals outside the initiative was not conducted, the fact remains that the programme in Côte d'Ivoire attracted fewer clients than that in Uganda.

Strengthening the health sector

The educational efforts of the initiative were assessed as positive in both countries. In Uganda, laboratory follow-up was strengthened by the donation of CD4 counting equipment. The growing interest of the countries' advisory boards in opportunistic disease management has resulted in more operational follow-up centres.

Three challenges to be met in the months ahead are: integrating the advisory boards' guidance on HIV management into national treatment guidelines; regulating antiretrovirals and advanced drugs for the treatment of opportunistic infections as part of the countries' national drug management policy; and preparing to make the initiative sustainable after UNAIDS reduces its subsidy.

Societal impact

In both countries, the presence of the initiative galvanized people with HIV and AIDS by holding out some hope for them, and led to a wide mobilization of health sector staff around HIV and AIDS. It also resulted in a great deal of discussion of AIDS in the media – not only about the cost of HIV treatment but also HIV prevention. By raising the visibility of the epidemic, this level of discussion may enhance prevention efforts and yield significant benefits that extend beyond the clients and health care providers of the initiative.

Better prospects for preventing infections in those with HIV

Given the limited diagnostic facilities available in developing countries and the high costs of many drugs for treating opportunistic infections, let alone antiretrovirals, the option of prevention is receiving renewed attention. The bulk of evidence now suggests that a few relatively inexpensive drugs could help ward off severe illness and add months, if not years, to the lives of HIV-positive people in even the poorest developing countries. Indeed, preventive drugs had begun to prolong survival in the high-income countries even before antiretroviral therapy was available.

One drug is isoniazid, which has been shown to be effective in warding off 60% of active tuberculosis episodes in people with HIV. In at least one study, isoniazid

Automated Records Management System
Hex-Dump Conversion

prevention prolonged life significantly for those who were infected with both HIV and the bacillus that causes tuberculosis. A simple regimen costs on average just a few cents a day for both the medicine and the health services involved. Tuberculosis prophylaxis is especially important because in half the cases HIV-infected individuals develop a form of TB which cannot be easily diagnosed and which thus goes untreated. Diagnosing disseminated tuberculosis requires sophisticated laboratory equipment that is largely unavailable in many of the poorer developing countries. This is why UNAIDS and WHO have recommended since 1998 that a simple and inexpensive regimen for preventing tuberculosis should be part of the essential care package for people with HIV (see Table 1, page 98).

New developments point the way to preventing other severe infections. Cotrimoxazole – a pill combining an antibiotic and a sulfa drug which has helped prevent Pneumocystis carinii pneumonia, the biggest AIDS-related killer in high-income countries – was tested for its preventive impact in Côte d'Ivoire. In one study in Abidjan, where the drug costs of a 12-month regimen were just US$ 17.50, cotrimoxazole prophylaxis resulted in significantly fewer severe infections (as measured by hospital admissions). In another study, cotrimoxazole warded off infections so successfully that it extended life by half a year. The drug combination appeared to be effective in preventing some bacterial pneumonias, diarrhoeal diseases and infections of the blood, and possibly toxoplasmosis (a parasitic brain disease) and isosporiasis (a parasitic infection of the intestines). In the light of these hopeful findings it is urgent to implement cotrimoxazole regimens in sub-Saharan Africa as part of the essential care package for adults and children living with HIV (see Box 20). At the same time, scientists will need to keep careful watch so that the value of this drug combination is not undermined by the development of resistance to it.

Box 20. Use of cotrimoxazole prophylaxis in people with HIV/AIDS in Africa

In March 2000, UNAIDS and WHO brought together clinicians, public health specialists, national AIDS programme managers, people living with HIV/AIDS, donors and AIDS activists to discuss the use of cotrimoxazole as preventive therapy for HIV-positive individuals in Africa. The outcome of this consultative workshop in Harare, Zimbabwe, was that cotrimoxazole prophylaxis for people who have already developed symptoms of HIV infection should be part of the essential care and support package. The participants recommended dosages, defined criteria for patient eligibility, and issued recommendations for training, education and capacity development in countries.

The UNAIDS Secretariat is working with WHO to ensure rapid implementation of these recommendations through resource mobilization efforts. By July 2000, through consultative meetings with national governments, 14 African countries participating in the US Government's LIFE Initiative will have considered making cotrimoxazole prophylaxis part of their care package.

A new incentive for testing?

Experience from around the world shows that seeking counselling and HIV testing is not an easy step to take. In the high-income countries, the hope of benefiting from early treatment created a major incentive for people to find out whether they were infected. As therapies improved – even before the advent of antiretrovirals – people who suspected they might have HIV saw that they stood

Automated Records Management System
Hex-Dump Conversion

to gain months or years of life by getting tested. Isoniazid and cotrimoxazole prophylaxis – which can only be offered to people with proven HIV infection, in contrast to some other forms of health care described in this chapter – may similarly increase people's interest and willingness to be tested for HIV. If these preventive regimens are made more widely available along with HIV counselling and testing services, the survival benefits for individuals and their families are likely to be compounded by the benefits of large-scale testing, including reduced HIV transmission to partners and to infants, and greater visibility of the insidious HIV epidemic.

National responses to the epidemic: factors that make a difference

This report demonstrates that the AIDS epidemic is a true development crisis that threatens the social and economic fabric, and the political stability, of whole nations.

Yet this report also shows that the epidemic is not out of control everywhere; some countries and communities have managed to stabilize HIV rates or achieve a turnaround, and some have maintained very low prevalence rates, due to a range of factors that are not yet fully understood. Other communities have made significant progress on care and support for people both infected and affected. A closer look at individual country responses, and at the corresponding achievements and failures, helps pinpoint some of the factors behind these successes.

Looking back over past efforts against the epidemic the initial reaction of many countries was to try to persuade individuals and selected groups to change their behaviour by providing information about HIV/AIDS. Gradually, however, behaviour change was understood to require more than mere information; the importance of decision-making and negotiation skills, accessibility of commodities and services, and supportive peer norms became increasingly apparent.

By the mid-1980s, it was well appreciated that individuals do not always control their own risk situations. This led to the development of prevention programmes aimed at enabling particular groups or communities such as sex workers and men who have sex with men to adopt safer behaviour. At the same time, as individuals infected with HIV earlier in the epidemic gradually fell ill and died, challenging family and community structures alike, the need to provide health care and cushion the epidemic's impact became increasingly obvious. Simultaneously, the importance of work on non-discrimination, protection and promotion of human rights, and against the stigmatization brought by HIV/AIDS, was more widely recognized, including the importance of involving different sectors of society.

With the mid-1990s, and deepening epidemics in many countries, came a growing realization that HIV/AIDS is also a development challenge. To the extent that people's vulnerability to infection has social and economic roots, often including marginalization, poverty and women's subordinate status, these conditions need to be tackled as a way of making society as a whole less vulnerable to HIV over the long term.

Automated Records Management System
Hex-Dump Conversion

Advancing other social goals such as education, empowerment of women and human rights protection are important for reducing overall societal vulnerability to infection, as well as critical in their own right. At the same time, planners need to bear in mind that development projects such as the construction of a major highway or the creation of free-trade zones may exacerbate the epidemic by promoting rapid urbanization, splitting families and depriving individuals of familiar social support systems. These negative effects need to be anticipated and actively countered.

Common features of effective national responses

Analysis of effective programmes shows that a number of features characterize the responses of communities and countries which have already managed to stabilize or reverse their epidemic trends. This is not to say that there is one ideal expanded response or universal blueprint, but some basic, common principles of effective response can be identified. It is important for each country to find locally relevant pathways to a response that are likely to include most, if not all, of the elements summarized below.

Successful national responses have generally comprised the following features:

1. Political will and leadership

Political will expresses the national commitment and provides overall leadership to the nation in response to AIDS. Effective responses are characterized by political commitment from community leadership up to a country's highest political level.

Such commitment leads to high-profile advocacy and helps bring in all the sectors and players, along with the necessary human and financial resources. It is also critical for making the hard political choices often involved in adopting intervention methods that really work – such as making sex work safer – and can lead to helpful policy changes and supportive legislation.

Ultimately, the success of a programme is determined by the dedication and efforts of the change agents who are closest to its level of impact. They, however, need to be constantly motivated, supervised and supported by the political leadership.

2. Societal openness and determination to fight against stigma

To be effective, programmes need to make HIV visible and the factors leading to its spread, discussible. Programmes need to make people aware of the existence of HIV and how it is spread, without stigmatizing the behaviours that lead to its transmission. They also need to facilitate discussion about an individual or community's own vulnerability, and how to reduce it. This involves dissipating fear and prejudice against people who are already living with HIV or AIDS.

Successful programmes impart knowledge, counter stigma and discrimination, create social consensus on safer behaviour, and boost AIDS prevention and care skills.

These can be accomplished cost-effectively through mass media campaigns, and through peer/outreach education and life-skills programmes in schools and workplaces.

Programmes such as TASO in Uganda have demonstrated the enormously positive impact of openness and honesty in facing HIV. Ensuring that counselling

and voluntary HIV testing are available, so that an individual can find out her or his HIV status, is a further critical ingredient in counteracting denial.

3. A strategic response

A single, powerful national AIDS plan involving a wide range of actors – government, civil society, the private sector and (where appropriate) donors – is a highly valuable starting point. The development of a country strategy begins with an analysis of the national HIV/AIDS situation, risk behaviours and vulnerability factors, with the resulting data serving to prioritize and focus initial action. It is essential to find out where people in the country are already infected, where they are most vulnerable, and why. Effective strategy development then involves drawing on evidence-based methods of HIV/AIDS prevention, care and impact alleviation

– "best practices" – recognizing that some of these may be culturally sensitive (e.g. sex education in schools) or require hard political choices (e.g. needle exchange for injecting drug users). At the same time, attention needs to be given to ensuring that the relevant services and commodities such as condoms or STD services are acceptable, affordable and available. Given the resource constraints facing many countries, the development of a strategy will also involve some prioritization.

Effective strategies offer both prevention and care. As illness mounts in the epidemic, so does the need for health care and social support. Care services have benefits that extend beyond caring for sick individuals. They help convince others that the threat of HIV is real and they therefore make prevention messages more credible. Messages and programmes that build compassion and skills in health care settings, communities and families are needed right from the start, and combined training for prevention and care helps reduce costs.

An important point about programme elements is that they tend to work in synergy. Individual features of effective action can be found in most programmes. The tragedy is that in many countries, action remains sporadic and patchy rather than comprehensive. "Boutique" projects may provide services for one or two communities, while large areas of the countryside have nothing. Many programmes have yet to become comprehensive in either geographical coverage or content. The national response may focus solely on sex workers, for example; elsewhere, efforts may go into AIDS and life skills education among the young in schools and out of schools, but the risks and vulnerability of men who have sex with men are ignored. While human and other resource constraints may hamper efforts to scale up, a sound strategic plan based on epidemiological evidence and best practices will at least ensure basic coverage.

Strategic planning of national responses is neither easy nor quick. But as the experience of a number of countries has proved – for example, Botswana, Cambodia, China, Côte d'Ivoire, Dominican Republic, Guatemala, Honduras, Malawi, Mozambique, Papua New Guinea, Romania and the United Republic of Tanzania – it can be done effectively, and the process itself is critical in bringing on board a wide range of actors whose commitment is key to successful outcomes.

4. Multisectoral and multilevel action

Successful programmes involve multisectoral and multilevel partnerships between government departments and between government and civil society,

Automated Records Management System
Hex-Dump Conversion

with AIDS being routinely factored into individual and joint agendas. Only a combined effort will "mainstream" AIDS and establish it firmly on the development agenda.

Multisectoral and multilevel partnerships make sense for all stakeholders. Government sectors and businesses are affected in multiple ways by a serious epidemic and hence have an important stake in participating in AIDS prevention, care and support at all levels, but especially in ensuring sustained, large-scale programmes.

Ministries of Labour for example can mandate workplace prevention programmes in the private sector. Ministries of Defence can use their budgets to implement programmes for the military, and Ministries of Education for teachers, schoolchildren and their parents. Private firms can contribute in cash and in kind. While Ministries of Health undoubtedly have a critical role to play in responding to the epidemic, leaving the management of the overall national response to them is unlikely to prove effective in the longer term. NGOs, who are trusted by vulnerable populations, are best positioned to support prevention programmes in collaboration with these communities themselves. The mass media can promote safer behaviour and tolerance through their own channels.

5. Community-based responses

The eventual outcome of the AIDS epidemic is decided within the community. People, not institutions, ultimately decide whether to adapt their sexual, economic and social behaviour to the threat of HIV infection. They are the subjects of the response to AIDS, not merely the objects of outside interventions. Therefore, responses to HIV are in the first instance local: they imply the involvement of people where they live – in their homes, their neighbourhoods and their workplaces.

Community members are also indispensable for mobilizing local commitment and resources for effective action. In particular, people living with HIV/AIDS must play a prominent role and bring their unique experience and perspective into programmes, starting from the planning stage.

Community mobilization against HIV/AIDS is taking place successfully all over theworld. The activities carried out in community projects are as diverse as the peoples and cultures that make up these communities. Some are entirely "home-grown" and self-sufficient, while others have benefited from external advice and funding. Some are based in religious centres, others in medical institutions, and still others in neighbourhood meeting places. Many concentrate on public education, others on providing care, and still others on prevention and other goals.

6. Social policy reform to reduce vulnerability

HIV transmission is associated with specific risk-taking behaviours. These behaviours are influenced by personal and societal factors that determine people's vulnerability to infection. To be effective, risk-reduction programmes must be designed and implemented in synergy with other programmes, which, in the short and long term, increase the capacity and autonomy of those people particularly vulnerable to HIV infection. Therefore, the question is how to address directly the societal forces which determine, more than anything else, vulnerability to HIV/AIDS. Issues such as gender imbalance and the inability of women to negotiate when, how and with whom they have sex is a social policy

Automated Records Management System
Flex-Dump Conversion

issue. The chronic and acute poverty of urban households that leads to their eventual breakdown and the migration of children to the street is not an issue that can be easily addressed at a household or community level alone.
Addressing the societal forces which determine vulnerability to HIV requires engagement at the policy level and political will and resources. Effective social policy reform is a long-term agenda, but even small-scale and incremental steps can send important messages about political commitment to reducing the vulnerability of individuals and communities to infection.

7. Longer-term and sustained response

Even a comprehensive response to HIV/AIDS does not yield immediate results. Measurable impact may take four to five years to develop. Therefore, a long-term approach must be taken, which involves building societal resistance to HIV. Beginning with the youngest generation, the reinforcement of safer attitudes and behaviour will gradually fortify a generation against the spread of AIDS, and in time have a significant impact on incidence.
Effective programmes are characterized by focused action and steadily expanding coverage. To begin with, using existing resources, it makes strategic sense to focus on important vulnerable populations and geographic areas where rapid HIV spreadtakes on the characteristics of an emergency. Planners must nevertheless take into account the need to reach many different populations, including those who will become exposed tomorrow: individual risk and vulnerability change over the life cycle as children mature into adolescence and adulthood.
There is also evidence that continued vigilance is critical even when behaviour change appears to have become established. The use of condoms among a newly sexually active generation of men who have sex with men for example cannot be assumed, just because an older generation changed its behaviour. Gradually, without losing focus, action must expand steadily until complete country coverage is achieved.

8. Learning from experience

The last 15 years of HIV prevention and care have led to the development of a rich body of experience and expertise. While it is essential that individual countries "own" their response there is a great deal of evidence that some policies, strategies and technologies are particularly effective: that which UNAIDS calls "best practice".
Drawing on best practice and adapting it to local circumstances is valuable both at the outset, and as the response matures. Learning within a national context is also important.
District bureaucracies provide the critical link between local and national activities.
The district level is well placed in many countries to analyse, document and disseminate what they learn from the local responses. They can then press for, and negotiate with, the national authorities the changes and reforms needed in key sectors to sustain local responses. There are multiple examples of good HIV "projects"
– successful interventions that have identified the recipe for success in a given environment. They can provide valuable insights to national programmes.

Similarly, national programmes are in a strong position to scale up local responses to the national level by incorporating local lessons into their strategic planning and reform processes. For example, governments can effectively adopt policy changes and programme approaches that have "passed the test" at the local level.

Box 21. International support for national responses

Donor assistance to HIV/AIDS has increased substantially over time. In 1998, 14 of the largest donors in the OECD Development Assistance Committee provided US$ 300 million for HIV/AIDS activities. In 1987 – soon after it was first recognized that HIV had spread massively in many developing countries – levels of official development assistance (ODA) funding to AIDS were only at 20% of the levels seen a decade later. This increase has occurred at the same time that overall ODA contributions to developing countries have steadily declined.

Unfortunately, as spectacular as this increase appears, it has not kept pace with the spread of the epidemic – or even the most basic requirements for HIV programmes of the most-affected countries. During the same period, the number of infections has risen from 4 million to over 34 million, a figure that continues to grow given the more than 5 million new infections annually. Furthermore, increases in donor support had begun to level off between 1996 and 1998, and it remains less than just 1% of donor countries' total annual ODA budgets. Against the backdrop of soaring infection rates, this trend is of critical concern.

However, recent indications from donors are encouraging. For example, funding by the United States for global HIV/AIDS activities increased by US$ 65 million in 2000 and is set to increase by as much as an additional US$ 100 million in 2001. The donor response to the International Partnership Against AIDS in Africa has also been positive.

This important new initiative – the objectives of which are to curtail the spread of HIV, reduce its impact on human suffering and halt the reversal of social and economic development in Africa – includes donors as one of its five key constituencies.

Representatives of donor countries are participating in all phases of its development, and their greater understanding of, and involvement in, national planning processes are paying off in increased support.

In addition, there is increasing recognition that HIV/AIDS is not only a major threat to development, but also a threat to peace-building and human security in Africa. This has resulted in higher levels of political awareness and more substantial financial commitments. An additional US$ 180 million in donor funding for activities in Africa was announced at the historic Security Council meeting in January 2000. The challenge is to ensure that this growing enthusiasm results in a steady increase in concrete support to national HIV/AIDS prevention and control programmes – in Africa and elsewhere.

To do this, emphasis must be placed on building partnerships between donors and the most-affected countries. In this way a sense of shared responsibility can be created both for improving prevention and care as well as for addressing the formidable, multifaceted development challenges this epidemic presents.

9. Adequate resources

The reassignment of national priorities must be reflected in a reallocation of budgets. There are success stories in developing countries where government

Automated Records Management System
Hex-Dump Conversion

budgets for AIDS have been increased significantly; for example in Brazil, China, India and Thailand. At the same time, however, it is a fallacy to assume that because designated AIDS funding is limited, so must AIDS action be. Effective programmes identify opportunities to involve partners with similar goals and objectives, and capitalize on synergies between AIDS and other programmes. If the action needed for risk-reduction and vulnerability-reduction becomes part of the mainstream of national life, direct costs will be less, the benefits will have many spin-offs, and programmes are more likely to be sustainable. For example, including information on HIV/STDs and life skills in a school curriculum has only marginal costs, but the resulting decision- making and negotiation skills may bring about extra benefits such as declines in STDs, unwanted pregnancies and drug use. Similarly, boosting the educational and economic opportunities of young girls in rural areas not only reduces HIV transmission by providing alternatives to commercial sex, but also contributes to sustainable rural development and an improvement in the status of women.

Redirecting to AIDS existing project resources already programmed for social funds, education and health projects, infrastructure and rural development is fully justified, as the AIDS epidemic is undermining the very goals of these other investments.

Even though international financial assistance is not always necessary, international assistance is crucial in many poor countries with limited public budgets.

Box 22. Debt relief

Some 95% of HIV-infected people live in developing countries, most of them in sub-Saharan Africa. The world's poorest countries together owe around US$ 2 trillion in external debt.

Lack of funds for an expanded response to AIDS has been worsened by these high levels of foreign indebtedness. Across Africa, national governments pay out four times more in debt service than they spend on health and education.

In order to mount effective national AIDS prevention programmes, countries in Africa will need to spend at least US$ 1–2 billion a year, far more than is currently being invested.

Sources that might be tapped for these additional resources include increased donations from the private sector and foundations, expansion and redirection of development assistance, and reallocations within countries' own public budgets.

Relieving countries' debt burden is one of the more promising new approaches that could increase the funds flowing into programmes to roll back the AIDS epidemic in Africa. By relieving debt in the poorest countries – which, often, are the ones with the highest HIV and AIDS figures – money now exported to service debt could be reinvested into AIDS prevention and care.

A major initiative to reduce debt over the next few years will take place under the Highly Indebted Poor Country initiative (HIPC), supported by all the major creditor governments from the OECD countries and implemented by the World Bank and International Monetary Fund.

In a typical debt relief agreement, portions of a country's debt will be cancelled in exchange for the debtor government's commitment to mobilize domestic resources for specific purposes, such as a poverty eradication scheme or an intensified national AIDS effort.

Automated Records Management System
Text-Dump Conversion

Such transactions have succeeded since the 1980s in the field of environmental conservation, for instance, by protecting rainforests from logging.
At the heart of debt reduction deals under HIPC lies the challenge of agreeing on significant goals in poverty reduction and on measurable indicators of progress towards these goals. Lending countries will have greater incentives to reduce debt if there are clear and measurable ways of assessing the benefits. For example, a medium-term AIDS-related target might be to provide low-cost treatments to a specific percent-age of the population suffering from the most common opportunistic infections.
Measurable indicators for monitoring progress would likely include the availability of specific generic medicines in primary health care centres.
During the first months of 2000, several countries in Africa have started to feature HIV/AIDS more prominently in their poverty-reduction strategies and in related HIPC debt relief agreements. This is encouraging. But a concerted effort by a coalition of interested African government officials, civil society representatives, creditor governments, and United Nations and multilateral agencies will be required to ensure that debt relief is actually used to mobilize substantially increased funding for AIDS.

Conclusion

Two decades of action against the epidemic have generated important insights into an effective response. While international political, financial and technical support are important, lowering incidence and mitigating the epidemic's impacts must be a nationally driven agenda. To be effective and credible, national responses require the persistent engagement of the highest levels of government. Countries that have adopted forward-looking strategies to fight the epidemic are reaping the rewards in falling incidence. Other countries are yet to see the fruits of their efforts, and in the absence of rapid and visible results, sustaining a response becomes more difficult.
However, evidence shows that the combination of approaches described in this chapter have brought about a lowering of incidence in some countries. At present, and until the arrival of a vaccine, these approaches are the strongest weapons in our fight back against HIV/AIDS.

Annex 1. How reliable are estimates of HIV infection and AIDS deaths?

It is important to stress that the estimates given in the table in Annex 2 (see pages 124-135) and many of the country- and regional-level figures given elsewhere in this report are estimates rather than exact counts of infections or deaths. Every time new estimates of HIV infections or AIDS deaths are released, questions are asked about the source and validity of the data, the methods used to arrive at estimates, and whether the figures reflect the "reality" of the epidemic. These questions arise for all diseases, especially those common in developing countries, where reporting systems are poor and many births and deaths – and most illnesses – go unrecorded. In fact, in many countries, the information on which HIV estimates are based is better than the information available for most other diseases.

Automated Records Management System
Hex-Dump Conversion

The approach to estimating HIV prevalence and AIDS deaths varies according to whether the HIV epidemic has reached the general population, or whether it is still largely concentrated in groups with high-risk behaviour.

In largely heterosexually driven epidemics where there is evidence that men and women in the general population have become infected with HIV in significant numbers, HIV surveillance is based mostly on tests performed among pregnant women attending antenatal clinics that have been selected as sentinel surveillance sites.

Anonymous specimens of blood left over from tests performed as part of routine care for pregnant women are tested for antibodies to HIV. Many countries with heterosexual epidemics in sub-Saharan Africa and a few countries in Asia and the Caribbean have conducted HIV prevalence studies in selected antenatal clinics more or less regularly since the end of the 1980s. The more regular the studies, the clearer the picture of current prevalence. Where data are not available for the current year, all available data points are plotted on a curve, and an estimate for the current year is made according to what is known about the course of epidemics with predominantly heterosexual transmission. To account for differences in the spread of HIV, this is generally done separately for urban and for rural areas.

Pregnant women seeking antenatal care are chosen for HIV surveillance because they provide easy access to left-over blood samples, and because they are fairly representative of the general population. Even in the least developed countries the coverage of antenatal care is high. In recent years a series of population-based studies in urban and rural communities have made it possible to validate the results of sentinel surveillance in pregnant women. These studies offer important insights into the differentials of HIV infection by age and sex. They also confirm that sentinel surveillance in pregnant women yields remarkably robust estimates for HIV prevalence in the general population of reproductive age, as shown in Figure 28.

In countries where the HIV epidemic is concentrated in a few groups with high-risk behaviour – mostly drug injectors and men who have sex with men, as well as sex workers and their clients – the methods for estimating HIV prevalence are different.

This is the case in most countries in Asia, the Americas and Europe. Here, because there are very few HIV infections in the general population, and because many of the infections are in groups largely or entirely made up of men, data from pregnant women are of very limited use. Rather, HIV estimates in such cases are based on information on HIV prevalence in each group of people with high-risk behaviour, together with estimates of the size of each of these populations. Since these behaviours are often socially unacceptable and sometimes illegal, information on both HIV prevalence levels and the size of the population affected can be much harder to come by. Consequently, uncertainties around these estimates may well be greater for countries where the epidemic is concentrated in specific groups.

epi_ext/img055.gifepi_ext/img055.gif

Automated Records Management System
Flex-Dump Conversion

Source: Sentinel surveillance data from antenatal clinics and population-based studies, selected African countries, 1990-1998

In the industrialized world, where the availability of antiretroviral therapy provides a powerful incentive to get tested for HIV for anyone who thinks he or she may have been exposed to the virus, surveillance systems increasingly include data from HIV testing and – where available – HIV reporting. In addition, robust AIDS case registration systems with reporting rates of up to 80% and higher allow for the use of statistical back-calculation methods. However, such methods have become less useful since the introduction of antiretroviral therapies, because it is no longer easy to define the relationship between initial HIV infection and the onset of AIDS in patients in treatment.

In regions where life-prolonging therapy is not widely available, simple back-calculation procedures are used to generate estimates of new HIV infections and of HIV-related deaths. These procedures are based on the well-known natural course of HIV infection which determines the relationship between HIV incidence, prevalence and mortality. Similarly, estimates for HIV infections through mother-to-child transmission (including breastfeeding) and HIV mortality in children can be calculated. These estimates are based on age-specific fertility rates in countries and on region-specific rates of mother-to-child transmission which are documented in numerous studies.

