

Treatment, trade & aid

responding to the HIV/AIDS pandemic



ashm

Australasian Society for HIV Medicine Inc

First published in 2004 by the
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Printed by: Finsbury Printing, Adelaide

National Library of Australia cataloguing-in-publication data:
Coinfection. HIV and Viral hepatitis: a guide for clinical management
Includes index.

ISBN 1 920773 18 5

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Introduction

As an organisation closely involved in the response to HIV/AIDS in Australia and New Zealand, the Australasian Society for HIV Medicine (ASHM) shares concerns that the benefits and lessons learnt in terms of prevention, treatment and care be spread widely and quickly to deal with the world-wide epidemic.

Global prevalence

An estimated 38 million people globally were living with HIV/AIDS at the end of 2003. More than three million died during that year. While sub-Saharan Africa is still the worst-affected, other regions face

rising infection rates. Many developing countries have also seen a rise in infection rates.

In the Asia Pacific region, 7.4 million were estimated to be living with the disease at the end of 2003. While the adult prevalence rate is still under 1% in most countries in this region, countries such as India and China have such large populations that this still represents a significant number of people infected. In a number of countries, higher infection rates in some provinces and amongst certain groups (such as sex workers and injecting drug users) indicate an expanding epidemic. Cambodia, Myanmar and Thailand already have to contend with serious nationwide epidemics. Countries such as Vietnam, Papua New Guinea and Indonesia also face rising infections. Chapter 1 provides an overview of the epidemic in the region.

Treatment

Despite the expanding epidemic, access to life-saving treatments remains inadequate. The benefits of antiretroviral therapy are obvious from the experience in developed countries – which have seen a 70% drop in HIV/AIDS deaths. It is now widely recognised that treatment aids prevention efforts, and helps to alleviate fear and stigmatisation. An estimated six million people in developing countries need immediate treatment, but only 8% are receiving it.

The impact of improved quality of life and life expectancy on development is also significant. HIV/AIDS is a disease which flourishes along existing social faultlines associated with poverty, gender inequality and violence. In turn, it also worsens these divisions. The link between HIV/AIDS and development is a strong one, which is increasingly being recognised internationally.

Despite concerns that treatment is too complex for resource-poor settings, treatment and care have been successfully implemented in a number of countries, and in small-scale projects such as those run by Médecins Sans Frontières. These programs have shown that treatment works, when sensitively designed with a focus on community participation and adapted to local circumstances. These programs have also shown that adherence can be successfully negotiated. Treatment programs in resource-poor settings require a comprehensive approach based on prevention linked to treatment, care and support. All of this necessitates a government-wide effort in leading and coordinating this approach, and maximising the scarce resources available.