The estimates published in this report (apart from those specifically referenced otherwise) are based on the information available in March 2000. They are provisional. WHO and UNAIDS, together with staff at national AIDS programmes and research institutions, keep HIV/AIDS estimates under constant review with a view to updating them as improved knowledge about the epidemic becomes available and as advances are made in the methods for deriving estimates.

The purpose of publishing these estimates is to help governments, nongovernmental organizations and others who have a stake in bringing HIV/AIDS under control to gauge the status of the epidemic in their country and to monitor the effectiveness of efforts at prevention and care being made by all partners.

Annex 2. HIV/AIDS estimates and data, end 1999

The estimates and data provided in the following table relate to the end of 1999 unless stated otherwise. They are given in rounded numbers. However, unrounded numbers were used in the calculation of rates and regional totals, so there may be small discrepancies between the regional/global totals and the sum of the country figures.

Adults in this report are defined as men and women aged 15–49. This age range captures those in their most sexually active years. While the risk of HIV infection obviously continues beyond 50, the vast majority of those with substantial risk behaviour are likely to have become infected by this age. Since population structures differ greatly from one country to another, especially for children and the upper adult ages, the restriction of "adults" to 15–49-year-olds has the advantage of making different populations more comparable. This age range was used as the denominator in calculating the adult HIV prevalence rate.

Automated Records Management System
Hex-Dump Conversion

The methodology used to produce the country-specific estimates in the table has been described in full elsewhere (Schwartländer et al. AIDS 1999; 13:2445–2458).

Notes on specific indicators listed in the table

1. People living with HIV/AIDS, end 1999

These estimates include all people with HIV infection, whether or not they have developed symptoms of AIDS, alive at the end of 1999.

For country estimates marked with an asterisk, not enough data were available to produce an estimate of HIV prevalence for end 1999. For each of these countries the 1994 prevalence rate published by the WHO Global Programme on AIDS (Weekly epidemiological record 1995; 70:353–360) was applied to the country's 1999 adult population to produce the estimates given in the table. No country-specific models were produced for countries marked with an asterisk. For data columns containing few or no country estimates, the regional totals were calculated on the basis of a regional model.

Adults and children

Estimated number of adults and children living with HIV/AIDS at the end of 1999. Children are defined as those aged 0–14.

Adults (15–49)

Estimated number of adults living with HIV/AIDS at the end of 1999.

Adult rate (%)

To calculate the adult HIV prevalence rate, the estimated number of adults living with HIV/AIDS at the end of 1999 was divided by the 1999 adult population (aged 15–49).

Women (15–49)

Estimated number of women living with HIV/AIDS at the end of 1999.

Children (0–14)

Estimated number of children under age 15 living with HIV/AIDS at the end of 1999.

2. AIDS orphans

Orphans, cumulative

Estimated number of children as of end 1999 having lost their mother or both parents to AIDS before age 15 since the epidemic began. Some of the orphaned children included in this cumulative total are no longer alive; others are no longer under age 15.

3. AIDS deaths, 1999

Adults and children

Estimated number of adults and children who died of AIDS during 1999.

4. Population, 1999

Total (thousands)

Total population in 1999 (UN Population Division, Department of Economic and Social Affairs, United Nations Secretariat).

Adult (thousands)

Population aged 15–49 in 1999 (UN Population Division, Department of Economic and Social Affairs, United Nations Secretariat).

5. Ranges of uncertainty around prevalence and mortality estimates

Automated Records Management System
Flex-Dump Conversion

The best estimates of HIV prevalence and AIDS deaths are given under indicators 1 and 3 (see above). Depending on the reliability of the data available, there may be more or less uncertainty surrounding each such estimate. Indicator 5 therefore presents both low and high estimates for certain variables. The wider the range, the greater the uncertainty surrounding the country's estimates, which in turn depends mainly on the quality, coverage and consistency of the country's surveillance system.

While a measure of uncertainty applies to all estimates, in this report ranges of uncertainty are presented for the following key variables:

- ***the estimated number of adults and children living with HIV/AIDS at the end of 1999***
- ***the estimated number of AIDS deaths in adults (15–49) during 1999***
- ***the estimated number of AIDS deaths in children (0–14) during 1999.***

6. Estimated HIV prevalence rate (%) in young people, end 1999

The estimated number of young people (15–24) living with HIV/AIDS at the end of 1999 divided by the 1999 population of young people (15–24). These country-specific estimates are expressed as a range generated by regional modelling.

7. HIV prevalence rate (%), data from selected populations

Percentage of people tested in each group who were found to be infected with HIV.

Most of these data are from routine sentinel surveillance (see Annex 1).

For each of the groups the table gives the year of the most recent report, the median for all surveillance sites, the minimum and the maximum.

Data from surveillance among pregnant women at antenatal care clinics are broken down into urban populations and populations living outside major urban areas. Truly rural areas often have no sentinel surveillance sites at all.

Nearly all the data on groups with high-risk behaviour such as injecting drug use and sex work come from studies in urban areas. Data marked with an "r" are from rural studies, often conducted in small towns outside major urban centres. An "n" denotes a nationwide number that does not allow for a rural–urban breakdown.

Women in antenatal care clinics – major urban areas

Women in antenatal care clinics – outside major urban areas

Male patients with a sexually transmitted infection (STI) – major urban areas

Female sex workers – major urban areas

Injecting drug users – major urban areas

8. Prevention indicators

Condom availability

- condoms available per capita

Total number of condoms available for distribution, during the 12 months preceding the report, per adult (15–49). This includes imports, local manufactures, private-sector condoms and socially marketed condoms. The year indicates the date of the most recent report.

- condom access (%)

The percentage of adults (15–49) that have access to condoms. The year indicates the date of the most recent survey.

Reported non-regular sexual partnerships (%)

utomated Records Management System
ex-Dump Conversion

The percentage of adults who report having had at least one sex partner other than their regular sex partner(s) in the 12 months preceding the report. An "a" denotes the proportion for both sexes combined. Urban samples are marked with a "u". A "y" denotes the proportion for those not living with a spouse or other stable partner. The year indicates the date of the most recent survey.

Reported condom use with non-regular partner (%)

The percentage of adults who report having used a condom during the most recent intercourse with a non-regular sex partner. An "a" denotes the proportion for both sexes combined. Urban samples are marked with a "u". The year indicates the date of the most recent report. The age range indicates the age group of the population included in the survey.

Table of country-specific HIV/AIDS estimates and data, end 1999(html - xls)

Global surveillance of HIV/AIDS and sexually transmitted infections (STIs) is a joint effort of the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance, initiated in November 1996, is the main coordination and implementation mechanism through which UNAIDS and WHO compile the best information available and help improve the quality of data needed for informed decision-making and planning at national, regional and global levels. This work is done in close collaboration with national AIDS programmes worldwide and with other national and international experts and institutions.

What Makes an Economy HIV-Resistant?[1]

René Bonnel

ACTAfrica

World Bank

July 18, 2000

Abstract

HIV/AIDS is a major development crisis. In recent years it has reversed the development gains of the last generation in many developing countries. Preliminary estimates suggest that Africa's income growth per capita is being reduced by about 0.7 percentage points per year because of HIV/AIDS. For those African countries affected by malaria, growth was further lowered by 0.3 percentage points per year. Such reduction is large when compared with the historical growth of 0.4% achieved in 1990-97. Various factors related to poverty, inequality, gender inequality, labor mobility and ethnic fractionalization have facilitated the rapid spread of HIV. But what has made HIV/AIDS able to undermine economic and social development is its erosion of some of the main determinants of economic growth such as social capital, domestic savings and human capital. It is through such channels that the HIV epidemic was transformed from a health issue into an economic disease that impairs economic and social development. Because it prevents an increasing share of the population from participating in economic growth, the HIV/AIDS epidemic increases poverty. The result is a vicious circle whereby HIV/AIDS reduces economic growth and increases poverty, which in turn accelerates the spread of HIV. Without strong and immediate action, it will prove quite difficult to overcome the cost of inaction latter on.

[1] The results included in this paper should be viewed as preliminary. The opinions expressed here do not necessarily reflect those of the World Bank.

Automated Records Management System
Hex-Dump Conversion

Introduction

In the early model of Malthus, the relationship between population growth and per capita income was negative. Population growth in the context of a fixed amount of land and technology was projected to lead to lower income per capita. This Malthusian framework described quite well the evolution of per capita income for most of human history. For example, Europe's Black Plague, which resulted in a smaller population, led to higher real wages.[2]

The conclusion that lower population growth could increase income per capita underlied the early economic analysis of HIV/AIDS. As in Malthus'model, lower labor force growth due to AIDS-related mortality was projected to increase per capita income[3]. However, there was an offsetting factor. To the extent that domestic savings would fall, domestic investment would decline, which would lower per capita income.[4] This was most likely to occur if most of the medical costs entailed by HIV/AIDS were financed out of domestic savings rather than out of consumption and if the country could not mobilize external financing.

Whether per capita income would increase or decrease was therefore an empirical question. In most cases, a decline in the rate of growth of per capita income was judged to be the most realistic outcome, but the reduction was quite modest of the order of 0.1 to 0.3 percent per year.[5] In some cases such as Botswana, per capita income was projected to increase as a result of HIV/AIDS mainly because AIDS was projected to affect labor force growth more than national saving[6], but Botswana's situation is clearly unusual.

Compared to other policy interventions such as stimulating growth or reducing poverty, the modest estimated impact of HIV/AIDS seemed to justify the policy of benign neglect that characterized most developing countries in the 1990s. Yet, the recent descriptions of the social and economic impact of HIV/AIDS are not consistent with the predictions of these models. To some extent, this can be explained by the speed and scale of the epidemic, which have been much worse than projected. Compared to what was projected in the early 1990s the scope of the epidemic was certainly unexpected[7]. But the main reason is that the impact of the HIV/AIDS epidemic on growth is not adequately captured by Solow-type growth models. In such models, the impact of the HIV/AIDS epidemic on labor force, human capital and domestic saving is usually projected exogenously whereas

---

2 For an analysis of population growth and per capita income, see Galor and Weil (1999).

3 To increase the model's realism, other considerations were introduced that would lower economic growth. These included the extent to which the labor force affected by AIDS was highly skilled or the extent to which the productivity of the labor force would be reduced due to HIV/AIDS (see Over, 1994).

4 For example see Cuddington (1993). Another approach consisted of estimating a CGE model and projecting the sectoral effects of a reduction in the labor force (Kambou, Devarajan and Over, 1992).

5 See Ainsworth, Martha and Over, Mead. 1994. "Aids and African Development".

6 Because of Botswana's excellent international credit rating, any shortfall in domestic saving could easily be offset by borrowing from abroad with the result that the stock of capital would not fall.

7 The number of new HIV infections in Africa was projected to remain at 1 million (base case) and to reach 2 million by 2000 under a worst case scenario ("Investing in Health" World Development Report 1993, p.101; World Bank). However, new infections reached 4 million in Africa in 1999 (UNAIDS, 1999).

Automated Records Management System
Hex-Dump Conversion

they are endogenous to the growth process and are determined by policy incentives and institutions. As analyzed in recent papers, economic growth cannot be adequately accounted for simply by factor accumulation. Policy incentives are what matter.[8]

Such an analytical framework underlies the analysis of the development impact of the HIV/AIDS epidemic. The starting point is a modified neoclassical growth model. In general, developing countries growth will depend on initial income, investment in physical and human capital and institutions. Such a model suggests that poor countries should have a high rate of return to capital and grow faster than developed countries. However, there are several factors that could interfere with this result. In particular, institutional and policy distortions can lower the return to investment and reduce growth rates. The hypothesis underlying this paper is that the HIV/AIDS epidemic has lowered the rate of return to investment in human capital, and is undermining a broad range of institutions that matter for economic growth. The result is a worsening of the process of development, which in turns facilitates the spread of the HIV epidemic in developing countries.

The paper is organized as follows. The first section discusses the main economic and social determinants of HIV/AIDS. The second section discusses the channels through which HIV/AIDS affects economic growth. The econometric model is presented in the third section along with the empirical results.

I - From Economic and Social Development to HIV/AIDS

Several economic, sociological and cultural variables account for the spread of the HIV epidemic. The main economic variables that have been identified include: life expectancy, human capital, income inequality, gender inequality, and the extent of labor migration.[9] As expected, there is a strong relationship between good health (reflected in life expectancy) and HIV/AIDS. Because access to health services is generally dependent on the level of income, there is a positive association between income inequality and HIV/AIDS (Figure 1).

Unequal regional development among countries as well as within countries can induce labor migration to urban areas or other countries. The resulting concentration of single men in urban areas or investment project sites is generally accompanied by a parallel increase in commercial and casual sex with a concomitant rise in the risk of HIV infection.

Gender and income inequality make societies more vulnerable to HIV because a woman who is poor relative to men, will find herself exposed to a much greater risk of getting infected with the HIV virus. As shown by Figure 2, empowerment of women through greater economic independence is associated with a lower HIV prevalence rate

---

[8] See for example Easterly (1999).

[9] "Confronting AIDS". World Bank Research Report (1997).

Automated Records Management System
Hex-Dump Conversion

(Figure 2).[10] Increasing women's economic independence does two things. First, it provides women with the financial and legal independence they need to take into account their own welfare at crucial times. Without such independence, women are often not in a position to follow safe prevention techniques which have been found to reduce the risk of HIV infection. Limits on independence include land inheritance laws and legal obstacles to opening banking accounts and starting their own businesses. Second, the availability of market employment opportunities increases the opportunity cost of prostitution. On one hand this implies that fewer women will become commercial sex workers to survive, and on the other hand it also leads to more condom use by commercial sex workers.

A key determinant of economic independence is education. It is therefore not surprising that education is associated with a lower HIV prevalence rate (Figure 3). Education also operates to raise the costs of becoming infected[11] and, particularly if it includes sexual education, it will improve the knowledge of the risks entailed by unprotected sexual relations. Both factors increase the incentives to invest in HIV prevention activities and account for the broad negative relationship between education and HIV.

Sociological and cultural variables include the type of sexual relations, religious belief, and the structure of societies. The type of sexual relations is important because it affects the relative spread of HIV among men and women. In Africa, HIV is mainly spread through heterosexual relations. As a result, HIV/AIDS affects men and women much more uniformly than in other countries. Religious belief is also an important factor, but its interpretation is subject to conflicting interpretations. Being of Muslim religion is generally associated with a lower HIV prevalence rate, but this could be due to male circumcision, which is thought to reduce the risk of infection.

Ethnic fractionalization could be an important determinant of the HIV prevalence rate to the extent that it entails discrimination against some ethnic groups in the allocation of public expenditures. Ethnically-diverse societies, with some groups being more affected by HIV than others, may experience difficulty in agreeing on spending priorities. The result may be less public spending on public goods as documented by Alesina, Baqir and Easterly (1999). However, this effect may be offset by strengthening community-based response to the HIV epidemics as this may facilitate the formation of a broad-based response in the face of an HIV epidemic.

Epidemiological variables include cofactors that increase the risk that sexual contacts will result in HIV infection. Male circumcision has recently been mentioned as a possible factor that reduces infection risk. But the most important cofactor is probably ulcerative sexually transmitted diseases. As is usual in epidemiological models, the age of the epidemic, i.e. how long it has been since the first infectious case was reported in a country, affects the evolution of the HIV prevalence rate over time. Because HIV/AIDS weakens the immune response, it gradually becomes the main cause of opportunistic

---

[10] The share of female labor in the industrial sector was taken as an indicator of the lack of market opportunities for women.

[11] The cost is proportional to the lost earnings resulting from AIDS-related mortality. This means that educated workers have higher incentives to invest in HIV prevention measures than unskilled workers.

Automated Records Management System
Hex-Dump Conversion

infections such as tuberculosis. There are also some indications that HIV is a cofactor of malaria. All these factors combine to make HIV/AIDS one of the most potent diseases of developing countries.

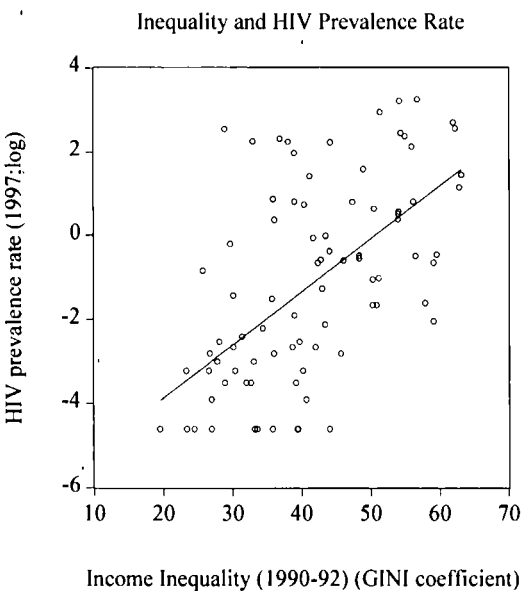


Figure 1

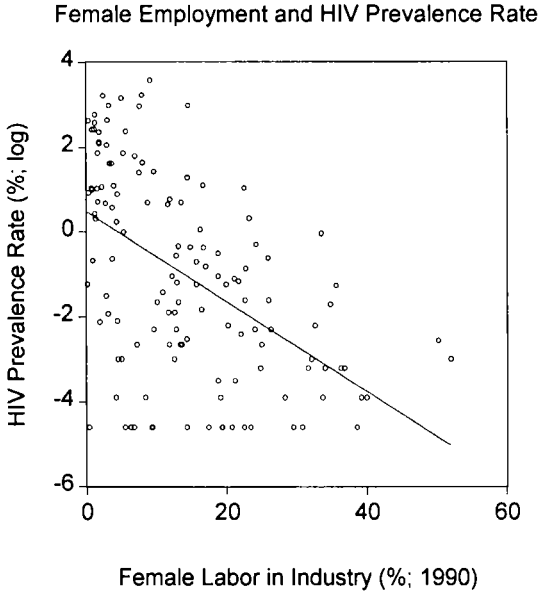


Figure 2

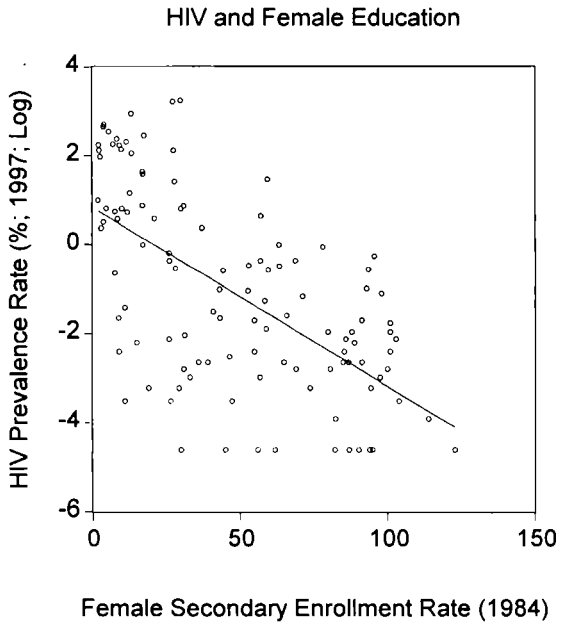


Figure 3

Automated Records Management System
Hex-Dump Conversion

The evidence shown in the previous graphs suggests that the spread of the HIV epidemic is related to various economic, sociological and cultural characteristics. This was further explored through a cross-country regression of the HIV prevalence rate for some 60 developing countries for which data was available. Table 4 (Annex) provides statistical evidence that education, increased job opportunities for women, and cultural belief associated with circumcision reduce the prevalence of HIV. The coefficients of these variables are highly statistically significant even when controlling for the level of income per capita and infrastructure by countries. Similarly, income inequality, ethnic fractionalization, and the age of the epidemic increase the spread of HIV/AIDS. In total, these factors explain about 70 percent of the variation of the HIV prevalence rate among developing countries.

In many countries, however, HIV/AIDS remains an "invisible" disease. Because of the long incubation period of the HIV virus (7-8 years on average), there is a long lag between the moment the first HIV infection is reported and the time when the economic effects of the epidemic are felt. This means that in most countries the full economic impact of the HIV epidemic has yet to register.

II - From HIV/AIDS to Economic and Social Stagnation

What gives HIV/AIDS its extraordinary impact on economic and social development is its ability to undermine key determinants of economic growth such as human capital, domestic savings, social capital, and sound macroeconomic outcomes.

Investment in human capital is likely to be adversely affected by the shortened life expectancy resulting from HIV/AIDS. To the extent that the benefits of education can only be recovered over a shorter time horizon, investment in education and on-the-job training are likely to decline. This hypothesis was tested through a cross-country regression of the change of the secondary school enrollment rate between 1990 and 1996 on the HIV prevalence rate. Other variables such as the 1990 enrollment rate, the 1990 per capita income and an index of the level of infrastructure development (phones per capita) were included to account for initial conditions as well as a dummy variable for Southern Africa. The growth rate of GDP per capita was added because growth could affect savings. The results (Table 5, Annex) indicate that the HIV epidemic was statistically significant in reducing school enrollment rates.

Domestic savings. A similar regression was carried out for domestic savings (Table 5, Annex). The results also suggest that domestic savings rates were adversely affected by the HIV/AIDS epidemic.

Macroeconomic policy. Sound fiscal, monetary and exchange rate policies have consistently been found to be extremely important for growth. However, diversion of private and public resources from investment to treatment and care of HIV/AIDS can induce a worsening of domestic savings and fiscal deficits. This deterioration would be reflected in country ratings of macroeconomic policy. In addition, the loss of human capital might adversely affect the macroeconomic management capacity of governments.

Automated Records Management System
Hex-Dump Conversion

As shown in Table 2 (Annex), there is some econometric evidence that macroeconomic outcomes –as measured by the World Bank ratings of macroeconomic performance of developing countries— are negatively affected by the HIV/AIDS epidemic.

Private sector development. Investment decisions by firms could be adversely affected by the increased cost of labor due to the attrition resulting from AIDS-related mortality. In addition, private sector development would suffer to the extent that the quality of regulation and of the legal environment would be eroded by HIV/AIDS. Such factors have been found to be important for economic growth. This hypothesis was tested by using a recent set of indicators that include the quality of regulation, government effectiveness, the extent of graft, the rule of laws, the extent of participation in politics, and the degree of political instability.[12] As summarized in Table 2 (Annex), the econometric data suggests that the HIV/AIDS epidemic is adversely affecting the quality of regulation and the effectiveness of governments. But the impact on laws, political instability, graft and democracy was not statistically significant.

Social capital has recently emerged as an additional important determinant of growth.[13] Because HIV affects the social structure of local communities, it could erode existing social network and traditional support mechanisms in the face of external shocks. The result might be a generation of AIDS-related orphans who would have to grow without the support and guidance of adults.

The broad relationship between HIV/AIDS and policy and institutional variables is summarized in Table 1. Some 70 developing countries were classified into two groups according to whether the HIV prevalence rate was below or above 0.4%. The objective was to separate countries into those that would not be much affected by HIV from those that would be.

The data of Table 1 is consistent with the hypothesis that HIV/AIDS affects a broad range of institutions. In all cases, the institutional rating are much worse for countries with an HIV prevalence rate above 0.4% than for those countries with HIV prevalence rate below 0.4%. However, it should be stressed that the data of Table 1 only indicates that there is a relationship between HIV and institutions and policy ratings, but the causality could be from institutions to HIV. For example, it seems more plausible that political instability affects the spread of HIV rather than the reverse. Similarly, graft and HIV may be related, but the relationship may be due to other factors that affect both graft and HIV/AIDS.

---

[12] See Kaufman (1999 and 2000).

[13] For example, trust and civic cooperation have been found important for growth (Knack and Keefer (1995)

Automated Records Management System
Hex-Dump Conversion

Table 1: HIV/AIDS and Indices of Policy and Institutional Ratings

	HIV Prevalence Rates	
	Below 0.4%	***Above 0.4%***
Macro Policies 1/	3.74	3.40
Democracy	-0.08	-0.25
Political Instability	-0.16	-0.48
Government Effectiveness	-0.23	-0.40
Regulation	-0.06	-0.16
Law	-0.22	-0.51
Graft	-0.32	-0.45

Note: 1/ The index for macroeconomic policies is from the World Bank. A lower value indicates a worse rating. Other indicators are from Kaufman (1999).

HIV/AIDS and economic growth

The overall effect of the HIV epidemic is to lower the stock of human and physical capital. But, due to the long incubation period of the HIV virus (7-8 years), the adjustment process is likely to be drawn out over time with the rate of growth of the stock of human and physical capital falling gradually. The behavior of GDP during the HIV/AIDS epidemic would therefore reflect a similar gradual downward adjustment. The consequence is that the impact of HIV/AIDS is mainly to reduce the growth rate of GDP rather than to decrease abruptly the level of per capita income.

The economic impact of HIV/AIDS will not be uniform across countries or even within countries. Countries that are well developed with a strong health infrastructure can usually mobilize the resources needed to prevent early on the rapid spread of HIV/AIDS. They can take advantage of a widespread medical infrastructure to dispense the medication that can allow HIV-infected individuals to remain engaged in economic activities. Furthermore, because of their well-developed educational system and stock of human capital, the AIDS-related loss of human capital does not entail the same consequences it has in countries where skilled labor is already in short supply.

By contrast, countries which do not have such resources are particularly vulnerable to a rapid spread of HIV and a subsequent vicious downward circle. This is especially true for countries with already weak social capital, which gets further eroded by the spread of HIV/AIDS. In such an environment, a vicious cycle is set in motion whereby lower growth increases poverty. With the infection of adults in families, breadwinners fall ill and stop earning. Children are then often taken out of school to look after the ill members of the families, which sharply constrains children's opportunities for higher income later in life. In such circumstances, the poor are forced to reduce their expenditure on food, which reduces further their resistance to the opportunistic infections made possible by HIV/AIDS. The consequence is an increase in the poverty rate and the reversal of most development gains of the last decade.

Automated Records Management System
Hex-Dump Conversion

III - The Structural Model

The empirical relation between HIV/AIDS and economic growth during the 1990-97 period was investigated by relating the growth rate of GDP per capita to the HIV prevalence rate for some 70-80 developing countries for which data is available. [14] GDP per capita was chosen as an indicator although it is a biased estimate of the impact of HIV/AIDS. Because it is calculated by dividing GDP by the surviving population, it neglects the welfare of the generation that died because of HIV/AIDS. The principal reason for focusing on GDP per capita is simply that it is widely used in growth regressions.

One of the main difficulties involved in assessing the impact of HIV/AIDS on growth is a fundamental identification problem. Does HIV affects policy variables and institutional variables, or do institutional variables --for example, political instability-- cause HIV? To address that question, a system of three equations is used to model explicitly the interactions among HIV/AIDS, policy and institutional variables and growth.

The first equation expresses economic growth as a function of macroeconomic policy ratings, institutional variables and other variables that are important determinants of economic growth. Macroeconomic policy ratings and institutional variables are in turn linked to the HIV prevalence rate through a second equation. The third equation expresses the HIV prevalence rate as a function of the main determinants that were found to be important for the spread of HIV.

Growth Equation. The starting point is a growth framework that is similar to that found in the growth literature (see for example Barro, 1996). The average rate of growth of GDP per capita for country i (Growthi) is expressed as a function of policy and institutional variables (POLi) as well as a list of additional variables (Zi) that potentially explain growth in country i. These variables include the natural log of the initial per capita income of country i (LnYi), human capital (HCi), and other exogenous variables (such as the existing infrastructure and geography). In mathematical terms, the growth equation for country i can be written as:

$$(1) \qquad Growthi = \alpha_0 + \alpha_1 LnYi + \alpha_2 POLi + \alpha_3 HCi + \alpha_4 Zi + Ui$$

where α_0 is a constant and Ui is a random disturbance term for country i.

HIV and Policy and Institutional Variables. Variables likely to influence policy and institutional variables are the level of development (proxied by the number of phones per person, LNPhone94), the stock of human capital (HCi), the rate of economic growth

[14] Developed countries were excluded partly due to the lack of data concerning some of the policy variables that were used in the econometric estimation, and partly because the spread of HIV in developed countries reflects different causes (non-heterosexual) than Africa. Other countries in Eastern Europe that showed a substantial fall in the rate of growth of GDP per capita were also excluded as the declines were due to political factors that were not captured in the growth equation.

Automated Records Management System
Hex-Dump Conversion

(Growthi) during the previous period, and the rating of policies at the beginning of the period (ICRG90). They are therefore included in equation (2) as well as a dummy variable for Southern Africa.

The simple epidemiological model described in Annex has one important implication, namely that the change in the HIV prevalence rate is a function of the prevalence rate and its square. The reason for this is that the relationship between the rate of growth of GDP per capita and HIV is non-linear. It tends to follow an inverted U-curve. Since policy variables are highly correlated with economic growth, the relation between policy variables and the HIV prevalence rate is also non-linear. In equation (2), the policy variable (POLi) is therefore expressed as a function of HIV and the square of HIV (in logarithms).

$$(2) \quad POli = \gamma_0 + \gamma_1 LnPhone94 + \gamma_2 HCi + \gamma_3 ICRG90 + \gamma_4 Growthi + \gamma_5 Ln(HIVi) + \gamma_6 (LnHIVi)^2 + + \gamma_7 Dummy + Wi$$

HIV and its determinants. The determinants of HIV/AIDS, discussed in the previous section, are included as variable Xi in equation (3). Economic growth (Growthi) is included to test whether the HIV prevalence rate is affected by reverse feedbacks from growth.

$$(3) \quad Ln(HIVi) = \beta o + \beta_1 Xi + \beta_2 (Growthi) + \beta_3 Xi + Vi$$

Empirical Results

Equations (1), (2) and (3) were first estimated using Ordinary Least Squares (OLS). The assumption underlying OLS is that the explanatory variables are exogenous. In fact, they may be endogenous to the 1990-97 growth process. As is standard in the growth literature, the explanatory variables were therefore measured at the beginning of the 1990s to reduce the bias that endogeneity may introduce. Such solution was not feasible for the HIV prevalence rate and the policy and institutional variables since their value was only available for the mid-1990s. The alternative standard solution of using instruments for these endogenous variables was followed and the three equations were estimated using Two Stage Least Squares (TSLS). Different specifications were also tried for the growth equation to test for the importance of HIV/AIDS and other infectious diseases such as malaria.

An empirical issue is which policy and institutional variables to include in the growth equation (1). In principle, the ratings for government effectiveness, regulation and macroeconomic policy could be included in the regression, but this would introduce multicollinearity as these variables are highly correlated. For this reason, the results are shown with the ratings for law and macroeconomic policy.

As a proxy for the stock of human capital, school enrollment rates were used. While they do not measure satisfactorily the stock of human capital –in particular, they exclude on

Automated Records Management System
Hex-Dump Conversion

the job training—they perform better than some of the more comprehensive estimates of human capital.[15]

The ***Ordinary Least Squares*** (OLS) results of estimating the growth equation (1) are consistent with the findings of the growth literature (Table 1, first column). Nearly all the coefficients are statistically significant with the expected sign. The coefficient of income per capita is negative, which is consistent with the hypothesis of conditional convergence of GDP per capita between poor and rich countries.[16] The level of infrastructure and the primary school enrollment rate are significant with the expected positive effect on GDP growth. Nevertheless, this regression does not explain Africa's growth too well. The coefficient of the dummy variable for Latin America is quite large, implying that most of the difference in growth between Africa and Latin America is left unexplained.

Introducing HIV/AIDS as an additional explanatory variable indicates the importance of infectious diseases for Africa's growth. As shown by the second column of Table 1 (Annex), the dummy variables for Africa and Latin America are no longer significant, but the coefficient of the HIV prevalence rate is highly significant.

Malaria and growth. What could account for the large OLS estimate of the impact of HIV on growth is the omission of relevant variables from the growth regression. If these variables are positively correlated with HIV, the coefficient of HIV would be biased upwards as it would include their impact. Among the possible diseases that are important for Africa, malaria stands out.[17] Following the approach of McCarthy, Wolf and Wu (2000), data on the morbidity caused by malaria was used to construct an index of morbidity rate per 100,000 persons.[18] The average malaria morbidity rate for 1985-90 was included in the regression, but the results were quite similar if the 1990 index was used instead.

Overall, the significance of the malaria variable is low, but this is due mainly to the quality of the data on malaria. In any case, the results are quite similar to the ones obtained by McCarthy, Wolf and Wu (2000). They suggest that the per capita growth of the countries affected by malaria was reduced by 0.3 percentage points per year in 1990-97. As shown by the third column of Table 1 (Annex), including the malaria morbidity rate in the growth regression does not affect much the estimated impact of HIV/AIDS on growth.[19]

---

[15] For examples, the Barro estimates of the number of years of schooling did not perform well.

[16] See for example Barro (1996)

[17] For an econometric analysis of the impact of malaria, see also Sachs and Gallup (1998)

[18] Published by the World Health Organization (WHO) in its Weekly Epidemiological Record, 8/13/99, www.who.int/wer.

[19] As an alternative to the 1990 malaria rate, the increase in the average morbidity rate from 1985-90 to 1990-95 was also included, but it was not significant. The most likely reason is data issues. Some large increase in morbidity rates are shown for some countries, which are too large to be readily explainable. Most likely, it reflects differences in data collection.

Automated Records Management System
Hex-Dump Conversion

Interaction between growth and policy variables. A key shortcoming of the preceding econometric estimates is that they do not explain how HIV/AIDS affects economic growth. This can be done by substituting the equation for the macroeconomic policy rating into the growth equation. The estimated growth impact of HIV is then equal to the coefficient of macroeconomic policy rating (Table 1, fifth column) multiplied by the coefficient of the HIV prevalence rate in the policy equation (table 2, second column).

Figure 4 shows the reduction in the growth rate of GDP per capita resulting from HIV/AIDS while holding constant the other factors that affect growth. For countries with a low prevalence rate the estimated growth impact is small. For Africa with an average HIV prevalence rate of 8 percent, the rate of growth of GDP per capita was reduced by about 0.7 percentage points per year in the 1990s. One reason for the large impact of HIV/AIDS is that it includes the effect of AIDS-related opportunistic infections. Because HIV/AIDS's extensive spread in Africa, most of Africa's tuberculosis is now associated closely with HIV/AIDS. There are also recent indications that HIV is a cofactor of malaria as well.

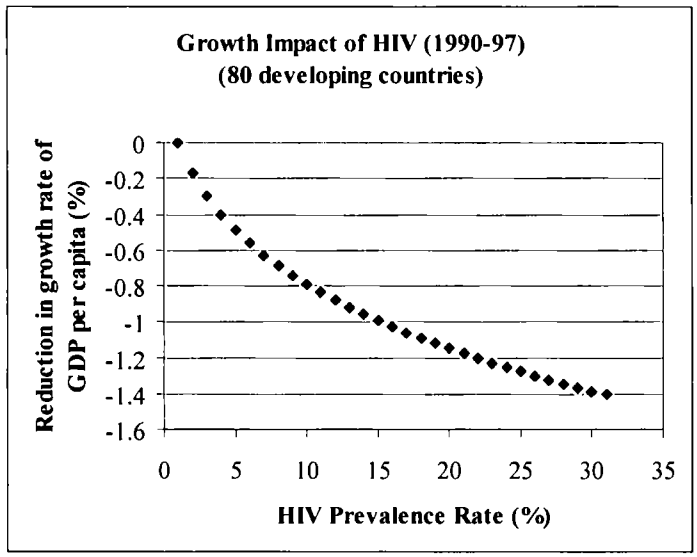


Figure 4

For Africa with an HIV prevalence rate of 8 percent, the reduction in the growth rate of GDP per capita amounts to 0.7 percentage points per year on average. This is quite substantial since the countries included in the sample have grown by 0.4 percent per year in the 1990s.

Empirical Results (Two Stage Least Squares)

The OLS estimates shown in the previous section assume that both the HIV prevalence rate and the policy variables are exogenous. However, these variables are most likely to be endogenous. The most important issue, however, is how to identify the system of equations (1), (2) and (3). However, there are a number of restrictions on the coefficients

Automated Records Management System
Hex-Dump Conversion

of the three equations which make it possible to estimate the growth equation with TSLS and using instrumental variables for the endogenous variables.

The first simplification concerns the equation for HIV. The coefficient of policies and economic growth on the HIV prevalence rate are not statistically significant. This holds under a number of different specifications. This implies that policies and economic growth can be omitted from the HIV equation. Similarly, past or current economic growth is not statistically significant in the equation for the policy variables. This makes it possible to eliminate the growth variable from that equation.

The result is a recursive system that can be identified. The main remaining issue is the endogeneity of the ratings for macroeconomic policy and the rule of law in the growth equation, but that can be addressed by using instruments that are highly correlated with these variables.

As shown by Table 1 (last column), the TSLS results for the growth equation are broadly similar to the OLS estimates. Some of the estimated coefficients are no longer significant, but this is most likely due to the reduction in the sample size due to some of the instruments that were used in the TSLS procedure. In any case, the overall estimated impact of the HIV/AIDS is quite similar to the value obtained through the OLS estimates. In the case of Africa, the estimated reduction in growth amounts to 0.9 percentage points (TSLS) versus 0.7 percentage points (OLS).

How to increase Economies' Immunity to HIV

Slower economic growth has profound implications for the spread of HIV/AIDS. What it does is facilitate the spread of the epidemic by reducing the demand for prevention activities as well as the supply of HIV/AIDS prevention and care services. Since the benefits from HIV prevention are roughly proportional to earnings that can be earned over the remaining lifetime, slower economic growth will make it less profitable for households to invest in prevention activities. In addition, some of the structural factors that could slow down the spread of the HIV epidemic are undermined. Such factors include education and income and gender inequality. When economic growth slows down, investment in education falls. This in turn worsens women's employment opportunities in the formal sector and their scope for economic independence. At the household level, the HIV epidemic has a particular severe impact as it nearly certainly ensures that those households that are already poor will not be able to cope with the loss of income and increased expenditures entailed by HIV/AIDS. The overall result is a worsening of poverty, which facilitates further the spread of HIV/AIDS.

The resulting vicious cycle makes it even more difficult for governments to respond adequately to the HIV epidemic. The reason is that the slower economic growth reduces budgetary revenues at the same time that the HIV epidemic undermines the capacity of government services, particularly in the health and education sectors, to provide the needed social services. As is shown by the experience of Southern African economies, the HIV/AIDS epidemic has not spared government services; in fact, the HIV prevalence

Automated Records Management System
Hex-Dump Conversion

rate in the education, health and general government services is as high as in the general population.

Reversing the spread of the HIV/AIDS epidemics and mitigating its impact will therefore require four sets of measures:

- Sound macroeconomic policies. Among the determinants of growth, macroeconomic policies have the largest impact on growth. In view of recent work showing that growth has a substantial impact on poverty, growth-enhancing policies may create a virtuous circle. Growth can provide the fiscal resources needed for governments to address on a sustainable basis the effects of the HIV/AIDS epidemic.

- Increasing the participation of households, and particularly the poor, in economic growth. This means addressing the legal or social constraints which adversely affect the capacity of seropositive individuals from participating in economic activities.

- Enhanced health policies. Increased focus on basic care and treatment of AIDS-related opportunistic infectious diseases such as tuberculosis as well as treatment of key cofactors of HIV such as STDs, which have the potential of extending life expectancy substantially. Both the drugs and the medical knowledge to address these diseases are available.

- Structural policy reforms aimed at addressing some of the factors that account for income inequality, gender inequality (unequal employment opportunities for women), and the role of ethnic divisions.

Automated Records Management System
Hex-Dump Conversion

Annex 1

Economic Growth and the HIV/AIDS Epidemic

The most plausible hypothesis is that economic growth is a function of the absolute change in the HIV/AIDS prevalence rate. The implication can be analyzed in the context of a simple model of infectious diseases. In such a model each infected person makes c.dt contacts over the period dt.

If I(t) is the number of infected individuals at time t, and P(t) is the total population, the percentage of the population that is not infected is given by:

$$\frac{[P(t) - I(t)]}{P(t)}$$

This implies that the number of new infections caused by one person is simply:

$$\frac{c.dt[P(t) - I(t)]}{P(t)}$$

Since each of I(t) infected individuals makes c contact per period, the increase in the number of new infections during period dt is:

$$\frac{dI(t)}{dt} = \frac{c.I(t).dt.[P(t) - I(t)]}{P(t)}$$

By definition, the prevalence rate h(t) is equal to I(t)/P(t). Taking the derivative of h(t) and substituting its value in the preceding expression gives:

$$\frac{dh(t)}{dt} = c.h(t).[1 - h(t)]$$

This equation makes it possible to simplify the relation between economic growth and the change in the prevalence rate. The change in the prevalence rate (which is not known) can be replaced by its approximation in terms of h and h^2.

Table 1: Growth and HIV/AIDS (1990-97)

	Rate of growth of GDP per capita				
	OLS	**OLS**	**OLS**	**OLS**	**TSLS**
Constant	0.14**	0.11**	0.12**	0.12**	0.027
	(2.99)	(2.62)	(2.64)	(2.13)	(0.3)
Log GDP 1990	-0.033**	-0.029**	-0.03**	-0.03**	-0.01
(purchasing power adjusted)	(-4.2)	(-3.9)	(-3.9)	(4.1)	(0.8)
Log phone per capita 1994	0.014*	0.014*	0.013*	0.019**	-0.001
	(1.96)	(1.9)	(1.8)	(2.9)	(-0.1)
Macro rating (1998)	0.010*	0.014**	(0.012**	0.01**	0.008
	(1.95)	(3.08)	(2.86)	(1.99)	(0.3)
Law rating (1995-96)	0.017**	0.014**	0.017**	0.016**	0.024*
	(2.63)	(3.04)	(3.0)	(2.6)	(1.9)
Primary enrollment rate1990	0.0004**	0.0005**	0.0005**	0.0004**	0.0005*
	(2.22)	(3.2)	(3.2)	(2.3)	(1.8)
Log of HIV		-0.0002	-0.0015		
		(-0.93)	(-0.66)		
(Log of HIV)(Log of HIV)		-0.0025**	-0.002**		
		(-3.4)	(-2.51)		
Malaria morbidity			-5.1E-07	-7.6E-07*	-6.6E-07
(per 100,000 persons)			(-1.13)	(-1.9)	(-1.4)
Dummy variable Latin America	0.020**	0.010	-0.0008		
	(2.38)	(-0.97)	(-0.09)		
Dummy variable Africa	-0.004	-0.004	-0.007		
	(-0.5)	(-0.41)	(-0.72)		
R^2	0.33	0.46	0.47	0.33	0.41
No. observations	86	81	78	83	47

Notes:
Heteroscedasticity-consistent t statistics in parentheses (White correction). * indicates significance at 10% level; ** significance at 5%.
TSLS: instruments include: LnGDPPC90, Primed90, index of democracy (Voice from Kaufman, 1999), 1990 country rating (from Institutional Investor), the 1990 share of factor receipts in exports, the 1990 share of urban population and the 1990 access to safe water.

Automated Records Management System
Flex-Dump Conversion

Table 2: Macroeconomic Policy and HIV/AIDS 1/

	Macroeconomic Policy Rating (1998)	
	Ordinary Least Squares	***Two Stage Least Square***
Constant	1.57 (1.0)	1.82 (1.3)
Growth rate of GDP per capita (1980-90)	0.20 (0.04	
Log of HIV prevalence rate (1997)	-0.21** (-2.2)	-0.34** (-3.1)
Log of HIV, square	-0.06** (-2.4)	-0.11** (-2.7)
Institutional Country Rating (1990) 2/	0.019 (1.6)	0.023* (1.96)
Log of phone (1994)	0.029 (0.14)	
Primary school enrollment (1990)		-0.014** (-2.2)
Log of GDP per capita (1990)	0.162 (0.5)	0.27 (1.15)
Dummy variable for Southern Africa	1.12** (2.7)	1.91** (3.8)
R^2	0.25	0.29
No of observations	58	46

Notes: Heteroscedasticity-consistent t statistics in parentheses (White correction).
1/. World Bank unpublished ratings.
2/ Institutional Investor Ratings: average for 1990.
3/ TSLS: instrument list: Log of GDP per capita (1990), primary school enrollment rate (1990), 1990 country rating (from Institutional Investor), the 1990 share of factor receipts in exports, the 1990 share of urban population, share of Muslims in population, share of female labor times ethnic fractionalization index, 1980-90 rate of growth of GDP per capita, dummy variable for Southern Africa, and number of years since beginning of HIV epidemic.

Automated Records Management System
Hex-Dump Conversion

Table 3: Institutional Variables and HIV/AIDS 1/
(Ordinary Least Squares Estimates)

	Law2/	*Regulation 2/*	*Government Effectiveness 2/*
Constant	-2.9** (-3.6)	-1.31** (-2.4)	-1.77 (-1.5)
Log of GDP per capita (1990) 3/	0.26 (1.7)	n.s.	-0.09 (-0.4)
Secondary school enrollment rate (1990)	n.s.	0.001 (0.2)	0.002 (0.4)
Growth rate of GDP per capita (1980-90)	3.36.2 (1.05)	-1.73 (-0.5)	0.44 (0.14)
Log of phone per capita (1994)	0.26* (1.7)	0.26** (2.4)	0.25 (1.7)
Institutional Country Rating (1990) 4/	0.022** (2.4)	0.009 (1.19)	0.025** (3.14)
Log of HIV prevalence rate (1997)	-0.09 (-1.4)	-0.17* (-2.0)	-0.12 (-1.6)
Log of HIV, squared	-0.01 (-0.5)	-0.051** (-2.8)	-0.048** (-3.2)
Dummy variable for Southern Africa	0.52 (1.5)	0.96** (2.3)	0.58* (1.9)
R^2	0.52	0.38	0.45
No of observations	64	61	60

Notes:
1/ Heteroscedasticity-consistent t statistics in parentheses (White correction). ** indicates that the coefficient is statistically significant at the 5% level; * indicates statistical significance at a 10% level.
2/ Kaufman (1999).
3/ In purchasing power parity terms.(World Development Indicators).
4/ Institutional Investor Guide; average economic rating by country (1990).

Automated Records Management System
Hex-Dump Conversion

Table 4: Determinants of HIV Prevalence Rates by Country (1997) 1/

	Log of HIV	
	OLS	***TSLS***
Constant	-1.7	-1.83
	(-0.9)	(-0.8)
Log of Phones (1994)	-0.84**	-0.57
	(-2.18)	(1.1)
Time (years since first HIV case)	0.38*	0.35**
	(2.9)	(2.5)
Religious beliefs (Muslim, % of population)	-0.024**	-0.025
	(-5.2)	(-5.2)
Labor migration	0.004**	0.003**
(Average share of factor receipts as % of exports in 1990-95)	(3.2)	(2.9)
Gender Inequality	-0.035*	-0.046**
(1990 share of female labor force in industry)	(-1.7)	(-2.0)
Ethnic fractionalization	0.027**	0.026**
	(3.5)	(3.5)
Secondary enrollment rate (1990)	-0.016	-0.023
	(-1.2)	(-1.3)
Growth (average GDP per capita, 1990-95)	4.6	-4.0
	(0.5)	(-0.5))
R^2	0.69	0.71
No of observations	59	55

Note:

1/ Heteroscedasticity-consistent t statistics in parentheses (White correction). ** indicates that the coefficient is statistically significant at the 5% level; * indicates statistical significance at a 10% level.

2/ TSLS: Instruments used: the 1990 share of factor receipts in exports of goods, economic growth in 1980-90, the log of the 1990 GDP per capita, share of Muslims in population, share of female labor in industry, female secondary school enrollment in 1990, years since beginning of HIV epidemic, secondary school enrollment rate in 1990 and a dummy variable for Southern Africa.

Automated Records Management System
Hex-Dump Conversion

Table 5: Education, Domestic Saving and HIV Prevalence Rate

	Increase in secondary enrollment rate (1990-95)	*Change in domestic saving rate (1990-96)*
Constant	-6.73 (-1.2)	0.46 (0.1)
Gross domestic saving rate (1990)		-0.28** (-2.8)
Secondary enrollment rate (1990)	-0.11* (-1.6)	-0.10** (-2.02)
Growth rate of GDP per capita (1980-90)	124.3** (3.54)	86.6** (2.4)
Log of phones per capita (1994)	5.06** (2.1)	2.49* (1.8)
Log of HIV prevalence rate (1997)	-0.39 (-0.62)	-1.18 (-1.5)
Log of HIV, squared	-0.49** (-2.6)	-0.61** (-2.6)
Dummy variable for Southern Africa	11.2** (2.8)	10.2** (2.2)
R^2	0.40	0.38
No of observations	64	77

Note:

1/ Heteroscedasticity-consistent t statistics in parentheses (White correction). ** indicates that the coefficient is statistically significant at the 5% level; * indicates statistical significance at a 10% level.

Automated Records Management System
Hex-Dump Conversion

References

Ainsworth, Martha and Over, Mead. 1994. "Aids and African Development" The World Bank Research Observer. 9(2)

Alesina, Alberto, Reza Baqir, and Easterly William. 1999 "Public Goods and Ethnic Divisions" Quaterly Journal of Economics, November 1999.

Barro, Robert J., Sala-I-Martin, Xavier. 1995. "Economic Growth". 1995

Caldwell, John C., 2000. "Rethinking the African AIDS Epidemic". Population and Development Review 26 (1): 117-135, March 2000

Collier, Paul, Hoeffler, Paul. 1999. "On Economic Causes of Civil War". Oxford Economic Papers 50 (1998), 563-573.

Cuddington, John T., 1993. "Modeling the Macroeconomic Effects of AIDS with an Application to Tanzania" The World Bank Economic review 7 (2):173-89

Easterly, William and Ross Levine. 1997. "Africa's Growth Tragedy: Policies and Ethnic Divisions," Quaterly Journal of Economics, CXII (4), 1203-1250.

Gallup, John Luke, Sachs, Jeffrey D. (1998). "The Economic Burden of Malaria" Harvard Center for International Development. October 1998

Galor, Oded, and Weil, David N. 1999. "From Malthusian Stagnation to Modern Growth", American Economic Review, May 1999, 89 (2):150-155

Kambou G. S., S. Devarajan and Mead Over. 1992. "The Economic Impact of AIDS in an African Country: Simulations with a General Equilibrium Model of Cameroon." Journal of African Economies 1(1):109-30

Kaufman, Daniel, Kraay, Aart, and Zoido-Lobaton, Pablo. 1999. "Aggregating Governance Indicators". Policy Research Working Paper, World Bank No.2195

Knack, Stephen, Keefer, Philip. 1997. "Does Social Capital Have an Economic Payoff? A Cross-Country Investigation" The Quaterly Journal of Economics, November 1997.

Knack, Stephen, Keefer, Philip. 1995. "Institutions and Economic Performance: Cross-Country Tests Using Alternative Institutional Measures". Economics and Politics, 7 (3): 207-227

McCarthy, F. Desmond, Wolf, Holger, and Wu, Yi. March 2000. Policy Research Working Paper No. 2303, World Bank

Automated Records Management System
Hex-Dump Conversion

Annex 1: Theories about the impact of viral differences on ease of infection.

"Explanations for diversity and unpredictability still allude us." Kevin de Cock

Theories about the impact of viral differences on ease of infection continue to focus on a strain of HIV-1 known as subtype C. In southern Africa, which had little HIV-1 until the 1990s, subtype C accounts for most of the infections. One difference, seen in studies of isolates from Malawi and Ethiopia, is in the cell surface receptors that HIV docks onto.[1] Persons infected with subtype C appear to have more copies of the virus that dock with a receptor that is most capable of establishing an *initial* infection. Max Essex from Harvard, also believes that subtype C may transmit more efficiently through herterosexual sex.[2] This efficiency, is increased even more with the existence of STIs. Researchers speculate ' that these conditions may explain the explosive spread of subtype C. Other researchers see these speculations as just that. And others find the explanation just too simple. (See the 23 June 2000 issue of *Science* for more information).

Others are looking at the immune system of people living in Africa, and that it appears to be more highly 'activated' (presumably because they most constantly fend off a much broader range of diseases). A higher level of activation should mean more CD4 cells—HIV's main target—circulating in the blood. Scientists from Isreal suggest that immune activation of the host is a dominant factor in the pathogenesis of AIDS in Africa and that helminth (worms) infections are central in that activation.