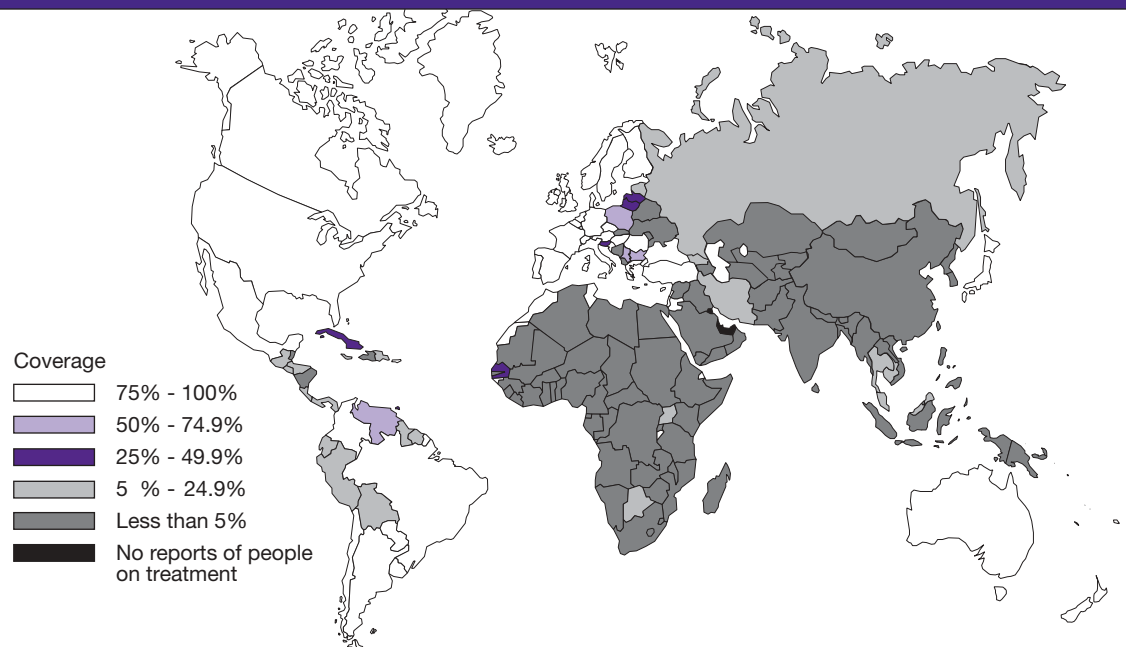
Regional HIV/AIDS statistics and features, end of 2003				
Region	Adults & children living with HIV/AIDS	Adults & children newly infected with HIV	Adult prevalence (%)*	Adult & child deaths due to AIDS
Sub-Saharan Africa	25.0 – 28.2 million	3.0 – 3.4 million	7.5 – 8.5	2.2 – 2.4 million
North Africa & Middle East	470,000 – 730,000	43,000 – 67,000	0.2 – 0.4	35,000 – 50,000
South & South-East Asia	4.6 – 8.2 million	610,000 – 1.1 million	0.4 – 0.8	330,000 – 590,000
East Asia & Pacific	700,000 – 1.3 million	150,000 – 270,000	0.1 – 0.1	32,000 – 58,000
Latin America	1.3 – 1.9 million	120,000 – 180,000	0.5 – 0.7	49,000 – 70,000
Caribbean	470,000 – 730,000	43,000 – 67,000	0.2 – 0.4	35,000 – 50,000
Eastern Europe & Central Asia	1.2 – 1.8 million	180,000 – 280,000	0.5 – 0.9	23,000 – 37,000
Western Europe	520,000 – 680,000	30,000 – 40,000	0.3 – 0.3	2,600 – 3,400
North America	790,000 – 1.2 million	36,000 – 54,000	0.5 – 0.7	12,000 – 18,000
Australia & New Zealand	12,000 – 18,000	700 – 1,000	0.1 – 0.1	<100
TOTAL	40 million (34 – 46 million)	5 million (4.2 – 5.8 million)	1.1% (0.9 – 1.3%)	3 million (2.5 – 3.5 million)

* The proportion of adults (15 to 49 years of age) living with HIV/AIDS in 2003, using 2003 population numbers.

The ranges around the estimates in this table define the boundaries within which the actual numbers lie, based on the best available information. These ranges are more precise than those of previous years, and work is under way to increase even further the precision of the estimates that will be published mid-2004.

Source: UNAIDS, *AIDS Epidemic Update December 2003*, Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO), Geneva, 2003.

Estimated percentage of people covered among those in need of antiretroviral treatment



Source: World Health Organization (WHO), Geneva, November 2003. Reprinted with permission.
Available at: www.who.int/3by5/en/coverage2003.jpg

MSF Khayelitsha Project

Clinical analysis of 225 patients between April 2001 and late 2002

Duration on treatment	6 months	12 months
Mean weight gain	+6.4kg	+9.3kg
Proportion of those tested with undetectable viral load	91%	84%
Mean CD4 cell count change for those with serial measurements	+141/ mmm	+221/ mmm
Proportion surviving	86%	83%

Source: MSF South Africa, Department of Public Health of the University of Cape Town, Provincial Administration of the Western Cape, *Provincial Administration of the Perspectives and Practice in Antiretroviral Treatment: Antiretroviral therapy in primary health care: South African Experience*, World Health Organization, Geneva, May 2003, p. 4.

In the light of this, there has been a concerted effort at an international level to rapidly upscale treatment access. At the UN General Assembly meeting on HIV/AIDS in September 2003, the United Nations, World Health Organization and the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria declared the failure to deliver AIDS medicines to those who need them a global health emergency. The World Health Organization has embarked on a program of getting three million on treatment by 2005 (around half of those who need it), as a step towards universal access.