[1] HIV initially attaches to both a CD4 receptor and a coreceptor called CCR5 to establish an infection. Typically, as a person's immune system wears down, HIV begins favoring another coreceptor, CXCR4, over CCR5. But subtype C rarely makes the switch.
[2] In the January Journal of Infections Diseases, Essex and co-authors describe a chemical messenger secreted by immune cells that boosts HIV replication, particularly that of subtype C. And STI's increase secretion of this messenger.

Automated Records Management System
Hex-Dump Conversion

Annex 2: Lessons learned in working with specific population groups:

Young people:

Importance of beliefs and cultures
Difference between young men and young women
Importance of assuming not all youth are heterosexual
Value of peer to peer communication
Importance of appropriate counseling

Intravenous Drug Users

A Growing issue in Africa
Effective programs exist globally: need for peer outreach, sterile injecting equipment, drug dependence treatment, and VCT
Declining epidemics: NY from 51 percent of HIV prevalence in 1990 to 29 percent in '97 and in Brazil: from 63 percent in 1991 to 43 percent in '97.

PWLA

Successful programs for and by PLWA's exist

Sex work:

Importance of peer based approaches and outreach
Heightened vulnerability when sex work remains illegal

Gay men

Absence of clear trends
Increases in unprotected sex
Growing number of reports on men who have sex with men from developing countries

Emerging Concerns:

Need for sustained interventions
Social inequality (structural violence and its effects and SAP and its effects)
Economic issues
Impact studies uncommon
Most contentious issue, access to drugs and care
Stigma and discrimination persists: reports from Uganda and India that women are being forced to leave their homes once infection status is known.

Outstanding Issues:

1. Nature and consequences of denial
2. Migration and its consequences

Automated Records Management System
Hex-Dump Conversion

3. Need to work with especially vulnerable groups
4. Barriers to scaling up
5. Understanding oppression with in sexual relationships
6. Utilization of community –based research

Annex 3: Outstanding issues to MTCT

Primary prevention is essential because the exploding epidemic among young women of reproductive age and very high (30 percent) breastfeeding transmission when women are newly infected. One study in Zimbabwe reported that >10 percent of uninfected women became HIV+ in the two years following delivery while breastfeeding.

VCT services must be expanded so that HIV-infected women and partners may benefit from MTCT interventions when they become available. One approach is to provide HIV VCT within routine health services. In all cases, HIV counseling must be of the highest quality and testing should remain voluntary and confidential.

Breastfeeding support is needed, particularly in Africa, where alternatives to breastfeeding are not affordable, safe, or acceptable because of the stigma associated with not breastfeeding and other reasons. Research must continue on ways to make breastfeeding safer, including further examination of the risks/benefits of exclusive breastfeeding and early weaning. Health workers must be trained and communities sensitized on MTCT issues. Misunderstanding about HIV and infant feeding was reported in several countries. This has weakened child survival programs and could result in a deterioration of breastfeeding practices among non-infected women.

Drug resistance. There are only limited data on the likely emergence of drug resistance following short-course ARV treatment for MTCT. The clinical significance of observed markers of resistance is unknown. Drug resistance to nevirapine and zidovudine must be monitored closely as these drugs become more widely used.

Preparing for the future. Efforts must begin <u>today</u> to sensitize communities about MTCT of HIV and to train health providers and counselors about this issue. Health systems must be strengthened to facilitate introduction of MTCT and all other HIV/AIDS interventions.

Automated Records Management System
Hex-Dump Conversion

Annex 4: Cotrimoxazole Prophylaxis

Prophylaxis with cotrimoxazole is not widely used in Africa as it is in the United States. A study done in the Ivory Coast showed a marked reduction in morbidity and mortality in HIV-infected patients with tuberculosis who received cotrimoxazole. An operational assessment in Malawi showed that cotrimoxazole was well tolerated. However, reduction in mortality compared with historical controls was unimpressive, but the study is ongoing. This cheap intervention recently has been advocated by UNAIDS for HIV-infected patients with clinical evidence of immune suppression. Antiretroviral Treatment

Automated Records Management System
Hex-Dump Conversion

Annex 5: Access to ART

Access to ART is determined primarily by access to funds. Cheaper options are essential immediately, and realistic options exist. Thailand already manufactures didanoside (ddI), zidovudine (ZDV) and stavudine (d4T) at less than $ 30 per month. Price reductions could increase access to ART, such as the UNAIDS initiative in Cote d'Ivoire, where some reduction in price has extended HIV-care to 600 patients. A 16 percent price reduction was achieved by generic and cheaper sourcing.

Novel regimens, drugs or approaches to therapy provide interesting alternatives to currently used regimens. Hydroxychloroquine/chloroquine has in vitro activity against HIV, and in vitro synergy with hydroxyurea (HU). The fact that it is cheap and relatively well tolerated makes it a promising agent in combination ART. Twenty-three patients in Singapore were enrolled in a pilot open-label study of HU, chloroquine and ddI. The dose of HU was 500 mg daily, the ddI dose was 125 or 200 mg twice daily, and the chloroquine dose was 200 mg twice daily. Mean baseline CD4+ count was 242 cells/mm3, and viral load was 21,848 copies/mL. At 24 weeks, 17 patients were evaluated, and 6 achieved undetectable viral loads. The mean reduction in viral load was 1.22 log10 copies/mL and the mean CD4 count increase was 66 cells/mm3. Neutropenia and raised amylase were the only grade 3 adverse events reported.

The potential for eradication of HIV infection has been struck down by clear demonstration, that HAART is not completely suppressive and a latent HIV reservoir exists. Dr Fauci from the US National Institute of Health (NIH) described recent data from several major research labs to make this point. The reservoir of latently HIV-infected, resting T cells is established at the time of primary infection and it is not prevented by ART, even if administered during seroconversion. While HAART prevents cell-to-cell spread of HIV and can successfully suppress plasma viremia, pro-inflammatory cytokines constantly bombard the large lymphoid tissue reservoirs of HIV, creating a microenvironment that fosters persistent viral replication.

Continuous therapy may be complicated by toxicity (metabolic abnormalities, lipodystrophy syndromes, mithochondrial and liver toxicity) and adherence is challenging. Two studies from NIH presented promising preliminary data supporting the concept of intermittent therapy. The first report (4) discussed 9 of a planned 70 patients who had undetectable viral loads for at least 3 months and CD4+ counts of more than 300 cells/mm3. Patients were randomized to continue highly active antiretroviral therapy (HAART), or HAART in cycles of 8 weeks on therapy, and 4 weeks off. Patients were followed for a mean of 22 weeks and although CD4+ counts did not increase, viral loads remained less than 50 copies/mL while on treatment.

A second study evaluated even shorter cycles in 7 patients. They had to have viral loads of less than 50 copies/mL at enrollment and less than 500 copies/mL for at least 6 months. Four patients were continued on d4T

Automated Records Management System
Hex-Dump Conversion

lamivudine (3TC), ritonavir (RTV) and indinavir (IDV) for cycles of 7 days on treatment and 7 days off. Three patients had cycles of 2 days on, 5 days off. At 6 months, all those on the 7-day cycle maintained viral loads less than 50 copies/mL. Although one patient had a rebound in viral load in the second regimen, this was suppressed again on continuous therapy. These two studies suggest that once viral suppression has been achieved, short cycles of HAART may effectively maintain viral load control and CD4+ counts. The cost benefits are big, and both toxicity and adherence problems would be reduced. However there is concern that emergence of viral resistance could limit this approach.

Automated Records Management System
Hex-Dump Conversion

Annex 6: Conference Rapporteurs' Summaries of Sessions on Economics and AIDS

"Dollars & sense: Cost of Medical Care"

Mead Over: Co-Chaired this session. The rapporteur's comments follow.

The session focused on the need to address one of the most crucial problems in AIDS : money spent for medical care for HIV patients. The necessity for such a debate in the developing countries is obvious and highly urgent the session presenters, chairperson and audience agreed as far as it's been mentioned so many times at the Conference that poverty is a main factor for the spread of the epidemics while a deep silence is kept nationally and internationally about the amount of actually expenditures made to provide health care for HIV/AIDS patients. Therefore, the topic of the session was one expected to go much higher on the agenda of all key players in AIDS management and "to break the silence" of unwillingness to research in details the way funds are distributed.

The presenters provided the results of their studies on the specific amounts of expenditures for HIV treatment in their countries Tanzania, Thailand, United States, China and Rwanda. On the surface, the range of money spent per year per patient is huge: from 50$ in Tanzania, 63$ in Rwanda, 233$ in China, 250$ in Thailand and 7400$ in USA. A general conclusion was that the data are not completely reliable in terms of national representativeness because in all the studies they were derived from regional and limited medical practices and did not cover the whole scale of cases. Besides, most of the studies covered in-care patients, therefore they were not population-based, neither did they include hospital costs: this was specifically underlined by Chancharoen from Thailand, who found this a major obstacle for relevant conclusions.

Mead Over, co-chair of the session pointed out that no research has examined AIDS-treatment costs in comparison to all costs for medical care, including for treatment of chronic, cardio-vascular and other illnesses. Speakers and audience agreed that this would give much more relevant picture of the real situation.

Some of the interesting findings announced were made by Z.Wu who disclosed that the average AIDS treatment cost in China exceeds the annual income of a Chinese family; and by Bonnie Lubin from USA who has found in her research among Chicago, Illinois, poorest population AIDS patients, that in the recent years the cost per case significantly goes down. Another striking result was presented by P. Schneider from Rwanda who described how AIDS treatment is almost completely donor-dependent: 63 percent of the funds for AIDS patients care come from various donors and only 12 percent from the pocket of the diseased person. This may also be the case in a number of other African countries and gives good reason for serious rethinking of national treatment funding policies: it was agreed in the debate, with a number of specific

Automated Records Management System
Hex-Dump Conversion

questions and comments on the issue coming from the audience representing delegates from South Africa, Nigeria, Tanzania et al.

Another interesting finding in the Rwanda study gave the impetus for another discussion: the demography of the AIDS patients, which seemed to influence the amount of money spent by the patients themselves. With 63$ average expenditures per year the married HIV positive gave almost three times more for treatment: 182$. A general feeling was expressed by the audience and the other speakers that it would be great to carry out more systematic research to follow such trends, which obviously influence considerably the distribution of costs. Again, research should be much more focused and specific : the comments of the audience went on.

There was also a lively debate whether asymptomatic patients "cost more" than symptomatic patients because the studies in different countries resulted in completely opposite conclusions on this problem. Paul Coplan who was chairing the session said that this is only one more reason to review the research agenda in order to identify clear trends.

Coplan also underlined the disturbing tendency that even when some resources are available they are not evenly and wisely distributed. That's why according to him it is highly necessary to create such funding policies that the infrastructure of the treatment is improved and the AIDS patients medical care process is made more efficient. Finally, he was definite that the major conclusion of the session is that the research agenda needs to be changed : both nationally and internationally. While in developed countries in the very process of licensing a medication it is evaluated what is the cost-efficiency of the new drug and therefore quite a lot of research on costs is made, in developing countries where often governments don't even care to license medications the issue of cost/efficiency/funds distribution.

"Economic Impact of AIDS on Households and Organizations"

This session presented various studies attempting to capture the economic impact of HIV/AIDS on households and businesses. The papers were varied in their scope and the authors presented some findings that have important implications for policy and program design.

Sukhontha Kongsin's paper on the economic impact of HIV/AIDS on households in rural Thailand analyzed various household coping strategies. The study looked at the impact of chronic HIV morbidity, and tried to assess whether the impact and coping mechanisms of households are different within communities with active support services and less active support services.

The researchers interviewed members of six hundred rural households of which 50 percent had recently experienced chronic HIV morbidity. Half the sample came from a district in Phayao province in Thailand with very active support services, and the other half from a district with less active support

Automated Records Management System
Hex-Dump Conversion

services. Information was collected from household heads and caregivers involved in the care of the chronically ill. The fieldwork was undertaken between April and December 1999, and the results presented are preliminary.

It was found that to cope with chronic morbidity, households used various strategies, which included. decreasing household consumption, reallocating of labor, particularly by withdrawing children from school, dissaving, and sometimes depending on the extended family system or the community for support. The income of some household cases decreased by as much as 70 percent. It was also found that total income per capita and total consumption per capita decreased by 68.4 percent and 43.5 percent respectively. In an effort to maintain consumption level, the primary coping strategy used by households was to delve into their savings. When savings were spent, households resorted to borrowing. Households incurred per capita loans of 28.4 percent and per capita debt of 118 percent relative to total household income per capita. Each of these strategies had an negative impact on welfare of the household

Kongsin concluded that the high level of dissaving and significant percentage income devoted to health care expenditure indicated that HIV/AIDS could push households into poverty, and that actions should be taken to avoid this eventuality. She said that the adverse effects of HIV/AIDS illness on the poor households could be reduced by special assistance programs which include transfers of food, clothing and cash, access to credit, and schooling subsidies for children.

The second paper in this session presented a methodological approach to assessing the economic impact of AIDS on developing country firms. Presently, the impact of HIV in the workforce in developing nations is not well understood, and relatively few attempts have been made to quantify the effects of HIV/AIDS morbidity and mortality on the profitability of private sector firms. Most of the work done in this area was done early in the epidemic, and were based largely on interview or anecdotal data and made very little attempt to quantify the impact of significant increases in mortality in economically active age groups. The importance of such work cannot be underestimated as the private sector is the engine of economic growth and development.

Two models were developed to assess the AIDS costs to companies among employees. The first is a chronological model designed to demonstrate to business managers how HIV/AIDS is likely to affect a company's expenses and labor productivity. The second model reconfigures the cost data from the first model via the company's human resources and financial databases into discrete categories for the purposes of analysis. The 2nd model account for three kinds of costs: 1) direct or out-of-pocket costs, such as employee benefits and training; 2) indirect productivity costs, such as absenteeism and the loss of productivity experienced by sick workers; and 3) unmeasurable but potentially important effects on the morale, motivation, experience, and performance of the entire workforce. In order to estimate the future costs of AIDS, three pieces of information are critical to the analysis: 1) HIV/AIDS prevalence, morbidity, and

Automated Records Management System
Hex-Dump Conversion

mortality; 2) a detailed demographic projection of the workforce, and 3) identification of critical positions or skills within the firm. This kind of analysis will provide business managers, researchers and policymakers with a better understanding of the impact of AIDS on the different units within a company, and enhance strategic planning capabilities. To date, the response of the private sector to the HIV/AIDS epidemic has been passive and reactive. The model presents an opportunity for firms to analyze, and pre-emptively manage the impacts of AIDS in the workforce – protecting the all-important bottom line.

Robert Greener, the third speaker in the session, presented a paper on the impacts of AIDS on macroeconomic indicators such as GDP and unemployment in Botswana. To date, there have been two types of assessment. Qualitative assessments have tended to predict outright economic disaster, whereas, quantitative assessments have shown relatively small impacts. Greener started by saying that the aggregate macroeconomic impact is difficult to quantify and that the model he was using predicted a 25 year future scenario showing the economy of Botswana with and without the impact of AIDS.

Botswana has a very large mineral sector, based primarily on the diamond industry which accounts for one-third GDP and half of all government revenue. The mineral sector is in addition, a very capital intensive one, which to some extent, acts as a buffer against the impact of the epidemic.

A two sector- three-factor equilibrium model for the Botswana economy was constructed. The model distinguished between skilled and unskilled labor, and between the formal and informal sectors. The impacts of HIV/AIDS were hypothesized to operate through the supply of labor, and through investment growth. Greener also distinguished between morbidity and mortality impacts. Morbidity impacts would result in decreased production, increased expenses, decreased savings, investment and capital stock and decreased consumption. Mortality impacts would result in smaller population and labor force than in the absence of AIDS, younger age structure of labor force and therefore less experience and smaller skills base, the reduced availability of skilled labor and overall lower labor force participation rate.

Greener concluded that the constraints on savings and investment will not apply in Botswana because of high levels of savings, (42 percent of GDP) and investment (28 percent GDP) and significant foreign reserves. He did, however exclude the loss of investor confidence in his model.

In relation to the labor supply, Greener concluded that the population would be 28 percent smaller compared to the No AIDS scenario, and that GDP would be between 23-40 percent smaller after 25 years, which was roughly equivalent reduction in growth of between 0.8 and 1.4 percent per annum. He added that poor economic policy would have the same effect on growth. GPD/capita would either increase by 9 percent or decrease by 16 percent. However, government share of GDP will fall much less than household share, which is predicted to decrease by 10-20 percent. Unemployment is predicted to fall by 8 percent.

Automated Records Management System
Flex-Dump Conversion

among unskilled workers and skilled wages will rise by between 12-17 percent. Businesses will inevitably move towards more capital intensive methods of production.

In conclusion, Greener said that the Botswana economy is significantly more capital intensive than most African countries, and that this offered a shield against the labor impacts of HIV/AIDS. In addition, diamond revenues will continue to ensure that investment is not constrained by savings in the medium term. However, HIV/AIDS will worsen existing skilled labor shortages, and will put pressure on already overburdened systems to import expatriate skills. In the medium term, shortage of skilled labor may also have a significant negative impact on investor confidence. The predictions of the model are sensitive to small changes in investment growth. The results suggest that the key area for government intervention is in skilled labor supply, investment and productivity. Policy efforts should be devoted towards maintaining investment, especially in the private sector.

Q: Did you account for inward labor migration?
A: They assumed that only skilled labor would migrate inward. Any assumptions about the movements of unskilled labor would not change the conclusions.

The fourth speaker in the session was Nalugoda from Uganda. He spoke about HIV infection in rural households, in the Rakai District, Uganda. The objective of his study was to compare the distribution of HIV prevalence between adult heads and non-heads of households in rural Rakai district in order to assess which of these two groups was more vulnerable to infection. The study was conducted in 56 communities in Rakai district, southwestern Uganda.

Data was collected using the national Census, questionnaire information and biological samples of venous blood which were tested for HIV using two ELISA assays. 11539 adults aged 15-59 were sampled. Of these, 4962 (43 percent) were heads of households, 70.5 percent were male and 29.5 percent were female. Heads of households were predominantly married men. Female heads of households were predominantly separated, divorced or widowed. The age distribution of both male and female heads was similar. Of all male heads of households, 56.2 percent had 2 or more sexual partners in the last 5 years. Of all male non-heads of households, 31,6 percent had 2 or more sexual partners in the last 5 years.

HIV prevalence in the study population was high, with 16.9 percent of all adults aged 15 to 59 years being infected. Prevalence of HIV was higher among females, 19.0 percent, than in males, 14.1 percent. Among household heads, the prevalence of HIV was even higher; 21.5 percent of the 4962 household heads were HIV-positive, whereas among 6574 non-household heads, HIV prevalence was 13.3 percent. Analysis of characteristics such as age, marital status, number of sexual partners, circumcision, and condom use showed an association with HIV infection.

Automated Records Management System
Hex-Dump Conversion

Nalugoda concluded that the prevalence of HIV is generally higher among females than in males, but more males than females are heads of households, and in future households will lose more males to HIV/AIDS than females. Heads of households are more affected than non-heads of households, although calculations of adjusted rates of risk show that women are more at risk of becoming infected.

The final speaker in this session was Mead Over. The paper he presented looked at targeting assistance to AIDS-afflicted households in rural Tanzania. The researchers wanted to assess how effective transfers from governments, NGOs and international agencies have been to households surviving an AIDS death. The provision of assistance to AIDS survivors has been the focus of a great deal of operational work by international agencies, governments, and non-governmental organizations (NGOs) and most households receive transfers from the state and NGOs as well as from other households.

The study used a household survey from the Kagera region of northwestern Tanzania, to examine the consequences for household welfare, income distribution, and poverty of public and private transfers in response to a death. The questions that were posed included

Do the programs and transfers make a difference?
Are they targeted accurately?
Could overall well-being be improved by a simple re-orientation of assistance?
The researchers first examined the impact of these transfers on poverty and the distribution of income. Secondly they investigated whether donors respond only to the death or consider other factors, such as the poverty of the recipient. Thirdly they assessed the combined impact of private and public assistance, and examined whether private transfers were crowded out by public transfers? Although public transfers are relatively small, they may have an effect on private behavior. The benefits of public assistance programs are diminished to the extent that they displace private assistance.

The impact of an AIDS death on households can be quite devastating. Households devote significant shares of income to medical and funeral care, and decreased expenditure on food and clothes. Death also had a great impact on the lives of children: malnutrition is common in children living in households that experienced a death. Children are also more likely to be withdrawn from school when an adult dies. Overall, the impact of a death depends largely on the resources available to the household. Not all households suffer to the same extent but for the poorer households in the sample, both food expenditure and food consumption fell dramatically.

In terms of who saves, borrows and receives transfers, it was found that:

Among poor households, those without a death are more likely to be net lenders. Households with a death are more likely to be net recipients of transfers than those without a death (true for both rich and poor households). Wealthy

Automated Records Management System
Hex-Dump Conversion

households are more likely to be net donors of private assistance than poor households. For official/NGO assistance, wealthy households are more likely to receive assistance if they suffer a death while there was no distinction amongst the poorest households. This suggests deliberate targeting. Analysis showed overall that public transfers is more equitably distributed than private transfers which in most instances, went to wealthier households. Public assistance was most equitable, especially amongst the poorest households. The amount of private transfers received by poor households is a small fraction of that received by wealthy households, and the wealthy are twice as likely to receive private transfers from within the village as the poor. Both poor and wealthy are more likely to receive transfers from outside the village than within, and the wealthy are more likely to receive transfers from other provinces in Tanzania or abroad. Poor and wealthy households are equally likely to receive assistance from official sources, and even though assistance is targeted, the wealthy receive twice as much, per capita than the poor. The wealthiest 25 percent of households are more likely to give transfers to other households within the village.

Evidence suggests that while the impact of crowding out is small, assistance is not accurately targeted. Private transfers rise with income, and neither formal assistance nor informal transfers have any significant impact on poverty or inequality. Wealthy households are not just wealthy in terms of physical and human assets, but in terms of being able to access broader and wealthier networks of friends and relatives. They are thus more likely to receive assistance than poorer households. Those outside such networks, should more properly be the beneficiaries of targeted assistance. Over said that governments and NGOs should do a better job of targeting and that while some leakage is acceptable, the bulk of transfers should be concentrated on those who are unable to access assistance. The design of social assistance programs should take account of the fact that some non-AIDS households are desperately poor, and some AIDS households are not.

Automated Records Management System
Hex-Dump Conversion

Cost-effectiveness of voluntary HIV-1 counselling and testing in reducing sexual transmission of HIV-1 in Kenya and Tanzania

Michael Sweat, Steven Gregorich, Gloria Sangiwa, Colin Furlonge, Donald Balmer, Claudes Kamenga, Olga Grinstead, Thomas Coates

Summary

Background Access to HIV-1 voluntary counselling and testing (VCT) is severely limited in less-developed countries. We undertook a multisite trial of HIV-1 VCT to assess its impact, cost, and cost-effectiveness in less-developed country settings.

Methods The cost-effectiveness of HIV-1 VCT was estimated for a hypothetical cohort of 10 000 people seeking VCT in urban east Africa. Outcomes were modelled based on results from a randomised controlled trial of HIV-1 VCT in Tanzania and Kenya. Our main outcome measures included programme cost, number of HIV-1 infections averted, cost per HIV-1 infection averted, and cost per disability-adjusted life-year (DALY) saved. We also modelled the impact of targeting VCT by HIV-1 prevalence of the client population, and the proportion of clients who receive VCT as a couple compared with as individuals. Sensitivity analysis was done on all model parameters.

Findings HIV-1 VCT was estimated to avert 1104 HIV-1 infections in Kenya and 895 in Tanzania during the subsequent year. The cost per HIV-1 infection averted was US$249 and $346, respectively, and the cost per DALY saved was $12.77 and $17.78. The intervention was most cost-effective for HIV-1-infected people and those who received VCT as a couple. The cost-effectiveness of VCT was robust, with a range for the average cost per DALY saved of $5.16–27.36 in Kenya, and $6.58–45.03 in Tanzania. Analysis of targeting showed that increasing the proportion of couples to 70% reduces the cost per DALY saved to $10.71 in Kenya and $13.39 in Tanzania, and that targeting a population with HIV-1 prevalence of 45% decreased the cost per DALY saved to $8.36 in Kenya and $11.74 in Tanzania.

Interpretation HIV-1 VCT is highly cost-effective in urban east African settings, but slightly less so than interventions such as improvement of sexually transmitted disease services and universal provision of nevirapine to pregnant women in high-prevalence settings. With the targeting of VCT to populations with high HIV-1 prevalence and couples the cost-effectiveness of VCT is improved significantly.

Lancet 2000; **356:** 113–21

School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD (M Sweat PhD); **Center for AIDS Prevention Studies, University of California, San Francisco, CA, USA** (S Gregorich PhD, O Grinstead PhD, T Coates PhD); **Muhimbili Medical College, University of Dar es Salaam, Dar es Salaam, Tanzania** (G Sangiwa MD); **Queens Park Counseling Centre, Port of Spain, Trinidad, West Indies** (C Furlonge MD); **Kenya Association of Professional Counselors, Nairobi, Kenya, and University of Calgary, Calgary, Alberta, Canada** (D Balmer PhD); **and AIDSCAP, Family Health International, Arlington, VA, USA** (C Kamenga MD)

Correspondence to: Dr Michael Sweat, Johns Hopkins University, School of Hygiene and Public Health, 615 North Wolfe Street, Room E7140, Baltimore, MD 21205, USA
(e-mail: MSWEAT@JHSPH.EDU)

Introduction

In 1999, there were an estimated 5·6 million new HIV-1 infections and 2·6 million deaths from AIDS.[1] The burden of HIV-1 infection and AIDS is concentrated in less-developed countries. For example, Kenya, with a population of 28·4 million, now has about 1·6 million people infected with HIV-1,[2] and Tanzania, with a population of 31·5 million, has an estimated 1·4 million HIV-1-infected people.[3]

HIV interventions have been implemented in Kenya and Tanzania with assistance from foreign donors and multilateral agencies in an effort to address the profound health and social problems. Intervention efforts have included aggressive condom marketing, mass-media HIV educational efforts, peer educational efforts, and interventions targeted to specific risk groups such as truck drivers and sex workers. Despite the high concentration of HIV-1 infection in this region, few people currently have access to HIV-1 voluntary counselling and testing (VCT) services, which have been shown to reduce HIV-1 transmission.[4] In Uganda, for example, there is a countrywide system of low-cost HIV-1 VCT provision with centres that provide support after HIV-1 testing. Uganda is one of the few African nations in which HIV-1 prevalence has stabilised,[5,6] and the widescale availability of HIV-1 VCT coupled with high-quality post-test support services has made a major contribution to the success in AIDS prevention.[7] There is therefore growing support and demand for HIV-1 VCT services in other countries in this region.

There are compelling arguments for the provision of HIV VCT services in sub-Saharan Africa.[8] First, individuals have a right to know their infection status to protect themselves and others from infection and so they can plan for the future. Second, VCT may enable people to cope with the anxiety associated with HIV-1 serostatus. Third, early detection of HIV-1 may improve medical and psychosocial support for HIV-1-infected individuals. Finally, HIV-1 VCT promotes behaviour change in the short term.[4] HIV-1 VCT had not been rigorously evaluated until recently. A review of 50 studies by Higgens and colleagues[9] showed mixed results for the impact of counselling and testing on risk behaviours. Several studies showed behaviour change in association with knowledge of serostatus, with the greatest reductions in risk behaviour noted among HIV-1-infected men. In a more recent review of 35 studies the impact on behaviour was less conclusive.[10] Several of the studies reviewed were in Africa. One study in Rwanda among a cohort of childbearing women who received HIV-1 VCT reported significantly increased condom use.[11]

Demand for HIV-1 VCT will also probably grow in sub-Saharan Africa because of new efforts to make antiviral therapy available for groups such as pregnant women.[12–14] Studies on nevirapine[15] have shown its efficacy in stemming HIV-1 transmission from mother to child, and efforts are being made to make these therapies more widely available in less-developed countries.[16,17] There

Automated Records Management System
For personal use only. Not to be reproduced without permission of The Lancet.
Flex-Dump Conversion

have also been various policy efforts to make zidovudine available to African populations at a lower cost.[18,19] The increased use of antiviral drugs in less-developed countries will require increased HIV-1 VCT.[20]

Despite the efficacy of HIV-1 VCT in reducing risk behaviours, doubts remain about the long-term impact of HIV-1 VCT on risk behaviours; low rates of disclosure among people who have received HIV-1 VCT; negative social and psychological outcomes of HIV-1 VCT for some individuals;[21,22] and the lack of behaviour change among some individuals who receive HIV-1 VCT.[10] The cost-effectiveness of HIV-1 VCT in less-developed countries has not been systematically examined, and the cost of VCT is a crucial factor in the feasibility of antiviral therapies in these countries.[17]

We therefore undertook an incremental cost-effectiveness analysis of HIV-1 VCT in Nairobi, Kenya, and Dar es Salaam, Tanzania, by comparing pre-intervention and postintervention outcomes.

Methods

Intervention

The primary outcomes were generated from behavioural measures, and the modelled effects of behaviour change on HIV-1 incidence and DALYs saved from the intervention. We took a programme perspective for the analysis, and our primary research question was, "What are the health benefits of investment in HIV-1 VCT programmes?"

Details of the trial and intervention are described in the accompanying paper.[4] The study was carried out from 1995 to 1998. In Kenya, a free-standing clinic was established in a poor neighbourhood of Nairobi with a high population density. In Tanzania, the study site was a free-standing clinic on the grounds of Muhimbili Hospital, the national teaching hospital in metropolitan Dar es Salaam. Both sites were easily accessible to prospective clients. An additional study site was established in Port of Spain, Trinidad. The cost-effectiveness of the intervention there is being analysed separately because Trinidad has significantly lower HIV-1 prevalence than the African sites, and because the costs of the intervention differ substantially because labour and infrastructure costs are higher than in the east African sites.

People enrolled in the study were randomly assigned either HIV-1 VCT or a video-based HIV-1 health-education intervention. The effect of the intervention was measured in a cohort of 716 participants (median age 27 years [range 17–69]) in Nairobi and 601 (median age 26 years [17–65]) in Dar es Salaam. Comparisons in study outcomes were made with a similar group of participants assigned health education. Participants assigned health education were given free access to HIV-1 VCT after their 6-month assessment. By design the study sought to enrol 50% women and 33% of clients as couples. Actual enrolment resulted in 50% women in Kenya and 45% women in Tanzania, and 34% of participants enrolled as couples in Kenya and 35% as couples in Tanzania.

We present an incremental cost analysis of HIV-1 VCT compared with no intervention by use of the effects before and after the intervention. We adapted this approach rather than using data from the comparison study group because the health-education intervention is not replicable. Clients came to the study site primarily to receive HIV-1 VCT, and thus the effects of the health-education intervention on behaviour change cannot be generalised to a replicable intervention.

Estimation of DALYs saved

To estimate the number of DALYs saved, we first estimated the mean age of participants (29 years). We then calculated the number of DALYs lost from an HIV-1 infection due to both disability associated with AIDS and premature death from AIDS. We estimated that the life expectancy of a person aged 29 years in Kenya and Tanzania was about 40 years based on a review of available demographic data.[23,24] This life expectancy estimate is based on average life expectancy irrespective of HIV-1 infection for the base-case analysis. Comparisons are made between the life expectancy with and without AIDS. Disability weights for HIV-1 infection and AIDS were estimated to be 0·123 and 0·505, respectively.[25] Disease progression parameters were adapted from published data[26] that approximate an 8-year estimate for moving from HIV-1 infection to AIDS and a 1-year progression from AIDS to death, as identified by UNAIDS for less-developed countries. We adjusted the number of DALYs saved by age and discounted the number of DALYs saved to reflect age preferences.[27] Future costs and benefits were discounted at a rate of 3%, with sensitivity analysis for 0 and 6%. The total number of DALYs saved from the intervention was calculated by multiplying the annual number of infections averted by the number of DALYs from disability and early mortality saved per HIV-1 infection averted.

Measurement of costs

Intervention costs were calculated from estimates of the per-client quantity of goods and services used in delivery of the intervention. These were derived from cost worksheets developed for the project, project records, budgets, and interviews with project staff and managers. All research costs were subtracted and the final cost estimates used were adjusted by examination of actual costs of service provision when the research was terminated and each site transferred to pure service provision. The per-client cost of the intervention estimated reflects a free-standing clinic with capacity to process 3000 clients per year. The results of the analysis are presented per 10 000 clients under the assumption of multiple clinics operating in a given setting, and also to allow for easier comparison with other cost-effectiveness analyses. An annual discount rate of 3% was used in the base-case analysis. All costs were converted to US$ for presentation by use of 1998 currency conversion rates of 600 Tanzanian shillings and 63.9 Kenyan shillings per US$.

Study model

Estimates of the number of HIV-1 infections averted were derived from the following probability-based formula:[28]

$$\text{Probability of HIV-1 infection} = 1-\{P[1-R(1-FE)]^{N}+(1-P)\}^{M},$$

where P is the average HIV-1 prevalence among sexual partners of the target population, R the risk of HIV-1 transmission per act of unprotected sex (infectivity), F the fraction of sex acts when a condom is used, E the effectiveness of condoms, N the average number of sex

Automated Records Management System
Hex-Dump Conversion
For personal use only. Not to be reproduced without permission of The Lancet.

acts per partner, and M the average number of sex partners. Model estimates were calculated separately by combinations of HIV-1 infection status, sex, and enrolment in the study as a couple or individual (eight groups). Analysis for HIV-1-infected individuals reflects the number of HIV-1 infections that result from contact with HIV-1-uninfected sexual partners. For HIV-1-uninfected individuals, the model estimates the likelihood of their becoming infected with HIV-1 from their infected sexual partners. Thus, prevalent HIV-1 infections are excluded from analysis for those receiving HIV-1 VCT and their sexual partners. In high-prevalence settings, exclusion of prevalent HIV-1 infections from the analysis is important in making an accurate estimate. The model makes estimates of the number of HIV-1 infections that are likely to occur among HIV-1-uninfected people only. Each model variable was based on data from baseline and 12-month interviews. The analytical timeframe of the analysis reflects the impact of an averted HIV-1 infection on lifetime DALYs saved. As with other health interventions, the client receiving the intervention may have become infected at a point beyond the 1-year assessment period. Thus, the estimation of life-expectancy for calculation of DALYs saved reflects the population-level effect of AIDS mortality independently of the intervention effect.

Sensitivity analysis

We also did sensitivity analysis on the number of DALYs saved per HIV-1 infection averted with a large range of values to examine the effect of potential relapse in the intervention effect. Additional studies on the long-term impact of the intervention will be needed to assess the effect of relapse into risk behaviour more accurately, and the base-case analysis presented here should be regarded as illustrative of the average effect of sustained behaviour change. HIV-1 risk behaviour among people receiving HIV-1 VCT significantly declined at 6-month after the intervention, and declined again at the 12-month assessment.

Triangular probability distribution functions (high, most likely, low) were applied to each of the model parameters with the range of values described. The model was simulated by use of the Latin hypercube simulation (@Risk, Palisade Corporation, Newfield, NY, USA). This technique is designed to recreate accurately the input distribution by first stratifying the input probability distributions. Stratification divides the cumulative curve into equal intervals on the cumulative probability scale (0–1·0). A sample is then randomly taken from each interval or "stratification" of the input distribution. Sampling is forced to represent values in each interval, thus is forced to recreate the input probability distribution. Latin hypercube offers benefits over other simulation approaches in terms of increased sampling efficiency and it improves the analysis of situations in which low-probability outcomes are represented in input probability distributions. By forcing the sampling of the simulation to include these outlying events, Latin hypercube sampling assures results are accurately represented in simulation outputs.

For sensitivity analysis, the Latin hypercube technique thus systematically generated values of the model parameters that are similar to the defined probability distribution across simulation iterations. Iterations of the model were done until changes in the sampled variable values and associated model outcomes changed by less than 1·5% in both the mean and SD. Convergence of the simulation models was achieved with hundreds to thousands of simulation iterations. The resulting output is a set of varying values of model inputs (across all parameters simultaneously) and associated outcomes. This dataset was then used for multivariate sensitivity analysis. The results of this procedure thus also convey the degree of uncertainty in the model. Sets of parameters were differentially fixed or varied in various model simulations for specific sensitivity analyses. The ranges of outputs across simulation iterations were analysed, and descriptive statistics for the mean and range of simulation results are presented. Multivariate sensitivity analysis was done on simulation datasets by use of multiple regression across simulation iteration results.

We calculated the population-level outcomes by applying the mean values among population subgroups of interest and multiplying the probability of HIV-1 infection (from the equation) by the population size of the group analysed. The number of HIV-1 infections averted was calculated from the difference in estimates from baseline to follow-up for people enrolled in the HIV-1 VCT study group. The mathematical model used in this analysis had 94% accuracy in predicting HIV-1 incidence based on behavioural changes in a similar population in Africa.[29]

Epidemiological parameters

Base-case values for epidemiological model parameters are shown in table 1. HIV-1 seroprevalence was 20% (95% CI 17–23) in both Kenya and Tanzania. We assumed that the HIV-1 prevalence for sexual partners of HIV-1-infected study participants was equal to that of the index case. Sensitivity analysis was done on this parameter for values 33% higher and 33% lower than the base-case. For HIV-1-uninfected cases, we adjusted the HIV-1 prevalence parameter for their sexual partners to 10% lower than the HIV-1 prevalence of the study population, on the assumption that HIV-1-uninfected people are in sexual networks with lower HIV-1 prevalence than HIV-1-infected clients. Sensitivity analysis was done on this parameter by setting the value as equal to that of the study population, and at 20% lower than that value. HIV-1 infectivity values come from published data and were adjusted for sex and coinfection with sexually transmitted diseases. HIV-1 infectivity was assumed to be 0·02 per sex act between an infected man and an uninfected woman, and 0·01 per sex act between an infected woman and an uninfected man.[29] In the presence of genital ulcerative or non-ulcerative disease in either partner, the rate of transmission was assumed to be 0·06.[29] After adjustment for sex and observed sexually transmitted disease, we estimated that the overall HIV-1 infectivity rate was 0·0187 in Kenya and 0·0172 in Tanzania. Again, the HIV-1 infectivity parameter was adjusted for sex and coinfection within each stratum of analysis. Sensitivity analysis was done on the HIV-1 infectivity parameter with values 33% higher and 33% lower than these rates.

Sexual behaviour parameters were derived from specific questions asked to study participants about number and type of sexual partners, number and type of sexual acts, number of sexual acts in which a condom was used, and how many times the condom ruptured or slipped when used. These data were collected at baseline and at 6-month and 12-month follow-up. We used data from the baseline and 12-month surveys to estimate the degree of

Automated Records Management System
For personal use only. Not to be reproduced without permission of The Lancet.
Hex-Dump Conversion

Epidemiological parameters	Base-case estimate (95% CI)		Data source
	Kenya	Tanzania	
HIV-1 prevalence			
Index cases	0·20 (0·17–0·23)	0·20 (0·17–0·23)	Observed
Sex partners of HIV-1-infected index cases	0·20 (0·17–0·23)	0·20 (0·17–0·23)	Assumed same as index cases
Sex partners of HIV-1-uninfected index cases	0·14 (0·12–0·15)	0·13 (0·11–0·15)	Assumed 10% lower than index cases
Condom use per sex act			
Before intervention	19% (16–21)	26% (23–29)	Observed
After intervention	83% (80–87)	88% (78–98)	Observed
Condom efficacy			
Before intervention	95% (93–97)	90% (87–93)	Observed
After intervention	95% (93–98)	97% (95–99)	Observed
Average number of sex acts per partner			
Before intervention	54 (49–59)	54 (48–59)	Observed
After intervention	43 (36–50)	36 (30–42)	Observed
Average number of sex partners			
Before intervention	1·22 (1·14–1·29)	1·13 (1·07–1·20)	Observed
After intervention	1·32 (1·22–1·42)	1·34 (1·24–1·44)	Observed
HIV-1 infectivity	0·0187 (0·01–0·06)	0·0172 (0·01–0·06)	Adjusted for coinfection with sexually transmitted disease and for sex*

All values estimated for 1-year timeframe.

Table 1: **Base-case values for model epidemiological parameters**

behaviour change over 1 year. We likewise used the baseline, 6-month, and 12-month behavioural data to cross-check the validity of annualisation of model parameters for the sexual contact rates (number of partners and number of acts per partner). Survey questions assessed behaviours during the 2 months before the interview. Values for the average number of sex acts per partner were annualised (the 2-month value was multiplied by 6). The average number of sexual partners during the previous 2 months was assumed to be the same as the annual number of sexual partners, and would probably only be higher than the 2-month rate. Thus, we considered this to be a conservative estimate. We also examined variations in the number of sexual partners and contacts per partner across the baseline, 6-month, and 12-month interview data for the group not receiving HIV-1 VCT and found that the sexual contact rate over an annual period was similar to the annualised 2-month rate.

Condom use for study participants receiving HIV-1 VCT in Kenya and Tanzania increased significantly (table 1). The average annual number of sexual acts per partner decreased in both countries. However, the average number of sexual partners increased in Kenya and Tanzania. Sensitivity analysis was done on these sexual behaviour parameters with the upper and lower bounds of the 95% CI.

Economic parameters

The cost per client to provide HIV-1 VCT and the associated percentage of total costs by item are shown in table 2. These data are based on observed costs. A range of estimated costs was also collected at each study site and is based on a detailed cost worksheet completed by the clinic staff and management. In this exercise, each cost item was assigned a high, average, and low unit value and a high, average, and low estimate of the annual number of units used for each item. Variations in costs were based on fluctuations in the cost of labour, commodities, and services associated with HIV-1 VCT at each site and on estimates of clinic staff who were responsible for financial management of the projects. These ranges of cost-estimates were used in the sensitivity analysis (table 2).

Rental fees were estimated for a facility that housed a staff of five counsellors, a counselling supervisor, a project manager, a phlebotomist, and a receptionist. The clinics are both free-standing clinics and each has seven to ten private rooms, a reception area, and bathroom facilities. Training costs included the costs of an annual 3-day training retreat and training materials. The VCT clinic service was advertised with posters and flyers and short weekly radio commercials. Office furniture included desks, chairs, and basic filing cabinets. A computer was purchased in each site to process clients' records,

Economic parameters	Kenya			Tanzania			Data source
	Base-case estimate (US$)	Proportion of total costs (%)	Range estimate (US$)	Base-case estimate (US$)	Proportion of total costs (%)	Range estimate (US$)	
Building rent	2.33	8·7	1.89–2.84	3.47	12·0	1.67–5.33	Observed
Telephone and power	0.99	3·7	0.69–1.08	1.03	3·5	0.43–1.67	Observed
Training	0.02	0·3	0.01–0.03	0.19	0·6	0.08–0.33	Observed
Advertising	2.58	9·6	0.63–5.64	0.37	1·2	0.02–1.40	Observed
Office furniture	0.40	1·5	0.046–0.46	0.09	0·3	0.01–0.30	Observed*
Computers	0.19	0·7	0.10–0.25	0.42	1·5	0.15–0.92	Observed*
Audiovisual equipment (used for education during waiting periods)	0.03	0·1	0.02–0.04	0.10	0·3	0.05–0.18	Observed*
Labour	13.11	49·2	9.52–17.35	15.55	54·8	11.34–20.40	Observed
HIV-1 test kits, laboratory fees, and associated laboratory costs	6.76	25·4	4·34–10.09	7.04	24·3	2.18–16.25	Observed
Other consumables (paper, office supplies, &c)	0.16	0·6	0.13–0.19	0.67	2·3	0.33–1.00	Observed
Total cost per client	26.65	100	17.61–38.07	28.93	100	16.28–47.79	Sum of values above

*Distributed over 5 years. All values estimated for 1-year timeframe.

Table 2: **Base-case values for model economic parameters**

Automated Records Management System
Hex-Dump Conversion
For personal use only. Not to be reproduced without permission of The Lancet.

	Overall	Enrolled as a couple				Enrolled as an individual			
		Male		Female		Male		Female	
		HIV-1 positive	HIV-1 negative	HIV-1 positive	HIV-1 negative	HIV-1 positive	HIV-1 negative	HIV-1 positive	HIV-1 negative
Original sample size									
Kenya	716	23	99	29	91	29	208	65	172
Tanzania	601	17	87	24	81	17	210	48	117
HIV-1 infections averted									
Kenya	1104	164	89	166	91	194	78	230	91
Tanzania	895	92	85	194	75	57	33	319	40
HIV-1 infections averted as proportion of population subgroup									
Kenya	0·11	0·51	0·06	0·04	0·07	0·47	0·03	0·25	0·04
Tanzania	0·09	0·36	0·07	0·54	0·06	0·22	0·01	0·29	0·02
Cost per HIV-1 infection averted (US$)									
Kenya	249	54	426	68	379	58	1021	108	723
Tanzania	346	87	480	58	501	142	2970	107	1791
Cost per DALY saved (US$)									
Kenya	12.77	2.75	21.86	3.48	19.48	2.98	52.46	5.57	37.13
Tanzania	17.78	4.48	24.65	2.96	25.74	7.28	153.00	5.49	92.00

Table 3: **1-year cost-effectiveness of HIV-1 VCT per 10 000 clients**

accounting, and office correspondence. A video-cassette player was purchased for use in the waiting area to show educational materials during waiting periods.

HIV-1 testing was done by commercial ELISA. All reactive (positive) samples were confirmed with a second ELISA. Samples positive on both ELISAs were classified as positive. Any sample that was found to be positive on the first ELISA and negative on the second was tested by western blot. A standard laboratory fee was charged for HIV-1 testing at local reference laboratories. This fee included the costs of storage, quality control, and labour associated with laboratory testing. Capital equipment costs (office furniture, computer, and video player) were distributed over a 5-year period with a 3% discount rate, and then assigned an annual value.

Results

All results are expressed in terms of the effect per 10 000 people exposed to the intervention. This number was also a reasonable estimate of the number of clients who might be exposed to the intervention in a typical year in an urban setting with several clinic sites of similar scope to those in our study. Table 3 shows the overall outcome values across the entire study population, and by combinations of enrolment as a couple or individual, sex, and HIV-1 serostatus. For subgroup analyses, estimates of all epidemiological parameters were derived and used in the model separately. The overall values represent the outcomes when the base-case values were used and were calculated by applying the base-case values for subpopulations (combinations of sex, HIV-1 infection, and enrolment as couple or individual) and then summed for an overall value. At a per-client cost of $26.65 in Kenya, and $28.93 in Tanzania, the overall annual programme costs for 10 000 clients would be $266 500 and $289 300, respectively.

Over 1 year, HIV-1 VCT would avert 1104 HIV-1 infections in Kenya and 895 cases in Tanzania per 10 000 clients exposed to the intervention. The largest absolute number of HIV-1 infections averted is associated with HIV-1-infected women who receive HIV-1 VCT as individuals, followed by HIV-1-infected women who receive the intervention together with a sexual partner. However, the group that benefits most in terms of the proportion of HIV-1 infections averted is HIV-1-infected women and men enrolled as a couple (table 3). This group is followed by HIV-1-infected men and women presenting as individuals.

The cost per HIV-1 infection averted averaged $249 for Kenya and $346 for Tanzania. The difference between the two sites is mainly a result of the low degree of behaviour change among HIV-1-uninfected men in Tanzania who received HIV-1 VCT as individuals. These men were especially resistant to behavioural risk reduction. The cost per DALY saved represents the benefit of the intervention as a ratio of intervention costs to health benefits. On average, the cost per DALY saved was $12.77 in Kenya and $17.78 in Tanzania. In Kenya and Tanzania the most cost-effective group to target was HIV-1-infected men presenting as part of a couple. HIV-1 VCT was also very cost-effective for HIV-1-infected men and women presenting as individuals in both countries. In Tanzania, HIV-1 VCT was also especially cost-effective for HIV-1-infected women presenting as part of a couple.

Sensitivity analysis

Since many of the parameters in the model are based on assumptions and adjustments to observed data, and since they can vary in different settings, we did a sensitivity analysis to examine how outcomes are affected by variations in input values (tables 4 and 5).

In one-way sensitivity analysis, the model is insensitive to moderate changes in HIV-1 prevalence among the sexual partners of HIV-1-infected and uninfected individuals. This finding indicates that there is a large enough pool of uninfected contacts for HIV-1 transmission to occur, even in high prevalence settings such as urban Kenya and Tanzania. Variation in the sexual behaviour parameters also somewhat affects the model outcomes, although the 95% CIs were not so wide that they had significant effects on the base-case estimates. Changes in HIV-1 infectivity also affect the model outcomes, although not sufficiently to raise concerns over the validity of the results. The cost-effectiveness of the intervention is also sensitive to the cost per client to provide HIV-1 VCT, the number of DALYs per HIV-1 infection averted, and the discount rate used.

Multiway and multivariate sensitivity analyses are shown in table 5. In the worst-case scenario, with all model parameters set to be least advantageous to a cost-effective outcome, the cost per DALY saved was $27.36 in Kenya and $45.03 in Tanzania. The best-case scenario shows HIV-1 VCT to cost $5.16 in Kenya and $6.58 in

Automated Records Management System
For personal use only. Not to be reproduced without permission of The Lancet.
Hex Dump Conversion

	Average cost per DALY saved (1998 US$)	
	Kenya	Tanzania
Base-case*	12.77	17.78
HIV-1 prevalence of sexual partners of HIV-1-infected cases (same as population prevalence)		
33% higher than observed study population HIV-1 prevalence	12.26	16.79
33% lower than observed study population HIV-1 prevalence	13.27	19.04
HIV-1 prevalence of sexual partners of HIV-1-uninfected cases (10% lower than population prevalence)		
20% lower than observed study population HIV-1 prevalence	12.45	17.43
Same as observed study population HIV-1 prevalence	13.08	18.08
Percentage condom use (as observed)		
Upper bound of observed 95% CI	11.69	15.91
Lower bound of observed 95% CI	14.01	19.85
Condom efficacy (as observed)		
Upper bound of observed 95% CI	12.55	17.36
Lower bound of observed 95% CI	13.04	18.19
Average number of sex acts per partner (as observed)		
Upper bound of observed 95% CI	11.11	14.74
Lower bound of observed 95% CI	15.57	22.13
Average number of sex partners (as observed)		
Upper bound of observed 95% CI	11.07	15.18
Lower bound of observed 95% CI	14.68	21.19
HIV-1 infectivity (adjusted for sex and STD prevalence)		
33% decrease from base estimate	16.09	22.49
33% increase from base estimate	11.21	15.61
Cost per client of HIV-1 VCT (as observed, Tanzania $28.93, Kenya $26.65)		
Lowest estimates from field sites (Kenya $16.28, Tanzania $17.61)	8.55	10.62
Highest estimates from field sites (Kenya $38.07, Tanzania $47.79)	17.47	27.02
DALYs saved per HIV-1 infection averted (19·47 DALYs per HIV-1 infection averted)		
33% increase from base-case	9.66	13.45
33% decrease from base-case	18.30	25.49
Discount rate (3% discount rate)		
0% discounting	7.51	10.46
6% discounting	10.40	27.90

*Overall value in table 3.

Table 4: **One-way sensitivity analysis**

	Average cost per DALY saved (1998 US$)	
	Kenya	Tanzania
Base-case*	12.77	17.78
Worst-case scenario (all parameter values set for worst case)	27.36	45.03
Best-case scenario (all parameter values set for best case)	5.16	6.58
Two-way sensitivity analysis		
Intervention cost by DALY per HIV-1 infection averted		
Worst case (high cost/low DALY)	22.43	37.90
Best case (low cost/high DALY)	6.97	7.82
Intervention cost by HIV-1 infectivity		
Worst case (high cost/low infectivity)	19.57	30.63
Best case (low cost/high infectivity)	7.84	9.16
DALY per HIV-1 by HIV-1 infectivity		
Worst case (low DALY/low infectivity)	19.84	27.72
Best case (high DALY/low infectivity)	9.16	12.75
Three-way and four-way analyses		
Economic and epidemiological: intervention cost by DALY per HIV-1 infection averted by HIV-1 infectivity		
Worst case (high cost/low DALY/low infectivity)	27.74	39.72
Best case (low cost/high DALY/high infectivity	6.33	7.70
Behavioural: condom percentage by condom effectiveness by number of sexual acts by number of partners		
Worst case (low condom % and effectiveness/high number of sex acts and partners)	17.95	25.57
Best case (high condom % and effectiveness/low number of sex acts and partners)	10.16	13.33

*Overall value in table 3.