ASHM aims to increase the level of knowledge of the wide range of issues involved in scaling up access to treatment and care internationally – amongst those involved in the medical, public health and community response to HIV/AIDS in Australia and New Zealand, and amongst the public more generally. This publication considers a range of the challenges, considerations and debates involved in dealing with the epidemic internationally. ASHM does not endorse all the views represented here, but welcomes future discussion around these very important issues. By including the following chapters – written by those with much experience in the field – we have chosen to highlight a few main themes.

Upscaling treatment is recognised as a complex process which requires a concerted effort at all levels – international, national, provincial and community. The WHO has released antiretroviral guidelines, and is developing training modules based around these. These are based on simplified protocols, which open up the possibility of treatment being administered at a base level by nurses or community health workers. Chapter 2 will look at the WHO guidelines for delivering treatment, and the challenges involved in their implementation. Chapter 3 looks at the major challenges involved in maintaining a focus on prevention efforts, while rolling out treatment programs.

Dealing with the epidemic requires an injection of funds on a national and global level – to expand

treatment efforts, but also programs of prevention, testing, counselling and care, and health sector development more generally. International obligations in responding to the epidemic are established through the United Nations Special Session on HIV/AIDS *Declaration of Commitment on HIV/AIDS* (2001) and the Millennium Development Goals adopted by the UN in 2000.

In terms of overseas development aid, health has moved up the global agenda in recent years – and now makes up 13% of Australia's foreign aid. Additional funds and mechanisms will be needed to implement the goals enshrined in the comprehensive government strategy which resulted from a review of AusAID's HIV/AIDS and Development policy in 2004. Australia's commitment has recently been increased to A\$600 million by 2010.

Earlier in 2004, Australia also decided to make a contribution to the Global Fund of A\$25 million over three years (A\$8.3 million per year). However, the fund still faces a shortfall in funding required. Around the same time, New Zealand announced an additional NZ\$3 million of funding for international initiatives – with one million going to the Global Fund. (This was in response to concern over the growing epidemic in Pacific Island countries – which rely heavily on New Zealand for services in responding to the disease.) Chapter 4 will consider the Global Fund in detail.

Treatment efforts have been aided in recent years by price reductions of the drugs needed to treat the disease, and the development of simpler regimens. However, access to efficacious and affordable medicines (on a sustainable basis) through importation or domestic manufacturing is far from guaranteed. Chapter 5 will cover the issue of trade negotiations and pricing mechanisms – and their impact on access to therapy world-wide.

Chapter 6 considers some of the main ethical and human rights issues involved in the complex process of upscaling treatment access and responding to the epidemic more generally.

ASHM believes that it is more important than ever for those involved in the HIV/AIDS and development sectors in Australia and New Zealand to be informed and engaged in the response.

Engaging experience

ASHM is the representative professional body for medical practitioners and other health practitioners in Australia and New Zealand who work in the fields of HIV and related conditions. The sectors that support HIV healthcare, management and education in these countries are acutely aware of the successes and lessons learnt, and the need to contribute.

ASHM has particular experience in clinical training and support – a vitally important area in terms of treatment access.

HIV medicine as a specialty is not very old, even in developed countries, and those moving into this area in the developing world face significantly more challenges. Updating clinical knowledge on a regular basis is essential to ensure that practitioners are aware of new trends in treatment and any changes in the epidemic, such as the development of viral resistance to HIV/AIDS treatments. One-off clinical short courses will need to be backed up by on-the-job training, mentoring or rotation to increase skills and experience. We believe that training of healthcare workers needs to include an emphasis on prevention linked to care and treatment. It should include issues surrounding adherence, the necessity for a team approach, and sessions focussed on ethical issues. Training needs to include the active participation of people living with HIV/AIDS.

ASHM supports the principle of local control over training programs being implemented. We also support maximising the benefit to other countries of Australian and New Zealand expertise in HIV/AIDS treatment and care. This is of potential benefit in terms of learning for both local participants and developed country participants. The latter has the potential flow-on benefit of building up expertise in how to sensitively, appropriately and collaboratively assist the transfer of knowledge which has been built up over the last two decades.

The recent review of the national HIV/AIDS strategy in Australia has opened up more opportunities for supporting international activities and increased collaboration between the Department of Health and AusAID. Traditionally, HIV/AIDS activities funded through the Department of Health have had to be conducted solely within Australia. In addition, the tendering process for AusAID projects is focussed on individual technical expertise and limits the degree to which important sections of the Australian HIV/AIDS sector can be consistently and comprehensively involved. Other methods need to be developed to utilise the repository of institutional knowledge that has been built up over the years of the response to the epidemic in Australia – including the formation of organisations for people living with HIV/AIDS, national research centres, and a peak professional organisation for clinicians.

Another important part of the response in Australia has been government support for clinical, epidemiological and social research related to HIV/AIDS. However, research funding models create some barriers in terms of extending this into the international arena. The National Health and Medical

Research Council, for instance, only funds research and training throughout Australia. AusAID has traditionally been little involved in research funding.

We would like to see a greater contribution to the international research push to facilitate treatment access. Clinical priorities in this area include simpler drug regimens, and developing cheaper and simpler methods of diagnosis and monitoring. Close coordination in terms of surveillance data (including viral resistance) is also important. Social and behavioural research are also critical in developing and monitoring the success of various programs. Research efforts need to be more closely linked to aid projects – in order to maximise potential research outcomes and comprehensive evaluation of projects. Careful monitoring and evaluation is needed in all programs that are implemented, in order to maximise cross-fertilisation and the lessons learnt.

We welcome moves by the Australian and New Zealand governments to contribute more in this area, and we believe that there is an urgent need to collaboratively increase the involvement and input of those in the HIV/AIDS sector – both in direct programs and at a policy level. We look forward to future engagement and partnership in this area.

ASHM's international program

The main aim of ASHM's international program is to promote the expansion of knowledge and skills in implementing prevention, treatment and care in relation to HIV/AIDS – particularly in the Asia Pacific region. ASHM aims to conduct and support a range of activities to achieve this, including training activities, development of clinical resources, provision of technical expertise, policy and advocacy work, information distribution, and collaboration amongst organisations working in the field. The scope of ASHM's international program is, however, subject to funding availability.

Over recent years we have established an international sub-group of the ASHM Board, and an International Standing Committee provides expertise and identifies areas of possible activity. Interest groups within our membership have been established on international issues and Papua New Guinea (PNG) in particular. We are looking at ways of circulating information and encouraging involvement and discussion amongst our membership.

We have established an international stream at our annual conference. The conference aims to provide an opportunity to showcase ASHM's international program, address international issues and involve healthcare providers and policy-makers from the region. ASHM will continue to produce publications such as this monograph, as well as highlighting

Short Course in HIV Medicine



Participants in Cairns, October 2003.

Photo source: ASHM

international issues in its regular publications and email alerts. ASHM's website will be utilised and developed as a source of information on the global epidemic, training programs and resources. ASHM also runs sessions in Australia reporting back on developments in international conferences concerned with HIV/AIDS and can organise seminars on a range of issues.

Over the last few years, we have received AusAID funding for overseas delegates to attend the ASHM conference – and an associated short course in HIV medicine. This has enriched these aspects of our work, and been beneficial for participants. International delegates have also attended laboratory seminars. Through the National Reference Laboratory our members are already involved in WHO-supported programs of quality assurance in laboratories in the region and have significant experience to offer in this difficult (and sometimes neglected) area. The Asia Pacific NeuroAIDS Consortium is a collaboration which was initiated by ASHM members, and has met over the last two years – in conjunction with the ASHM conference.

ASHM aims to facilitate the development and implementation of short courses in regional countries for healthcare workers in HIV medicine (geared towards accreditation for treatment and care). We also hope to develop programs based around laboratory training and other specialty areas. This is dependent on interest being sought and funding secured. Courses are developed in collaboration with local partners, and in compliance with local guidelines on treatment and accreditation.

To this end, we have participated in formulating and running training programs in Papua New Guinea. In February 2004, around 50 healthcare practitioners attended a course on prescribing for HIV – held in Madang. In March 2004, ASHM implemented a capacity-development training

course for nurses in Mingende – under the aegis of the Collaboration for Health in PNG.

ASHM has many members who already have extensive experience overseas, and others who are interested in participating. We are maintaining and developing our database of those working in and with experience in this area – and can provide or advise on appropriate technical expertise for use in training in regional countries.