Multivariate sensitivity analysis (regression model), association between model parameters and average cost per DALY averted (standardised β coefficients greater than 0·10 are shown). Tanzania, R^2=0·91; Kenya, R^2=0·90. DALYs gained per HIV-1 infection averted (Tanzania −0·667, Kenya −0·604). Cost of intervention (Tanzania 0·502, Kenya 0·591). HIV-1 infectivity (Kenya −0·219). Number of sex acts before intervention among HIV-1-positive men enrolled as individuals (Tanzania −0·130). Number of sex acts before intervention among HIV-1-positive women enrolled as individuals (Kenya −0·251). Number of sex partners before intervention among HIV-1-positive women enrolled as individuals (Tanzania −0·101). Number of sex partners before intervention among HIV-1-positive men enrolled as individuals (Kenya −0·127).

Table 5: **Multiway sensitivity analysis**

Tanzania per DALY saved. Multiway sensitivity analysis was done for combinations of model parameters that were shown to affect the outcome significantly in one-way analysis. In general, interactions between variations in intervention costs, DALYs per HIV-1 infection averted, and HIV-1 infectivity account for the greatest impact in cost-effectiveness of the intervention. This is reified in the multivariate sensitivity analysis, which shows that the cost-effectiveness of HIV-1 VCT is most sensitive to the number of DALYs per HIV-1 infection and the cost of the intervention. Preintervention sexual contact rates among HIV-1-infected people had only a minor effect on the robustness of the model.

Targeting approaches

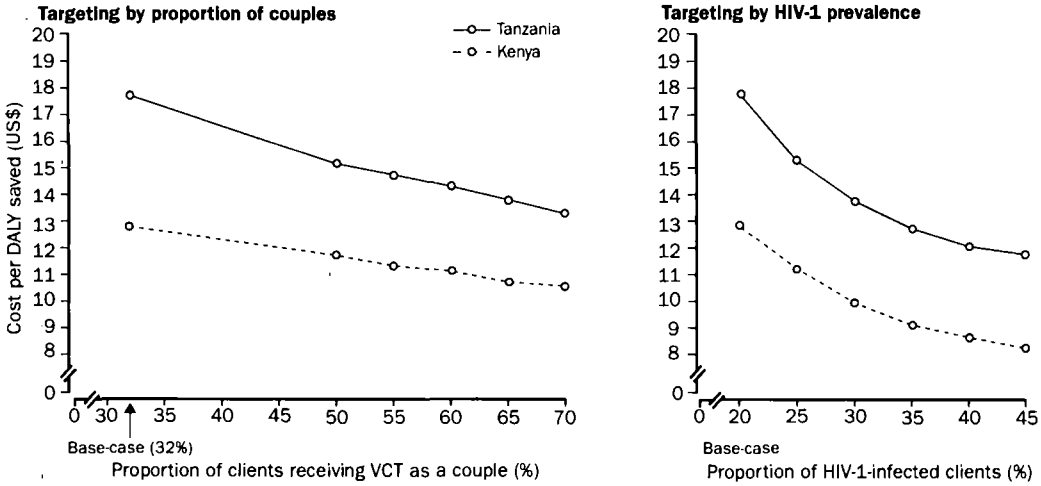
These findings indicate that variations in the targeting of clients for HIV-1 VCT would result in substantial improvement in the cost-effectiveness of VCT programmes. VCT provided to people who are HIV-1 infected, women, and couples yields the greatest benefits. To examine this effect more closely, variations in targeting approaches have been modelled. In the first scenario (figure), the proportion of clients receiving HIV-1 VCT as a couple was varied from 32% (base-case value) to 70% in six targeting strategies. The proportions of clients who are women and HIV-1 infected are held constant. There was a slight reduction in the cost per DALY saved as the proportion of clients enrolled as a couple was increased. Targeting by HIV-1 prevalence is also shown for 20% (base-case value) to 45% (figure), with the proportions of women and couples are held constant. The figure shows a significant improvement in the cost-effectiveness of the VCT intervention.

Discussion

US$50 per DALY saved has been recommended as a threshold for a public-health intervention in less-developed countries.[27] In the worst-case scenario, we estimated that the cost per DALY saved from HIV-1 VCT is $27.36 in Kenya and $45.03 in Tanzania. Thus, we feel that HIV-1 VCT should be considered as a cost-effective component of national HIV-1 prevention. For example, improved sexually transmitted disease services were estimated to cost $10 per DALY saved,[24] and universal provision of nevirapine costs from $5.25 to $10.51 per DALY saved.[17] Few other HIV-1 interventions have been subjected to rigorous cost-effectiveness analysis in less-developed countries. HIV-1 VCT also compares favourably with other non-HIV health interventions. For example, one DALY saved costs $20–$40 for immunisation for poliomyelitis, diphtheria, pertussis, and tetanus, $12–50 for treatment of acute respiratory infections,[30] $12–17 for other childhood immunisations (eg, measles[10]), $20–25 for school health programmes, $3–5 for short-course tuberculosis treatment, and $30–50 for management of sick-child programmes.[27] Moreover, the cost to avert one HIV-1 infection, at $369 in Kenya and $425 in Tanzania, is likely to be substantially less than the costs of treatment, not to mention the non-economic costs in suffering and social impact on families and communities.

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.



Sensitivity analysis of cost per DALY saved from VCT as function of targeting

This analysis also found that the cost-effectiveness of HIV-1 VCT can be significantly improved through reasonable targeting approaches. Combined targeting of couples and HIV-1-infected individuals would have an even greater impact on the cost-effectiveness and feasibility of the intervention. These sorts of targeting approaches are feasible. Targeting of HIV-1-infected clients could be accomplished through supporting VCT programmes in high-prevalence settings, by linkage of VCT to other services that reach high-prevalence populations (such as sexually transmitted disease services), and by encouraging people who showed previous risk behaviour or who are or were sexual contacts of known HIV-1-infected individuals to seek VCT. Targeting of couples could be encouraged through media campaigns, from referrals from health-care providers, and by linkage of VCT to other health services that reach couples, such as antenatal clinics and family-planning programmes.

Efforts to increase access to antiviral therapies in less-developed countries will also have implications for the provision of HIV-1 VCT. Marseille and colleagues[17] noted that, mainly because of the cost of HIV-1 VCT, universal provision of antiviral therapy such as nevirapine to women delivering children in areas of high HIV-1 prevalence may be more cost-effective than the targeting of therapy to HIV-1-infected mothers. This approach, however, does not take into account the significant benefits that the VCT itself provides, independently of the benefits of the nevirapine intervention. Thus, before decisions are made on whether to provide universal or targeted antiviral therapy for mothers and babies, the independent benefits of VCT should be included in estimations of cost-effectiveness.

Cost-effectiveness of HIV-1 VCT may also be improved through changes in the provision of the intervention. Our analysis found that the largest cost component of HIV-1 VCT was labour, followed by test kits and laboratory fees. An economy of scale could affect both of these cost components, as larger programmes could potentially use clinic and laboratory staff more efficiently, and with larger numbers of clients, programme managers might be able to negotiate discounts in the costs of laboratory kits and reagents. Such economy of scale has been achieved at the Ugandan AIDS Information Centre, a large VCT programme. The cost of providing VCT has declined significantly over time as the programme has grown (Elizabeth Marum, US Agency for International Development, Kampala, Uganda, personal communication). Care should be taken, however, because increased throughput of clients could compromise the quality of care, and with VCT, counselling is clearly an important component. Further studies on the relation between programme size and quality of care are thus needed.

Cost-effectiveness of HIV-1 VCT may also be improved with more intensive counselling efforts for those clients who do not respond well to the intervention. For example, HIV-1-uninfected men, especially those in Tanzania, who received the intervention as individuals, did not have as great a behaviour change as women or those who enrolled as couples. The VCT clinic in Dar es Salaam has since provided special training to counsellors to encourage them to spend extra time with HIV-1-negative men. Further studies should investigate why these HIV-1-negative men are more resistant to behavioural risk reduction, and what specific counselling approaches will be effective in such individuals.

Cost-sharing is another means to lower the cost of HIV-1 VCT to funding agencies and government health programmes. We assessed the willingness of clients to pay for services; after receipt of the service, they said that they would pay an average of $1.64 in Kenya and $5.11 in Tanzania.[31] After the study ended and the sites were converted to pure service provision, each site implemented fees based on these results. However, demand for the service declined significantly, especially in Tanzania. Therefore, each site lowered the fee to about $0.50 in Kenya and to $1 in Tanzania, and the number of clients increased to that before the initiation of fees.

There are some potential sources of error in the analysis that should be addressed. Self-report bias may have been present in the assessment of sexual outcomes. We addressed this possibility in sensitivity analysis by modelling the cost-effectiveness of the intervention with 95% CI of behavioural parameters. We found little impact on the overall findings. Self-reported risk behaviours at baseline and at 6 months were significantly associated with incident sexually transmitted diseases as shown by DNA testing of urine samples, indicating that

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

the self-reported sexual behaviours had a high degree of validity.[32]

Biological assumptions that may have contributed error to the analysis include the possibility that rates of sexually transmitted diseases and HIV-1 infections among partners of study participants were higher or lower than assumed. Sensitivity analysis did, however, confirm that even under much higher and lower rates of infection the base-case values remained robust.

Cost estimates may also have been a source of error. Careful attention was paid to comparisons of cost estimates to actual costs incurred in service delivery, and sensitivity analysis of cost parameters showed that even at the highest estimates the base-case estimate was increased to only $17.47 in Kenya and $27.02 in Tanzania per DALY saved. At the lowest cost estimates the base-case was $8.55 in Kenya and $10.62 in Tanzania. Thus, the range still allowed for reasonable interpretation.

Other potential sources of error in the model estimates are from values derived from published data, namely the HIV-1 infectivity values used. These were derived from a careful review of previous publications, and were subjected to adjustment for sex and coinfection with sexually transmitted diseases, and were assessed in sensitivity analysis. Those analyses showed that at 33% increased and decreased infectivity the base-case values were plausible. Results for Kenya and Tanzania were similar, even in the patterns across subpopulations analysed.

The final possible limitation of the analysis was the ability to generalise the results to other settings. We believe that the services rendered in this study are very similar to other VCT services in this region, on the basis of consultations with colleagues in dissemination workshops sponsored by the project. The study population also seems to be similar to that of other services in east Africa. However, care should be taken in generalising the effectiveness of VCT to other regions, cultures, and rural settings. Despite these limitations, HIV-1 VCT may have similar effects in other settings, and there is little evidence to suggest that the effects reported here would not be found elsewhere.

Finally, this analysis focused primarily on the benefits of HIV-1 VCT in terms of infections averted and the associated DALYs saved from the intervention. However, many other tangible benefits of VCT not addressed in this analysis bolster the need to support this important intervention. First, there are significant social and psychological benefits to knowing one's HIV-1 infection status. HIV-1 VCT gives people the ability to plan better for the future, assuages concerns over the status of their health, and gives them the ability to open discussion with sexual partners over potential risk behaviours. People should have the right to know whether they are infected with something as lethal and stigmatising as HIV-1.

As antiviral therapies become more widely available in less-developed countries, the need for HIV-1 VCT will increase substantially. What is needed now is political and policy support for this intervention to make it available to the vast numbers of people currently with little access.

Contributors

Michael Sweat designed the study, worked with each site to develop site-specific protocols, oversaw quality assurance at the sites, did cost-effectiveness and cost-recovery analyses, and wrote most of the paper. Steven Gregorich designed the forms and data management systems, organised and carried out database management, and assisted with analyses, interpretation, and editing of the paper. Gloria Sangiwa, Colin Furlonge, and Donald Balmer oversaw the study sites (Kenya, Tanzania, and Trinidad), and provided substantial input into the study design and all protocols. All site investigators had substantial input into the development of the site-specific protocol. Claudes Kamenga designed the study, worked with each site in the development of site-specific protocols, oversaw the design and implementation of the sexually transmitted disease protocol, and oversaw quality assurance at the sites. Olga Grinstead developed the counselling and quality assurance protocols, supervised implementation at the local sites, did analysis on negative outcomes, and assisted in analysis, interpretation, and editing of the paper. Thomas Coates oversaw the design and execution of the study, supervised the analyses, and assisted in the interpretation and editing of the paper. All investigators had substantial input into the interpretation of results.

Acknowledgments

We thank Elliot Marseille and Jim Kahn for their many helpful suggestions.

This research was supported by AIDSCAP/Family Health International under funding from USAID contract number USAID/HRN-5972-C-00-4001-00, by WHO, UNAIDS, and NIMH grant numbers 5R29MH57217-03 (Johns Hopkins University) and MH42459 (Center for AIDS Prevention Studies).

References

1 UNAIDS. AIDS epidemic update: December 1999. Geneva: UNAIDS, 1999.
2 UNAIDS. Epidemiological fact sheet on HIV/AIDS and sexually transmitted diseases: Kenya. Geneva: UNAIDS, 1998.
3 UNAIDS. Epidemiological fact sheet on HIV/AIDS and sexually transmitted diseases: United Republic of Tanzania. Geneva: UNAIDS, 1998.
4 Voluntary HIV-1 Counseling and Testing Efficacy Study Group. Efficacy of voluntary HIV-1 counselling and testing in individuals and couples in Kenya, Tanzania, and Trinidad: a randomised trial. *Lancet* 2000; **356:** 103–12.
5 Mertens TE, Low-Beer D. HIV and AIDS: where is the epidemic going? *Bull World Health Organ* 1996; **74:** 121–29.
6 Mugerwa RD, Marum LH, Serwadda D. Human immunodeficiency virus and AIDS in Uganda. *East Afr Med J* 1996; **73:** 20–26.
7 Marum E, Gumisiriza E, Moore M, Onen J. Impact of a social support club following HIV counseling and testing (CT), Uganda, 1993–1994. X International Conference on AIDS. Yokohama, August, 1994 (abstr 240C).
8 De Zoysa I, Phillips KA, Kamenga MC, et al. Role of HIV counseling and testing in changing risk behavior in developing countries. *AIDS* 1995; **9** (suppl A): S95–101.
9 Higgins DL, Galavotti C, Johnson R, O'Reilly KR , Rugg DL. The effect of HIV antibody counseling and testing on risk behaviors: are the studies consistent? VI International Conference on AIDS. San Francisco, July, 1990 (abstr ThD836).
10 Wolitski RJ, MacGowan RJ, Higgins DL, Jorgensen CM. The effects of HIV counseling and testing on risk-related practices and help-seeking behavior. *AIDS Educ Prev* 1997; **9** (suppl): 52–67.
11 Allen S, Serufilira A, Bogaerts J, et al. Confidential HIV testing and condom promotion in Africa. Impact on HIV and gonorrhea rates. *JAMA 1992;* **268:** 3338–43.
12 Thomas J. Access to AIDS treatment in developing countries: a global issue of equity and human rights. *AIDS Analysis Asia* 1998; **4:** 1–7.
13 Wilkinson D, Floyd K Gilks CF. Antiretroviral drugs as a public health intervention for pregnant HIV-infected women in rural South Africa: an issue of cost-effectiveness and capacity. *AIDS* 1998; **12:** 1571–80.
14 CDC. Administration of zidovudine during late pregnancy and delivery to prevent perinatal HIV transmission: Thailand, 1996–1998. *JAMA* 1998; **279:** 1061–62.
15 Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999; **354:** 795–802.
16 Renault B, Birmingham K. Call to buy nevirapine for developing countries. *Nat Med* 1999; **5:** 1093.
17 Marseille E, Kahn JG, Mmiro F, et al. Cost effectiveness of single-dose nevirapine regimen for mothers and babies to decrease vertical HIV-1 transmission in sub-Saharan Africa. *Lancet* 1999; **354:** 803–09.
18 Prescott N. Setting priorities for government involvement with antiretrovirals. In: Praag E, Fernyak S, Katz A, eds. The implications of antiretroviral treatments: informal consultation. Geneva: UNAIDS, 1997.
19 Anon. Glaxo cuts HIV drug cost for developing world. *Nature* 1998; **392:** 118.
20 Grinberg L. Expanded access to experimental drugs: activists seek more open programs. *AIDS Treatment News,* 1997 (number 282): 6–7.

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

21 Temmerman M, Ndinya-Achola J, Ambani J, Piot P. The right not to know HIV-test results. *Lancet* 1995; **345:** 969–70.
22 Rothenberg KH, Paskey SJ, Reuland MM, Zimmerman SI, North RL. Domestic violence and partner notification: implications for treatment and counseling of women with HIV. *J Am Med Womens Assoc* 1995; **50:** 87–93.
23 US Bureau of Census. Life-tables: Tanzania, Kenya. Washington, DC: US Bureau of Census International Database, 1999 (available online at www.census.gov/ipc/www/idbacc.html).
24 Gilson L, Mkanje R, Grosskurth H, et al. Cost-effectiveness of improved treatment services for sexually transmitted diseases in preventing HIV-1 infection in Mwanza Region, Tanzania. *Lancet* 1997; **350:** 1805–09.
25 Murray CL, Lopez AD, eds. The global burden of disease. Cambridge, MA: Harvard University Press, 1996.
26 Hendriks JC, Van Druten JA, Van Ameijden EJ, Van Griensven GJ, Coutinho RA. Estimation of progression of HIV infection among intravenous drug users using a death-included Markov model. XI International Conference on AIDS. Vancouver, July, 1996 (abstr ThC223).
27 World Bank. World development report: investing in health. New York: Oxford University Press, 1993.
28 Weinstein M, Graham J, Siegel J, Fineberg H. Cost-effectiveness analysis of AIDS prevention programs: concepts, complications, and illustrations. Washington, DC: National Academy Press, 1989.
29 Rehle T, Saidel T, Hassig S, Bouey P, Gaillard E, Sokal DC. AVERT: a user friendly model to estimate the impact of HIV/sexually transmitted disease prevention interventions on HIV transmission. *AIDS* 1998; **12** (suppl 2): S27–35.
30 Jamison DT, Mosley WH. Disease control priorities in developing countries: health policy responses to epidemiological change. *Am J Public Health* 1991; **81:** 15–22.
31 Sweat M, Balmer D, Sangiwa G. Cost to clients and willingness to pay for HIV counseling and testing in Kenya and Tanzania: results from the voluntary HIV counseling and testing study. XII International Conference on AIDS. Geneva, June–July 1998 (abstr 23135).
32 Coates T, Furlonge C, Mwakagile D, Kamenga C, Schacter J, Gregorich S. Validation of self-reported sexual risk behavior with STD incident rates: results from the voluntary HIV counseling and testing study. XII International Conference on AIDS. Geneva, June–July 1998 (abstr 14107).

For personal use only. Not to be reproduced without permission of The Lancet.

Efficacy of voluntary HIV-1 counselling and testing in individuals and couples in Kenya, Tanzania, and Trinidad: a randomised trial

*The Voluntary HIV-1 Counseling and Testing Efficacy Study Group**

Summary

Background Our aim was to determine the efficacy of HIV-1 voluntary counselling and testing (VCT) in reducing unprotected intercourse among individuals and sex-partner couples in Nairobi (Kenya), Dar es Salaam (Tanzania), and Port of Spain (Trinidad).

Methods Individual or couple participants were randomly assigned HIV-1 VCT or basic health information. At first follow-up (mean 7·3 months after baseline) health-information participants were offered VCT and all VCT participants were offered retesting. Sexually transmitted infections were diagnosed and treated at first follow-up. The second follow-up (mean 13·9 months after baseline) involved only behavioural assessment, and all participants were again offered VCT.

Findings 3120 individuals and 586 couples were enrolled. The proportion of individuals reporting unprotected intercourse with non-primary partners declined significantly more for those receiving VCT than those receiving health information (men, 35% reduction with VCT *vs* 13% reduction with health information; women, 39% reduction with VCT *vs* 17% reduction with health information), and these results were maintained at the second follow-up. Individual HIV-1-infected men were more likely than uninfected men to reduce unprotected intercourse with primary and non-primary partners, whereas HIV-1-infected women were more likely than uninfected women to reduce unprotected intercourse with primary partners. Couples assigned VCT reduced unprotected intercourse with their enrolment partners significantly more than couples assigned health information, but no differences were found in unprotected intercourse with non-enrolment partners. Couples in which one or both members were diagnosed with HIV-1 were more likely to reduce unprotected intercourse with each other than couples in which both members were uninfected. These changes were replicated by those in the health-information group diagnosed with HIV-1 at first follow-up.

Interpretation These data support the efficacy of HIV-1 VCT in promoting behaviour change.

Lancet 2000; **356:** 103–12
See Commentary page xxxx

*Members listed at end of paper

Correspondence to: Dr Thomas J Coates, Center for AIDS Prevention Studies, University of California, 74 New Montgomery #600, San Francisco, CA 94105, USA (e-mail: tcoates@psg.ucsf.edu)

Introduction

More widespread HIV-1 voluntary counselling and testing (VCT) in less-developed countries is advocated on the grounds that it provides an opportunity for education and behaviour change, and that knowledge of serostatus allows individuals to plan, make important life decisions, and to seek care and support.[1,2] But VCT is an expensive intervention compared with health education and other potentially effective counselling strategies,[3–5] and there are potentially negative social consequences of VCT, including family and relationship disruption, sexual violence, stigma, and discrimination.[6]

Advocacy for HIV-1 testing as a prevention strategy has been hampered, especially in less-developed countries, by the lack of efficacy data.[7–9] A comprehensive meta-analysis of VCT concluded that testing resulted in a reduction in risk for persons who are HIV-1 infected and for serodiscordant couples.[10] However, all but a few studies were observational in design, and the results are complicated by a variety of confounding factors. Previous research in Africa and USA has suggested that VCT is more effective for HIV-1 risk reduction when both partners participate, share their test results, and formulate risk-reduction plans based on serostatus results. In particular, a study of VCT carried out among a cohort of Rwandan women showed that HIV-1-seroconversion rates decreased in seronegative women whose partners were tested, but not in women whose partners were not tested.[11] Gonorrhoea rates decreased significantly in seropositive women. Substantial increases in condom use were also found among discordant couples in a research project in Zaire (Democratic Republic of Congo).[12] However, no experimental data have validated these important observations.

The Voluntary HIV-1 Counseling and Testing Efficacy Study was a three-site clinical trial carried out in 1995–98 to determine whether VCT, given to individuals or couples, might be effective in reducing risk behaviour associated with the sexual transmission of HIV-1.[6,13]

Methods

The study was carried out at three sites: Nairobi, Kenya (estimated HIV-1 prevalence 8–13%); Dar es Salaam, Tanzania (estimated HIV-1 prevalence 10–12%); and Port of Spain, Trinidad (estimated HIV-1 prevalence 1–2%). A detailed description of the methods has been published elsewhere[13] (intervention and training manuals, outcome measures, and survey details are available from the Center for AIDS Prevention Studies website: www.caps.ucsf.edu/capsweb/projects/c&tindex.html).

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

Study participants were recruited by each study centre through local media and direct soliciting from the community by site staff. For inclusion, participants had to be aged at least 18 years (all married people were considered adults), planning to remain in the area for 1 year, and not known to be infected with HIV-1. Partners with spouses or sexual partners already in the study were enrolled as secondaries and were permitted to receive the same services as their enrolled partner but as a non-participant. Participants in Tanzania and Kenya provided verbal informed consent, and participants in Trinidad provided written informed consent. The study was approved by the Committee on Human Research at the University of California, San Francisco, and by the ethics committees and national AIDS control programmes in each country.

Baseline survey

The structured standard face-to-face baseline survey was carried out before randomisation and assessed HIV-1 risk behaviour in the previous 2 months to minimise recall error while assessing an adequate sample of behaviour.[14] The interview went through extensive pretesting and was designed to limit reporting bias by adding preambles to sensitive questions shown to increase reports of risk behaviour.[15] Sexual behaviour was measured by asking a series of questions about the occurrence and frequency of vaginal and anal intercourse with each of the participant's five most recent partners over the past 2 months. Each partner was then assigned a partner type on the basis of the participant's relationship status and living arrangements: primary partner, non-primary partner, or enrolment partner (in the case of couples enrolling together). Primary partners were legal or common-law spouses or the boyfriend or girlfriend of non-married participants. Non-primary partners were other partners. Enrolment partners were any partner with whom the participant enrolled. Members of enrolled couples were interviewed individually and assured of confidentiality. Urine samples were collected from each participant, marked with the participant's study number, and stored at −20°C.

Interventions

Randomisation was stratified by site, sex, and couple or individual status (figure 1). Participants were assigned VCT or health information by allocation of sealed envelopes. Couples were always randomised together.

VCT was based on the US Centers for Disease Control and Prevention's client-centred HIV-1 counselling model.[16] This model includes personalised risk assessment, development of a personalised risk-reduction plan for each client, and is ideal for promoting cultural specificity.

Only participants assigned VCT had serum samples tested for HIV-1. Testing was by commercial ELISA and all reactive (positive) samples were confirmed with a second ELISA. Inconclusive tests were confirmed by western blot or immunofluorescence assay.[17] Participants were scheduled to return to receive their test results 2 weeks later. Participants who did not agree to be tested during their initial baseline visit were scheduled to receive additional counselling and were encouraged to return for as many counselling sessions before and after disclosure as they wanted. A condom demonstration and role play were provided.

Participants in the health-information intervention watched a 15 min video and participated in a discussion about HIV-1 transmission and condom use led by a health-information officer.[13] All participants (both interventions) received a supply of 25 condoms and a brochure showing correct condom use, and were invited to return for additional condoms at any time. Counsellors, health-information officers, and interviewers were trained in separate groups with standard training manuals.

Follow-up

The first follow-up visit interview was similar in format to the baseline survey. All participants assigned health information could start VCT during this visit if they wanted to. Cervical swabs were obtained from women to culture for *Neisseria gonorrhoeae* and antigen detection for *Chlamydia trachomatis*, and vaginal fluid was obtained for direct microscopy for the presence of *Trichomonas vaginalis* and *Candida albicans*. Men provided a urine sample for leucocyte esterase dipstick testing, and had a urethral swab to test for *N gonorrhoeae* and *C trachomatis* if the dipstick test was positive. All participants were tested for syphilis, and for HIV-1 if not tested at baseline.

Participants presenting with overt urethral or cervical discharge or with genital ulcer disease were treated while waiting for laboratory results. All follow-up urine samples were tested in the USA for *N gonorrhoeae* and *C trachomatis* by ligase chain reaction.[17,18] Investigators at each site were notified of any positive results so that sexually transmitted diseases not clinically detected during follow-up could be treated when participants returned for their results 2 weeks later. Frozen urine samples taken at baseline of those testing positive were then sent for testing to determine whether the sexually transmitted disease found was a new (incident) infection.

The second follow-up interviews were similar in format to the baseline interview. Participants assigned health information who started VCT during the first follow-up were retested at the second follow-up. No data on sexually transmitted diseases were collected at this visit.

Data analysis

All analyses were by intention to treat. The effect of the intervention was estimated for each outcome, with logistic regression and use of generalised estimating equations,[19] separately for men and women enrolled as individuals and couples. The model accounted for correlation of repeated measures between individuals. Explanatory variables included indicators for intervention group, time, study site, and their interactions. Because there was no effect of study site on intervention-group outcome, data were pooled for all analyses. Additional post-hoc comparisons for each outcome were made between intervention groups at each timepoint and between subsequent timepoints within intervention groups. Logistic regression models were used to estimate the effect of intervention, unprotected intercourse with primary partners (reported at first follow-up), and unprotected intercourse with non-primary partners (reported at first follow-up) on incidence of sexually transmitted disease

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

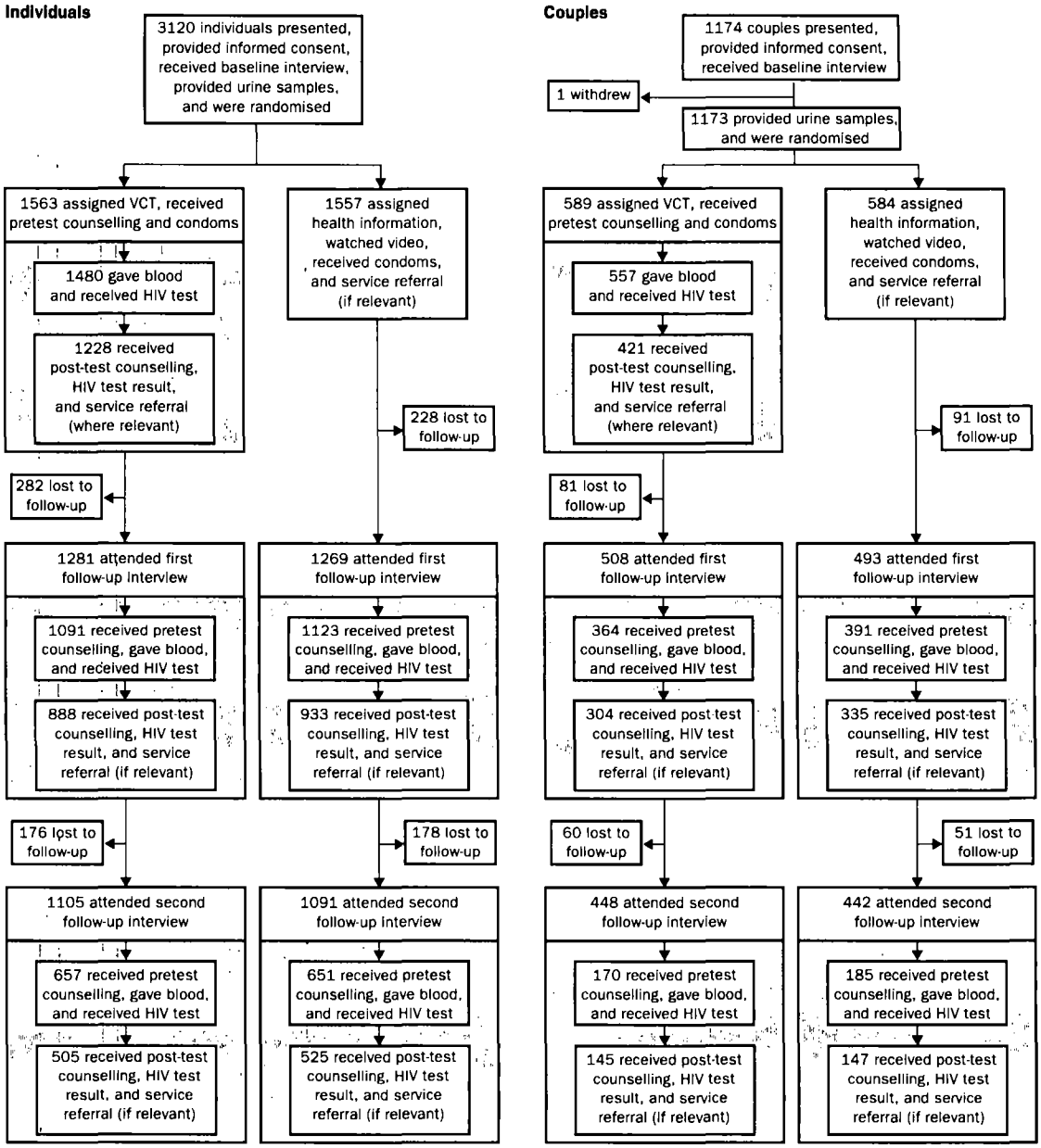


Figure 1: **Trial profile**

at first follow-up. A similar set of models was used to estimate associations between baseline HIV-1 serostatus, unprotected intercourse with primary partners, and unprotected intercourse with non-primary partners on incidence of sexually transmitted disease among participants assigned VCT at baseline. Data for men and women were pooled for these analyses. However, if significant interactions were found, separate effects were estimated by sex. All variables were binary.

Results

The 3120 people who enrolled as individuals (1534 men, 1586 women) were young, unmarried, and most had primary or secondary education (table 1). Those enrolling as couples (586 couples, 1172 people) were slightly older than those presenting for VCT as individuals and about two-thirds were married or cohabiting. 1026 (87·5%) members of the enrolment couples (490 [95·2%] in Kenya, 364 [82·0%] in Tanzania, and 172 [80·4%] in Trinidad) were also primary partners. We found no baseline differences between those assigned VCT and those assigned health information.

Interventions

Most participants assigned VCT were tested and received test results at baseline (table 2). At the first follow-up, nearly all participants assigned VCT at baseline decided to be retested. 1422 (89·4%) of participants in the VCT group at baseline who were tested and gave a first follow-up interview at the site

Automated Records Management System: Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

	Individuals		Couples	
	Counselling and testing (n=1563)	Health information (n=1557)	Counselling and testing (n=589)	Health information (n=584)
Age (years)				
Men	28·9 (9·7)	28·1 (9·1)	31·5 (8·4)	32·1 (32·1)
Women	28·6 (8·6)	28·5 (8·8)	25·9 (6·6)	26·7 (7·4)
Marital status				
Currently married				
Men	145 (19·3%)	115 (15·4%)	188 (64·8%)	198 (68·5%)
Women	178 (22·9%)	178 (23·0%)	177 (61·5%)	179 (61·7%)
Ever married				
Men	223 (29·7%)	205 (27·1%)	207 (71·4%)	214 (73·8%)
Women	367 (46·9%)	372 (47·7%)	207 (71·1%)	202 (69·7%)
Number of living children				
Male	1·0 (2·1)	0·8 (1·6)	1·6 (2·1)	1·7 (2·0)
Female	1·6 (2·0)	1·7 (2·0)	1·4 (1·7)	1·7 (2·7)
Education				
None				
Men	16 (2·1%)	8 (1·1%)	7 (2·4%)	13 (4·5%)
Women	67 (8·5%)	57 (7·2%)	21 (7·2%)	18 (6·2%)
Primary				
Men	353 (46·1%)	353 (46·3%)	165 (56·7%)	156 (54·0%)
Women	354 (44·7%)	365 (46·3%)	182 (62·8%)	181 (62·2%)
Secondary				
Men	334 (43·6%)	330 (43·3%)	94 (32·3%)	94 (32·5%)
Women	320 (40·4%)	325 (41·2%)	75 (25·9%)	80 (27·5%)
Post-secondary				
Men	62 (8·1%)	71 (9·3%)	25 (8·6%)	26 (9·0%)
Women	51 (6·4%)	41 (5·2%)	12 (4·1%)	12 (4·1%)

Data are numbers (percentages) or means (SD).

Table 1: **Sample characteristics**

were retested. 31 (15·8%) of 196 participants in the VCT group who were tested and gave an interview in or near their home, rather than at the site at the first follow-up, later returned to the site for a second HIV-1 test. Most individuals assigned to receive health information chose to be tested for HIV-1 at the first follow-up visit. 1476 (94·0%) of those who returned to the site at first follow-up were tested. Among 187 participants who gave an interview in their home, 34 (18·2%) later returned to the site to be tested. A substantial proportion of VCT and health-information participants were retested at the second follow-up visit (table 2). 1543 (66·7%) of those who gave an interview at the second follow-up at the site were tested. 89 (12·1%) of 737 participants who gave an interview at home later returned for an HIV-1 test.

Men (individuals and couples) who were tested for HIV-1 and received test results did not differ on any of the baseline sexual behaviour variables from men who did not receive test results. Women enrolling as individuals who did not receive testing or returned for test results were more likely to report unprotected sexual activity with primary partners than were women who received testing and returned for test results (p=0·033). By contrast, women enrolling as couples who did not receive HIV-1 testing or test results were less likely to report unprotected intercourse with enrolment partners than women who reported testing and received test results (p=0·043). Men and women, whether enrolling as individuals or couples, who received a positive test for HIV-1 were more likely to receive more than one post-test counselling session (all p<0·0001). Men who reported unprotected sexual intercourse with a non-primary partner and women who reported unprotected sexual intercourse with a primary partner were less likely to return for additional post-test counselling sessions (p=0·027 and p=0·045, respectively).

The retention rates (defined as the proportion of those who enrolled at baseline) from baseline to first follow-up (which occurred an average of 7·3 months after baseline randomisation) and second follow-up (which occurred at an average of 13·9 months after randomisation) are shown in table 3. We found no differences between retained and non-retained participants at second follow-up on any baseline sexual behaviour variables by use of a logit (generalised estimating equation) model with attrition status, intervention group, sex, study site, and the associated two-way interactions as explanatory variables.

	Individuals						Couples					
	Kenya		Tanzania		Trinidad		Kenya		Tanzania		Trinidad	
	VCT	HI	VCT	HI	VCT	HI	VCT	HI	VCT	HI	VCT	HI
Men												
Baseline*	250	250	249	248	269	268	131	127	111	111	53	54
Tested	237 (94·8%)	··	227 (91·2%)	··	264 (98·1%)	··	122 (93·1%)	··	105 (94·6%)	··	53 (100%)	··
HIV-1 seropositive†	29 (12·2%)	··	17 (7·5%)	··	10 (3·8%)	··	23 (18·9%)	··	18 (17·1%)	··	2 (4%)	··
Received test results†	204 (86·1%)	··	174 (76·7%)	··	235 (89·0%)	··	101 (82·8%)	··	68 (64·8%)	··	45 (85%)	··
First follow-up	202	209	197	199	222	220	120	113	92	90	44	38
Tested	160 (79·2%)	180 (86·1%)	180 (91·4%)	170 (85·4%)	203 (91·4%)	206 (93·6%)	82 (68·3%)	100 (88·5%)	68 (73·9%)	64 (71·1%)	36 (81·8%)	35 (92·1%)
HIV-1 seropositive†	18 (11·2%)	18 (10·0%)	14 (7·8%)	19 (11·2%)	6 (3·0%)	2 (1·0%)	12 (14·6%)	8 (8·0%)	9 (13·2%)	12 (18·8%)	1 (2·8%)	0
Received test results†	151 (94·3%)	160 (88·9%)	147 (81·7%)	150 (88·2%)	136 (67·0%)	151 (73·3%)	77 (93·9%)	89 (89·0%)	55 (80·8%)	56 (87·5%)	26 (72·2%)	26 (74·3%)
Second follow-up	174	182	184	176	192	189	105	106	79	80	41	32
Tested	89 (46·6%)	104 (57·1%)	143 (77·7%)	121 (68·8%)	129 (67·2%)	124 (65·6%)	41 (39·1%)	49 (46·2%)	23 (29·1%)	31 (38·8%)	23 (56·1%)	17 (53·1%)
HIV-1 seropositive†	8 (9·9%)	9 (8·7%)	10 (7·0%)	12 (9·9%)	3 (2·3%)	3 (2·4%)	3 (7·3%)	3 (6·1%)	5 (21·7%)	7 (22·6%)	1 (4·4%)	0
Received test results†	73 (90·1%)	98 (94·2%)	131 (91·6%)	110 (90·9%)	73 (56·6%)	90 (72·6%)	38 (92·7%)	43 (92·7%)	19 (82·6%)	25 (80·7%)	19 (82·6%)	10 (58·8%)
Women												
Baseline*	250	250	245	241	300	300	130	127	111	111	53	54
Tested	237 (94·8%)	··	226 (92·2%)	··	289 (96·3%)	··	120 (92·3%)	··	106 (95·5%)	··	51 (96·2%)	··
HIV-1 seropositive†	65 (27·4%)	··	73 (32·3%)	··	7 (2·4%)	··	29 (24·2%)	··	24 (22·6%)	··	2 (3·9%)	··
Received test results†	202 (85·2%)	··	159 (70·4%)	··	254 (87·9%)	··	100 (83·3%)	··	64 (60·4%)	··	43 (84·3%)	··
First follow-up	225	218	179	187	256	236	116	120	89	87	47	45
Tested	171 (76·0%)	198 (90·8%)	138 (77·1%)	145 (77·5%)	239 (93·4%)	224 (94·9%)	76 (65·5%)	93 (77·5%)	63 (77·5%)	60 (70·0%)	39 (83·0%)	39 (87·0%)
HIV-1 seropositive†	46 (26·9%)	59 (29·8%)	46 (33·3%)	40 (27·6%)	7 (1·5%)	4 (1·8%)	19 (25·0%)	15 (16·1%)	11 (17·5%)	17 (28·3%)	0	1 (2·6%)
Received test results†	160 (93·6%)	185 (93·4%)	114 (82·6%)	122 (84·1%)	180 (75·3%)	165 (73·7%)	71 (93·4%)	86 (92·5%)	49 (77·8%)	52 (86·7%)	26 (66·7%)	26 (66·7%)
Second follow-up	197	184	153	155	205	205	107	103	76	81	40	40
Tested	74 (37·6%)	84 (45·7%)	65 (42·5%)	62 (40·0%)	157 (76·6%)	156 (76·1%)	40 (37·4%)	42 (40·8%)	21 (27·6%)	26 (32·1%)	22 (55·0%)	20 (50·0%)
HIV-1 seropositive†	18 (24·3%)	18 (21·4%)	29 (44·6%)	20 (32·3%)	2 (1·3%)	3 (1·9%)	10 (25·0%)	8 (19·1%)	4 (19·1%)	8 (30·8%)	0	0
Received test results†	70 (94·6%)	75 (89·3%)	58 (89·2%)	51 (82·3%)	100 (63·7%)	101 (64·7%)	38 (95·0%)	35 (83·3%)	17 (81·0%)	24 (92·3%)	14 (63·6%)	10 (50·0%)

*Health-information (HI) group was not tested for HIV-1 at baseline. †Among those tested.

Table 2: **HIV-1 VCT experiences at baseline, and at first and second follow-up among men and women**

For personal use only. Not to be reproduced without permission of The Lancet.

Automated Records Management System Hex-Dump Conversion

	Individuals				Couples			
	Total	Kenya	Tanzania	Trinidad	Total	Kenya	Tanzania	Trinidad
At first follow-up	2550 (81·7%)	854 (85·4%)	762 (77·5%)	934 (82·2%)	1001 (85·3%)	469 (91·1%)	358 (80·6%)	174 (81·3%)
Men	1249 (81·4%)	411 (82·2%)	396 (79·7%)	442 (82·3%)	487 (84·7%)	233 (90·3%)	182 (79·3%)	82 (76·6%)
Women	1301 (82·4%)	443 (88·6%)	366 (75·3%)	492 (82·0%)	504 (86·0%)	236 (91·8%)	176 (79·3%)	92 (86·0%)
VCT	1281 (82·0%)	427 (85·4%)	376 (76·1%)	478 (84·0%)	508 (86·3%)	236 (90·4%)	181 (81·5%)	91 (85·9%)
Health information	1269 (81·5%)	427 (85·4%)	386 (78·9%)	456 (80·3%)	493 (84·4%)	233 (91·7%)	177 (79·7%)	83 (76·9%)
At second follow-up	2196 (70·4%)	737 (73·7%)	668 (68·0%)	791 (69·6%)	890 (75·9%)	421 (81·8%)	316 (71·2%)	153 (71·5%)
Men	1097 (71·5%)	356 (71·2%)	360 (72·4%)	381 (71·0%)	443 (75·5%)	211 (81·8%)	159 (71·6%)	73 (68·2%)
Women	1099 (69·3%)	381 (76·2%)	308 (63·4%)	410 (68·3%)	447 (76·3%)	210 (81·7%)	157 (70·7%)	80 (74·8%)
VCT	1105 (70·7%)	371 (74·2%)	337 (68·2%)	397 (69·8%)	448 (76·1%)	212 (81·2%)	155 (69·8%)	81 (76·4%)
Health information	1091 (70·1%)	366 (73·2%)	331 (67·7%)	394 (69·4%)	442 (75·7%)	209 (82·3%)	161 (72·5%)	72 (66·7%)

Table 3: **Retention rates**

Sexual behaviour change

Individual men and women assigned VCT were significantly more likely to reduce unprotected intercourse with non-primary partners from baseline to the first follow-up compared with men and women assigned health information (table 4, figure 2). These differences were seen in the differential reductions in the proportions of participants reporting unprotected intercourse (men, 35% *vs* 13%; women, 39% *vs* 17% [VCT *vs* health information]) and percentage reductions in the mean number of non-primary partners with whom participants had unprotected intercourse (men, 38% *vs* 15%; women 43% *vs* 22%). These reductions were maintained at the second follow-up. Individuals assigned health information at baseline reported reduced unprotected intercourse with non-primary partners once they had access to HIV-1 testing and counselling at the first follow-up, and their rates of unprotected intercourse nearly matched those of the original VCT group by the time of the second follow-up.

Couples assigned to VCT significantly reduced unprotected intercourse with enrolment partners compared with those assigned to health information (table 4). Men in the VCT group had a significantly lower rate of unprotected intercourse with enrolment partners than men in the health-information group at first follow-up; these rates were similar at second follow-up. The health-information group had a further reduction from baseline to second follow-up once they had access to HIV-1 VCT.

Incident sexually transmitted diseases

Incidence data for sexually transmitted diseases were available at first follow-up for 2279 (89·4%) of 2550

	Men						Women					
	Baseline	Follow-up		p			Baseline	Follow-up		p		
		First	Second	Baseline vs first	Baseline vs second	First vs second		First	Second	Baseline vs first	Baseline vs second	First vs second
Primary partner (individuals)												
Any intercourse												
VCT	310 (40·5%)	235 (37·9%)	196 (35·6%)	0·12	0·04	0·52	411 (51·8%)	340 (51·8%)	273 (49·1%)	0·97	0·25	0·25
Health information	298 (38·9%)	194 (30·9%)	203 (37·1%)	0·0002	0·51	0·003	391 (49·5%)	291 (45·4%)	242 (44·6%)	0·16	0·13	0·71
p	0·52	0·01	0·57				0·32	0·05	0·22			
Unprotected intercourse												
VCT	246 (32·1%)	163 (26·3%)	125 (22·7%)	0·002	<0·0001	0·16	369 (46·5%)	250 (38·1%)	195 (35·1%)	<0·0001	<0·0001	0·21
Health information	244 (31·9%)	149 (23·7%)	152 (27·8%)	<0·0001	0·08	0·04	344 (43·5%)	237 (37·0%)	185 (34·1%)	0·008	0·0006	0·24
p	0·90	0·31	0·06				0·19	0·18	0·84			
Non-primary partner (individuals)												
Any intercourse												
VCT	323 (42·2%)	239 (38·5%)	211 (38·4%)	0·17	0·10	0·78	237 (39·8%)	160 (24·3%)	124 (22·3%)	0·005	<0·0001	0·23
Health information	308 (40·2%)	273 (43·5%)	210 (38·4%)	0·10	0·43	0·02	256 (32·4%)	184 (28·7%)	137 (25·2%)	0·04	0·0008	0·13
p	0·44	0·07	0·98				0·27	0·10	0·19			
Unprotected intercourse												
VCT	237 (30·9%)	123 (19·8%)	88 (16·0%)	<0·0001	<0·0001	0·02	182 (22·9%)	91 (13·9%)	57 (10·3%)	<0·0001	<0·0001	0·03
Health information	229 (29·9%)	166 (26·4%)	111 (20·3%)	0·12	<0·0001	0·003	191 (24·2%)	125 (19·5%)	63 (11·6%)	0·008	<0·0001	<0·0001
p	0·62	0·01	0·06				0·50	0·009	0·52			
Enrolment partner (couples)												
Any intercourse												
VCR	252 (86·3%)	184 (72·4%)	157 (70·4%)	0·0002	<0·0001	0·32	257 (87·7%)	190 (76·3%)	157 (71·7%)	0·0002	<0·0001	0·24
Health information	263 (90·7%)	194 (82·6%)	161 (74·5%)	0·0004	<0·0001	0·006	262 (91·0%)	197 (80·1%)	147 (66·5%)	0·001	<0·0001	0·0002
p	0·01	0·02	0·55				0·20	0·19	0·36			
Unprotected intercourse												
VCT	224 (76·7%)	148 (58·3%)	122 (54·7%)	<0·0001	<0·0001	0·31	234 (79·9%)	157 (63·1%)	124 (56·8%)	0·0001	<0·0001	0·06
Health information	238 (82·1%)	164 (69·9%)	122 (56·5%)	0·001	<0·0001	0·002	233 (80·9%)	164 (66·7%)	115 (52·0%)	0·001	<0·0001	0·0003
p	0·04	0·008	0·75				0·45	0·17	0·61			
Non-enrolment partner (couples)												
Any intercourse												
VCT	60 (20·2%)	58 (22·7%)	47 (21·0%)	0·94	0·8	0·87	37 (12·6%)	31 (12·3%)	30 (13·6%)	0·73	0·45	0·25
Health information	59 (20·2%)	49 (20·5%)	39 (17·9%)	0·86	0·73	0·58	29 (9·9%)	25 (9·9%)	28 (12·6%)	0·77	0·08	0·13
p	0·75	0·83	0·43				0·11	0·33	0·51			
Unprotected intercourse												
VCT	40 (13·6%)	40 (15·6%)	31 (13·8%)	0·98	0·96	0·95	32 (10·9%)	21 (8·3%)	24 (10·9%)	0·09	0·77	0·05
Health information	43 (14·7%)	25 (10·55)	23 (10·6%)	0·15	0·21	0·94	18 (6·2%)	17 (6·7%)	16 (7·2%)	0·73	0·44	0·59
p	0·95	0·31	0·32				0·03	0·79	0·11			

Table 4: **Reported behaviour change among individuals and couples from baseline to first and second follow-up by treatment group and sex**

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

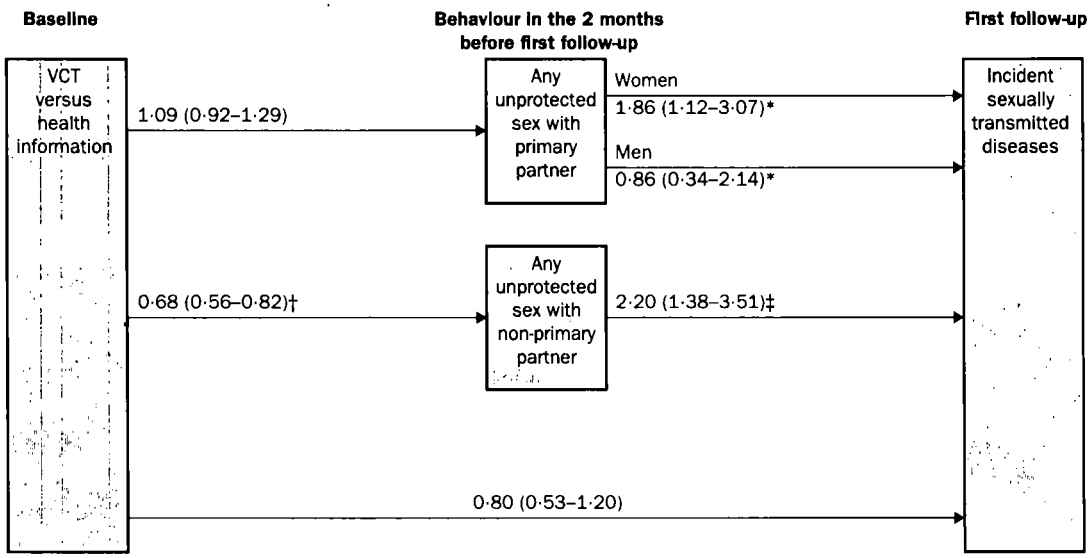


Figure 2: **Relation between intervention group allocation for individuals, probability of unprotected intercourse, and incident sexually transmitted infection before first follow-up**
Values are odds ratios (95% CI). *p<0·05; †p<0·0001; ‡p<0·001.

individuals and 853 (85%) members of couples. Missing data on incidence were multiply imputed using a logistic regression model.[20]

Figure 2 shows, for those enrolling as individuals, the results of logistic regression models describing the associations between intervention-group assignment, self-reports of behaviour in the 2 months before the first follow-up visit, and incident sexually transmitted diseases diagnosed at the first follow-up visit. Men and women enrolling as individuals and assigned VCT reported a significantly greater decrease in unprotected intercourse with non-primary partners than those assigned health information. Men and women who reported unprotected intercourse with non-primary partners were at substantial risk of acquiring a new sexually transmitted disease at first follow-up. Women, but not men, who reported unprotected intercourse with their primary partners were at greater risk of acquiring an incident sexually transmitted disease.

Among those enrolling as couples, men and women assigned VCT decreased unprotected intercourse with enrolment partners compared with those assigned health information (odds ratio 0·72 [0·53–0·99], p=0·014), and unprotected intercourse with non-enrolment partners substantially increased risk for acquisition of an sexually transmitted disease (odds ratio 2·97 [1·21–7·24], p=0·018).