In terms of other training activities, ASHM can organise clinical placements in Australia for overseas healthcare workers where funding allows. We hope to facilitate placements in resource-poor settings for professionals working in HIV/AIDS.

ASHM also aims to develop and implement other training programs within Australia to support overseas aid programs – subject to funding. These include seminars or courses for healthcare workers who require basic HIV training, and courses for healthcare workers (with HIV experience) who require overseas project management training. ASHM also provides workplace experience for students in fields such as development studies, HIV/AIDS and public health studies in resource-poor settings. The secretariat can also assist with student placement within our membership.

ASHM also aims to promote and participate in research collaboration internationally. We support linking research efforts to project activities, where possible.

ASHM has produced a range of printed and multimedia resources on clinical management of HIV, many of which are immediately or potentially of use internationally. These can be used as stand-alone learning tools or be integrated into training programs. These resources are available on our website, www.ashm.org.au. Orders for hard copies will be considered on a case-by-case basis. ASHM can adapt or create resources for use in particular settings in future.

While many aid projects are time-limited, HIV/AIDS is a chronic disease requiring ongoing treatment without interruption. Many of the social and behavioural changes needed in responding to HIV/AIDS will not be achieved quickly. One of the most important things that ASHM has to offer is ongoing collaboration between healthcare workers in the region via our annual conference, our resources and various formal and informal networks within our membership.

ASHM aims to provide support for similar organisations of health care professionals working in HIV treatment and care internationally. We also support the development of partnerships to promote collaboration and cooperation in relation to HIV/AIDS and development. We support the establishment of a

collaborative forum of Australian agencies conducting HIV/AIDS activities in international settings. This forum would share information, expertise and identify opportunities for collaborative ventures.

ASHM also aims to contribute to reviews of government, non-government and private sector policy related to HIV/AIDS prevention, treatment and care in resource-poor settings. ASHM has the ability to contribute to policy review in a range of other areas including research, project delivery, and professional accreditation. ASHM has prepared written submissions, contributed at public hearings, analysed various policy developments, and provided or advised on presenters.

ASHM aims to provide or advise on appropriate technical expertise in assisting the development of relevant policies in regional countries – such as policies and procedures required to establish training and accreditation for health care professionals providing HIV care and treatment, and the development of national treatment guidelines and HIV/AIDS strategies.

A major determinant of ASHM's capacity to maintain and expand its international program is access to funding support. If you would like more information, or would like to discuss project activities or make a donation, then please contact our national office.

We hope you find this publication useful.

Marina Carman

International and Policy Programs

Coordinator, ASHM

July 2004

HIV infection and AIDS in the Asia Pacific region

by John Kaldor

The Asia Pacific region is home to well over half the world's population, and a diversity of political systems, languages, religions and cultures. It should therefore come as no surprise that the HIV epidemic has run on many and varied pathways in the region over the past twenty years, and it is likely to continue to do so over the next twenty or more.

A number of countries of the region had reported small numbers of cases of HIV infection and AIDS by the mid-1980s, but virtually all could be portrayed as having occurred in foreign residents, or in people who had some link to other countries. Despite a few exceptions, such as the extensive epidemic of HIV infection among gay men in major Australian cities, and the contamination of blood products in Japan, leading to high levels of infection in people with haemophilia, most of the Asia Pacific countries went through to the mid-1980s viewing the HIV epidemic as something that was happening to other people.

This situation changed radically in the late 1980s, with the realisation that Thailand was facing a full-scale epidemic of HIV infection. Surveys found that infection rates had reached very high levels among people injecting drugs in Bangkok, and was present at substantial rates in female sex workers. In the north part of the country, the so-called 'general population' was beginning to be heavily affected too, with over 5% prevalence detected in pregnant women and military recruits by the early 1990s. It seemed that the Asia Pacific region was vulnerable to a major HIV epidemic after all.