The validity of self-reports of sexual behaviour was confirmed by the analysis of the agreement of self-reports between couple members, which was essential

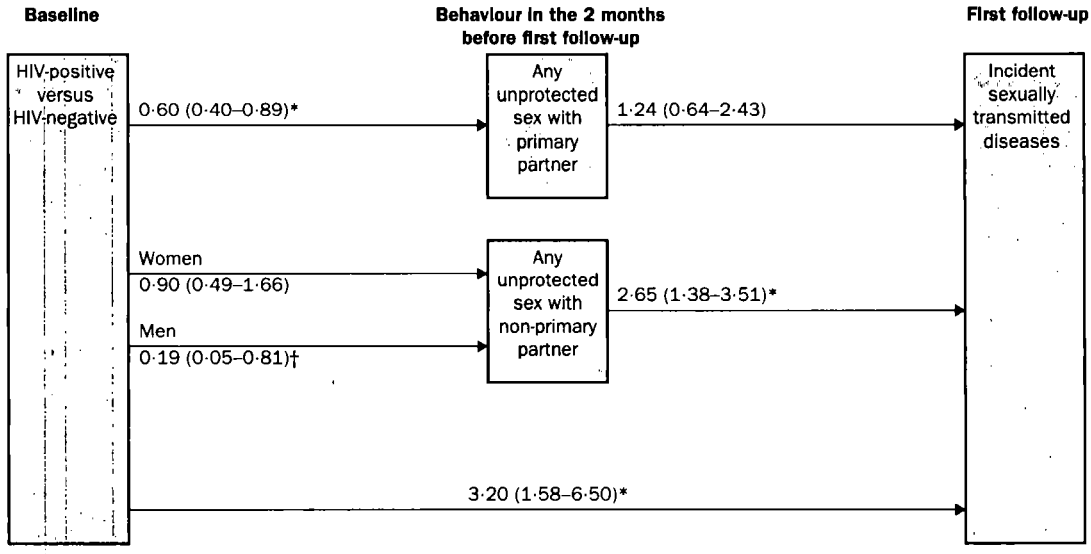


Figure 3: **Relation between baseline serostatus for individuals, unprotected intercourse, and incident sexually transmitted infection before first follow-up**
Values are odds ratios (95% CI). *p<0·01; †p<0·05.

For personal use only. Not to be reproduced without permission of The Lancet.

Automated Records Management System
Hex-Dump Conversion

	Any intercourse			Unprotected intercourse		
	HIV-1 positive*	HIV-1 negative†	p	HIV-1 positive*	HIV-1 negative†	p
Primary partner (individuals)						
Men						
Baseline	22 (39·3%)	271 (40·4%)	0·96	19 (33·9%)	215 (32·1%)	0·74
First follow-up	13 (31·0%)	215 (38·8%)	0·38	10 (23·8%)	147 (26·5%)	0·75
Second follow-up	11 (33·3%)	178 (35·9%)	0·83	7 (21·2%)	113 (22·8%)	0·75
Women						
Baseline	58 (40·3%)	330 (54·4%)	0·08	52 (35·1%)	299 (49·3%)	0·04
First follow-up	35 (31·0%)	292 (56·8%)	0·0005	26 (23·0%)	212 (41·2%)	0·004
Second follow-up	30 (31·0%)	231 (53·1%)	0·011	16 (16·7%)	170 (39·1%)	0·0002
Non-primary partner (individuals)						
Men						
Baseline	16 (28·6%)	288 (43·0%)	0·01	13 (23·2%)	214 (31·9%)	0·10
First follow-up	10 (23·8%)	216 (39·0%)	0·005	2 (4·8%)	114 (20·6%)	<0·0001
Second follow-up	10 (30·3%)	190 (38·3%)	0·05	2 (6·1%)	82 (16·5%)	0·006
Women						
Baseline	55 (38·2%)	171 (28·2%)	0·23	39 (27·1%)	135 (22·2%)	0·55
First follow-up	38 (33·6%)	112 (21·8%)	0·18	14 (12·4%)	70 (13·6%)	0·40
Second follow-up	32 (33·3%)	86 (19·8%)	0·19	9 (9·4%)	44 (10·1%)	0·47
Enrolment partners (couples)						
Men						
Baseline	67 (91·8%)	165 (84·2%)	0·24	59 (80·8%)	148 (75·5%)	0·83
First follow-up	33 (56·9%)	134 (75·7%)	0·002	24 (41·4%)	109 (61·6%)	0·0007
Second follow-up	34 (70·8%)	114 (70·8%)	0·46	19 (39·6%)	96 (59·6%)	0·002
Women						
Baseline	69 (95·8%)	167 (84·3%)	0·01	66 (91·7%)	148 (74·7%)	0·006
First follow-up	35 (62·5%)	139 (79·4%)	0·005	23 (41·1%)	119 (68·0%)	<0·0001
Second follow-up	30 (63·8%)	115 (73·7%)	0·08	14 (29·8%)	99 (63·9%)	<0·0001
Non-enrolment partners (couples)						
Men						
Baseline	15 (20·5%)	43 (21·7%)	0·89	13 (17·8%)	26 (13·1%)	0·23
First follow-up	17 (28·8%)	36 (20·3%)	0·20	11 (18·6%)	25 (14·1%)	0·32
Second follow-up	12 (25·0%)	30 (18·5%)	0·45	6 (12·5%)	22 (13·6%)	0·84
Women						
Baseline	11 (15·1%)	24 (12·1%)	0·23	10 (13·7%)	20 (10·2%)	0·17
First follow-up	13 (23·2%)	18 (10·2%)	0·008	9 (16·1%)	12 (6·8%)	0·02
Second follow-up	9 (19·1%)	19 (12·1%)	0·09	6 (12·8%)	16 (10·2%)	0·26

*For couples, at least one partner HIV-1 positive. †For couples, both partners HIV-1 negative.

Table 5: **Reported behaviour change from baseline to first and second follow-up by serostatus and sex for individuals and couples assigned VCT at baseline**

because couple members were interviewed separately and were assured of the confidentiality of their reports. The agreement between self-reports of sexual behaviour within couples was high (91% agreement in reports of sex with enrolment partner, 88% agreement in reports of unprotected intercourse with enrolment partner). The tetrachoric correlations were 0·83 and 0·85, respectively.

Analysis by HIV-1 serostatus

We thought it important in post-hoc analyses to describe, among individuals assigned VCT, differential changes among those infected with HIV-1 compared with those who were not infected. Men and women enrolling as individuals who were diagnosed as infected with HIV-1 at baseline were more likely than uninfected men and women to reduce intercourse with primary partners at first follow-up, and these changes were maintained at second follow-up (figure 3, table 5). Men diagnosed as HIV-1 infected at baseline were less likely than uninfected men to report unprotected intercourse with primary and non-primary partners at first follow-up, and these changes were maintained at second follow-up. Both infected and uninfected women reported similar rates of unprotected intercourse with non-primary partners. These results were matched by individuals in the health-information group who received VCT at first follow-up (table 6). Unprotected intercourse with non-primary partners increased risk for acquiring an sexually transmitted disease for both men and women. Individuals infected with HIV-1 were more likely to acquire a sexually transmitted disease over the follow-up period than uninfected individuals (figure 3).

Couples in which either or both of the members were HIV-1 infected at baseline were significantly less likely to report unprotected intercourse with enrolment partners at first follow-up than couples in which both members were uninfected, and these differences were maintained at second follow-up (table 5). Both groups reported similar rates of unprotected intercourse with non-primary partners at both follow-up visits. These rates were again matched by the health-information group from first to second follow-up once the group had access to HIV-1 VCT (table 6).

Discussion

Our findings reinforce the argument for the inclusion of HIV-1 VCT as part of a standard package of prevention strategies for less developed countries. Data have been previously reported about the high rates of transmission of HIV-1 among serodiscordant couples in sub-Saharan Africa and more recent data about the high rates of transmission of HIV-1 among serodiscordant couples in Uganda have been published.[21] Serious attention should be paid to the counselling strategy used for couples in our study. We attempted to combine respect for confidentiality and the individual's right to privacy with an opportunity to disclose test results in the presence of the counsellor. The counsellors reported that sessions with couples were more difficult, but also more satisfactory, than individual sessions.[22] They indicated

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

	Any intercourse			Unprotected intercourse		
	HIV-1 positive*	HIV-1 negative†	p	HIV-1 positive*	HIV-1 negative†	p
Primary partner (individuals)						
Men						
First follow-up	16 (41·0%)	155 (30·0%)	0·10	13 (33·3%)	119 (23·0%)	0·12
Second follow-up	8 (25·0%)	177 (38·4%)	0·17	3 (9·4%)	136 (29·5%)	0·005
p	0·12	0·0003		0·02	0·004	
Women						
First follow-up	35 (34·0%)	222 (47·8%)	0·14	28 (27·2%)	181 (39·0%)	0·08
Second follow-up	18 (22·5%)	201 (49·6%)	0·0006	9 (11·3%)	154 (38·0%)	<0·0001
p	0·08	0·46		0·005	0·76	
Non-primary partner (individuals)						
Men						
First follow-up	16 (41·0%)	224 (43·3%)	0·19	7 (17·9%)	136 (26·3%)	0·07
Second follow-up	8 (25·0%)	178 (38·6%)	0·03	3 (9·4%)	92 (20·0%)	0·02
p	0·13	0·03		0·26	0·004	
Women						
First follow-up	41 (39·8%)	125 (26·9%)	0·11	26 (25·2%)	87 (18·8%)	0·29
Second follow-up	35 (43·8%)	94 (23·2%)	0·02	11 (13·8%)	50 (12·3%)	0·91
p	0·76	0·12		0·05	0·002	
Enrolment partners (couples)						
Men						
First follow-up	33 (86·8%)	114 (85·7%)	0·86	28 (73·7%)	98 (73·7%)	0·90
Second follow-up	26 (72·2%)	103 (81·1%)	0·17	15 (41·7%)	83 (65·4%)	0·01
p	0·11	0·19		0·003	0·04	
Women						
First follow-up	31 (79·5%)	115 (87·1%)	0·30	26 (66·7%)	95 (72·0%)	0·77
Second follow-up	18 (54·5%)	97 (77·6%)	0·03	10 (30·3%)	79 (63·2%)	0·003
p	0·02	0·01		0·001	0·07	
Non-enrolment partners (couples)						
Men						
First follow-up	10 (26·3%)	22 (16·3%)	0·29	5 (13·2%)	12 (8·9%)	0·49
Second follow-up	9 (25·0%)	20 (15·7%)	0·37	4 (11·1%)	11 (8·7%)	0·70
p	0·88	0·94		0·72	0·97	
Women						
First follow-up	5 (12·8%)	5 (3·7%)	0·08	4 (10·3%)	2 (2·2%)	0·08
Second follow-up	8 (24·2%)	9 (7·1%)	0·02	4 (12·1%)	5 (3·9%)	0·10
p	0·12	0·14		0·72	0·28	

*For couples, at least one partner HIV-1 positive. †For couples, both partners HIV-1 negative.

Table 6: **Reported behaviour change from first to second follow-up by serostatus and sex for individuals and couples assigned health information at baseline**

their frustration in working with individuals at the difficulties that participants reported that they would have in reporting HIV-1 infection to a sexual partner or spouse. The opportunity to come together, to discuss serostatus results in a safe setting, and to negotiate a risk-reduction plan may be a strategy that could be considered in all studies of serodiscordant couples, and may have great potential to reduce the high rate of transmission among such couples in less-developed countries.

Women need communication and negotiation skills to enable them to discuss sexual and other issues with their partners.[23] These discussions are never easy to have. By providing a safe environment in which partners could discuss sexual behaviour with a counsellor who could help with all difficulties in such discussions, we built and implemented a strategy designed to allow open communication. We see this as beneficial, but not without negative consequences. In another study,[24] we reported that women enrolling as members of couples infected with HIV-1, compared with uninfected women, suffered negative life consequences such as physical beatings and break-up of relationships, especially when the spouse was HIV-1 negative. Keough and colleagues[25] reported common signs of depression in women who found out that they were HIV-1 infected. Thus, VCT strategies cannot be offered without giving the social, physical, and financial support needed to ensure that people who discover that they are HIV-1 infected have the protection and resources they need to cope with their disease, especially women.

Our study might be criticised because occurrence of incident HIV-1 infections was not used as an outcome. To determine whether the HIV-1 infection was incident, we would have needed either to collect serum and test for HIV-1 antibodies but not give individuals the results at baseline, or to test for HIV-1 but not provide counselling. Neither option was thought to be ethical. The study was not powered to detect significant differences between groups in the rate of incident sexually transmitted disease. Some might also question why we did not use standard testing and diagnosis of sexually transmitted diseases at baseline. We considered and rejected that option, because we believed it essential to assess, with as much precision as possible, the efficacy of VCT on risk reduction without confounding of sexually transmitted disease diagnosis and treatment. Had we included diagnosis and treatment at baseline, we would have been testing the impact of VCT plus sexually transmitted disease diagnosis and treatment rather than the efficacy of VCT alone.

There is substantial controversy about self-reported behavioural outcomes, especially when individuals are assigned intervention and comparison conditions. The self-reported behavioural data were collected under conditions designed to maximise validity. Behavioural interviewers assured the respondents of confidentiality; counsellors and other study personnel did not carry out these interviews. A significant relation between reported sexual behaviours and sexually transmitted disease rate was predicted at the outset. Confidence in these self-

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

reported outcomes is bolstered by the outcomes seen for incident sexually transmitted diseases. The self-reported behaviours were further verified by the strong association between self-reported sexual behaviour and incident sexually transmitted diseases.

This study supports the feasibility and beneficial effects of VCT on HIV-1-related risk behaviour. Our group has also established that the effects observed can have important public-health implications when assessed in terms of HIV-1 infections averted, and that the impact of this intervention can be as or more cost-effective than other interventions in more-developed and less-developed countries.[26] Cost-effectiveness analysis has shown that the benefits are especially evident when high-risk populations are targeted, and we have also shown that these VCT services attract higher-risk individuals than those found in the general population,[27,28] and may thus be a cost-effective resource for reducing risk among individuals more likely to contract or spread HIV-1. We have also established that there was high demand for these services and that individuals report themselves willing to pay for the service.[29]

Demand for VCT services may increase as medical management of people infected with HIV-1 improves in less-developed countries. Prophylaxis of opportunistic infections by simple generic drugs, prevention of perinatal transmission of HIV-1 through short-term oral treatment regimens, and safe alternatives to breastfeeding are major advances that may change readiness and acceptability of VCT. We have also reported on the adverse social consequences experienced by some individuals as a result of being diagnosed with HIV-1.[30] Thus, our findings reinforce the importance of confidentiality, trust between client and counsellors with respect to information management, and the inadvisability of promoting VCT in the absence of effective human rights assurances.[31]

The Voluntary HIV-1 Counseling and Testing Efficacy Study Group
Thomas J Coates (principal investigator), Olga A Grinstead, Steven E Gregorich, David C Heilbron, William P Wolf, Kyung-Hee Choi, Julius Schachter, Peter Scheirer, and Ariane van der Straten (Center for AIDS Prevention Studies [coordinating centre], AIDS Research Institute and Department of Medicine, and Department of Laboratory Medicine, University of California, San Francisco, CA, USA); Munkolenkole C Kamenga (principal investigator), Michael D Sweat (now at Johns Hopkins University), Isabelle De Zoysa (now at WHO), and Gina Dallabetta (AIDSCAP, Family Health International, Arlington, VA, USA); Kevin R O'Reilly and Eric van Praag (Global Programme on AIDS, WHO and UNAIDS, Geneva, Switzerland); David Miller, Monica Ruiz (now at Institute of Medicine, National Academy of Sciences), Samuel Kalibala (now at The Population Council), and Ben Nkowane (UNAIDS); Donald Balmer (principal investigator), Francis Kihuho, Stephen Moses, and Frank Plummer (Kenya Association of Professional Counselors, Nairobi, Kenya, and University of Calgary, Calgary, Canada); Gloria Sangiwa (principal investigator, now at The Population Council), Margaret Hogan, Japhet Killewo, and Davis Mwakigile (Muhimbili Medical College, University of Dar es Salaam, Tanzania); Colin Furlonge (principal investigator, Queens Park Counseling Centre, Port of Spain, Trinidad, West Indies).
Writing committee—T J Coates, O A Grinstead, S E Gregorich, M D Sweat, M C Kamenga, G Sangiwa, D Balmer, C Furlonge.

Acknowledgments
This research was supported by AIDSCAP/Family Health International with funding from USAID contract USAID/HRN-5972-C-00-4001-00; and by WHO, United Nations Programme on AIDS, and NIMH Center grant number MH42459 (Center for AIDS Prevention Studies).

References

1 Higgins DL, Galavotti C, O'Reilly KR, et al. Evidence for the effects of HIV antibody counseling and testing on risk behaviors. *JAMA* 1991; **266:** 2419–29.
2 Holtgrave DR, Valdiserri RO, Gerber R, Hinman AR. Human immunodeficiency virus counseling, testing, referral, and partner notification services: a cost-benefit analysis. *Arch Intern Med* 1993; **153:** 1225–30.
3 Kamb M, Fishbein M, Douglas J, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. *JAMA* 1998; **280:** 1161–67.
4 NIMH Multisite HIV Prevention Trial Group. A randomized clinical trial of small group counseling to reduce risk for HIV. *Science* 1998; **280:** 1889–94.
5 Shain RN, Piper J, Newton ER, et al. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted diseases among minority women. *N Engl J Med* 1999; **340:** 93–100.
6 De Zoysa I, Phillips KA, Kamenga MC, et al. Role of HIV counselling and testing in changing risk behaviour in developing countries. *AIDS* 1995; **9** (suppl A): S95–101.
7 Beardsell S. Should wider HIV testing be encouraged on the grounds of HIV prevention? *AIDS Care* 1994; **6:** 5–19.
8 Phillips KA, Coates TJ. HIV counseling and testing: research and policy issues. *AIDS Care* 1995; **7:** 115–24.
9 Wolitski RJ, MacGowan RJ, Higgins DL, Jorgensen CM. The effects of HIV counseling and testing on risk-related practices and help seeking behavior. *AIDS Educ Prev* 1997; **9** (suppl B): 52–67.
10 Weinhardt LS, Carey MP, Johnson BT, Bickman NL. Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985–1987. *Am J Public Health* 1999; **89:** 1397–405.
11 Allen S, Tice J, Van de Perre P, et al. Effect of serotesting with counselling on condom use and seroconversion among HIV discordant couples in Africa. *BMJ* 1992; **304:** 1605–09.
12 Kamenga M, Ryder R, Jingu M, et al. Evidence of marked sexual behaviour change associated with low HIV-1 seroconversion in 149 married couples with discordant HIV-1 serostatus: experience at an HIV counselling centre in Zaire. *AIDS* 1991; **5:** 61–67.
13 The Voluntary HIV Counseling and Testing Efficacy Study Group. The Voluntary HIV Counseling and Testing Efficacy Study: design and methods. *AIDS Behav* 2000; **4:** 5–14.
14 Catania JA, Gibson DR, Chitwood DD, Coates TJ. Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. *Psychol Bull* 1990; **108:** 339–62.
15 Catania JA, Binson D, Canchola J, Pollack LM, Hauck W, Coates TJ. Effects of interviewer gender, interviewer choice, and item wording on responses to questions concerning sexual behavior. *Public Opin Q* 1996; **60:** 345–75.
16 Centers for Disease Control. HIV prevention counseling: a training program. Atlanta, GA: United States Department of Health and Human Services, 1993.
17 Birkenmeyer L, Armstrong AS. Preliminary evaluation of the ligase chain reaction for specific detection of *Neisseria gonorrhoeae*. *J Clin Microbiol* 1992; **30:** 3089–94.
18 Dille BJ, Butzen CC, Birkenmeyer LG. Amplification of *Chlamydia trachomatis* DNA by ligase chain reaction. *J Clin Microbiol* 1993; **31:** 729–31.
19 Diggle PJ, Liang K-Y, Zeger SL. Analysis of longitudinal data. New York: Oxford University Press, 1994.
20 Rubin DB. Multiple imputation for nonresponse in surveys. New York: Wiley, 1987.
21 Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and risk of heterosexual transmission of HIV-1 among sexual partners. Presented at the 7th Conference on Retroviruses and Opportunistic Infections. San Francisco, February, 2000.
22 Grinstead O, van der Stratten A. Counselor perspective on the experience of providing HIV counseling in Kenya and Tanzania: the Voluntary HIV-1 Counseling and Testing Efficacy Study. *AIDS Care* (in press).
23 Karim QA, Karin SS, Soldan K, Zondi M. Reducing the risk of HIV infection among South African sex workers: socioeconomic and gender barriers. *Am J Public Health* 1995; **85:** 1521–25.
24 van der Stratten A, King R, Grinstead O, Serufilira A, Allen S. Couple communication, sexual coercion, and HIV risk reduction in Kigali, Rwanda. *AIDS* 1995; **9:** 935–44.
25 Keough P, Allen S, Almedal C, Temahagili B. The social impact of HIV infection on women in Kigali, Rwanda: a prospective study. *Soc Sci Med* 1994; **38:** 1047–53.
26 Sweat M, Gregorich S, Sangiwa G, et al. Cost-effectiveness of voluntary HIV-1 counselling and testing in reducing sexual transmission of HIV-1 in Kenya and Tanzania. *Lancet* 2000; **356:** 113–21.
27 Furlonge C, Gregorich S, Kalibala S, et al. Sexual risk behavior, knowledge, and attitudes in a population-based probability sample of

For personal use only. Not to be reproduced without permission of The Lancet.

Automated Records Management System
Hex-Dump Conversion

north and central Trinidad, WI: results from the Voluntary Counseling and Testing Efficacy Study. *AIDS Behav* 2000; 4: 49–62.

28 Killewo J, Gregorich S, Sangiwa G, Coates TJ. Sexual risk behaviors, knowledge and attitudes in a population-based probability sample of Dar es Salaam, Tanzania: results from the Voluntary Counseling and Testing Efficacy Study. Presented at the 12th World AIDS Conference. Geneva, June, 1998.

29 Sweat M, Sangiwa G, Balmer D, et al. Cost to clients and willingness to pay for HIV counseling and testing in Kenya and Tanzania: results from the Voluntary Counseling and Testing Efficacy Study. Presented at the 12th World AIDS Conference. Geneva, June, 1998.

30 Grinstead O, Hogan M, Gregorich S, et al. Being tested for HIV does not increase the incidence of negative life events in three developing countries: results from the Voluntary Counseling and Testing Efficacy Study. Presented at the 12th World AIDS Conference. Geneva, June, 1998.

31 Sangiwa G, van der Stratten A, Grinstead O. Client's perspective of the role of voluntary counseling and testing in HIV/AIDS prevention and care in Dar es Salaam, Tanzania: the Voluntary Counseling and Testing Efficacy Study. *AIDS Behav* 2000; 4: 35–48.

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

THE LANCET

Volume 356, Number 9224

What if we had an AIDS vaccine?

HIV infection these days is almost entirely sexually transmitted person-to-person. It is, therefore, preventable, in theory. The hunt for an AIDS vaccine is built on the depressing, if realistic, notion that human behaviour in matters sexual is not easy to alter, not by active intervention anyway. The facial expressions of Thai bus passengers being greeted by a humanised condom in last week's *Lancet* AIDS series paper are revealing. That sexual habits do change, for better or worse, has been clear since at least the 1960s but it is not obvious how that fact can be urgently harnessed in the AIDS era. Thus, on Sunday, July 9, when the international AIDS meeting opens in Durban, South Africa, an early item will be the launch of a strategy document from the International AIDS Vaccine Initiative, called *HIV vaccines for the world: preparing now to ensure access.*

Anticipating ridicule ("What vaccines?"), IAVI argues that the traditional model for global access to immunisation has meant that the developing countries get new vaccines 10-15 years after they are available in the rest of the world. This would be a disaster for Africa, where two-thirds of the world's HIV infections are now being seen. Thus, IAVI argues, we should start thinking today about new ways of delivering an AIDS vaccine to those who need it most. This looks like a re-run of the argument over access to anti-HIV drugs, where there has been some progress but falling well short of a happy solution. With antiviral agents the pharmaceutical industry has been willing to put money into research; several effective anti-HIV drugs have been licensed and many more are in the pipeline.

The hunt for an AIDS vaccine, on the other hand, has a very long way to go. IAVI's website (www.iavi.org) deplores the lack of commitment to this research. "...the number of products currently in the development pipeline [very recently changed to 'now in clinical testing'] is woefully inadequate", IAVI says. In fact there are around 30 candidates, and IAVI's July blueprint talks of "numerous products currently in various stages of development". The trouble is, only one is at the stage of a phase III trial and two are at phase II. Nobody knows how far down the line a successful vaccine will be. US president Bill Clinton wants one by 2007, and those vying for his job are being urged to commit to this goal. A vaccine manufacturer tells *IAVI Report* 8-10 years. The VaxGen phase III study could yield something about efficacy in a year or two but that would be just one product.

Nor is the time-scale the only problem. IAVI's hypothetical scenarios begin with protective efficacies of only 40%. The organisation also points out the differences between vaccinating vast numbers of at-risk adults and simply adding another arm to existing childhood vaccination schedules. The possibility that an AIDS vaccine would need tailoring for different parts of the world is a complication that previous immunisation policies have largely escaped. This is not just about variations in the virus. The delivery of a vaccine programme is daunting. IAVI has set out very demanding criteria for the choice of vaccine testing sites in Africa: political commitment, an effective AIDS control programme, local infrastructure, a history of international collaboration, ethics oversight, effective regulatory agencies, and trained personnel. All these will be required for effective delivery too.

IAVI is well supported financially and has in less than 5 years become a significant player in AIDS prevention. A tiered pricing policy for HIV vaccines would still leave a huge gap, and IAVI's exhortation to the G8 group of nations that they make a real financial commitment (not just words) should be heeded. The World Bank can help too, though its proposals have yet to appear. However, the danger in urging early attention to modification of classic market forces is that the assumption will develop that an AIDS vaccine, a magic bullet, is close. Appropriate technology solutions to the challenge of prevention might then be neglected. The spread of HIV could be slowed tomorrow on knowledge we already have–with far fewer financial challenges–and that option should not be forgotten.

The Lancet

Automated Records Management System
Hex-Dump Conversion

For personal use only. Not to be reproduced without permission of The Lancet.

Automated Records Management System

Hex-Dump Conversion