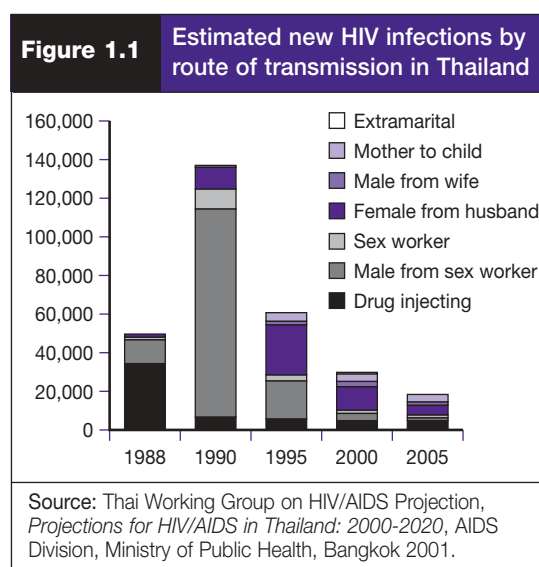
Further sites of extensive HIV transmission were detected elsewhere in the region by this time, and a number of countries began to conduct regular, large scale surveys of HIV prevalence in selected population groups. In some places, these surveys showed that the impact was falling most heavily on people who injected drugs, while in others, female sex workers were found to be most affected. Nevertheless, it seemed that in most countries, the overall levels of infection remained relatively low, far lower than had been seen in many African countries but also low compared to the Thai epidemic. By the mid-1990s, questions were again being asked about the real

potential for widespread HIV infection in the region, and whether the risk had been overstated.

Around this time, there was a growing realisation that the monitoring of HIV prevalence provided an incomplete picture of the potential for risk. A number of countries of the region started to carry out repeated behavioural surveys which, despite their methodological weakness of relying on self-report, gave an indication of the level of sexual and injecting risk in a range of population groups. These surveys showed that many of the countries of the Asia Pacific region had larger or smaller population groups that were at high risk of HIV infection, even if they had not yet experienced many cases of transmission.

Now, several years into the twenty-first century, we rely on a combination of serological and behavioural surveillance mechanisms to provide an indication of the current status of transmission and risk in the countries of the region.

No two countries use exactly the same surveillance system, so direct comparisons can be challenging, and there is even considerable intra-country variation in the information collected on HIV prevalence and risk. Nevertheless, thanks to these surveillance systems we are able to characterise the situation in a number of countries with some degree of confidence.



Thailand: the first large-scale epidemic, the first large-scale response

The factors that drove the rapid take-off of the Thai epidemic in the mid- to late 1980s were a combination of a very widespread sex industry, with a high proportion of men participating as clients, and a substantial population of people injecting drugs, primarily heroin. Infection rates increased steadily and the epidemic began to expand from the north to other parts of the country, until decisive preventive interventions, largely built around condom promotion, were undertaken in the early 1990s. As Figure 1.1 shows, the estimated numbers of new infections started to subside by the mid-1990s, and annual surveys of military recruits showed that the trend in HIV prevalence reached its peak, and began to turn down.

The Figure also shows the shift in transmission patterns that has occurred in the last ten years of the Thai epidemic, with spread increasingly occurring from married men to their wives, or from former sex workers to their husbands, rather than among sex workers and their clients (many of whom of course were those married men).

Cambodia: high levels of transmission have stabilised

The HIV epidemic was not detected in Cambodia until several years after it had been apparent at high levels in neighbouring Thailand, but once it hit it seemed initially to be heading for levels as bad as those seen in northern Thailand. Furthermore, it was

entirely driven by the sex industry, both workers and clients, apparently without the compounding effect of drug injecting. By the early 2000s, following a strong government response, there were signs that transmission was slowing, and that the prevalence of infection had reached a plateau overall and was falling in younger sex workers.

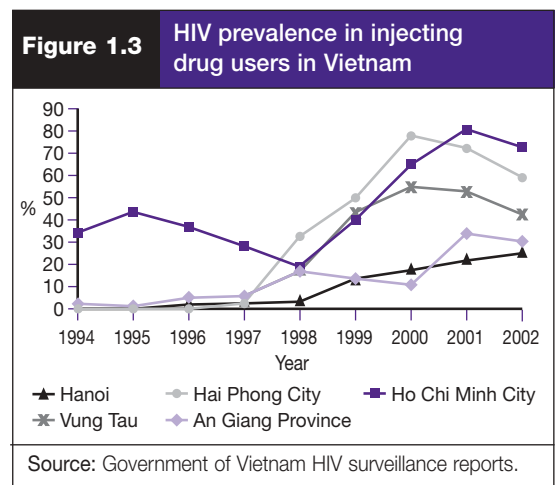
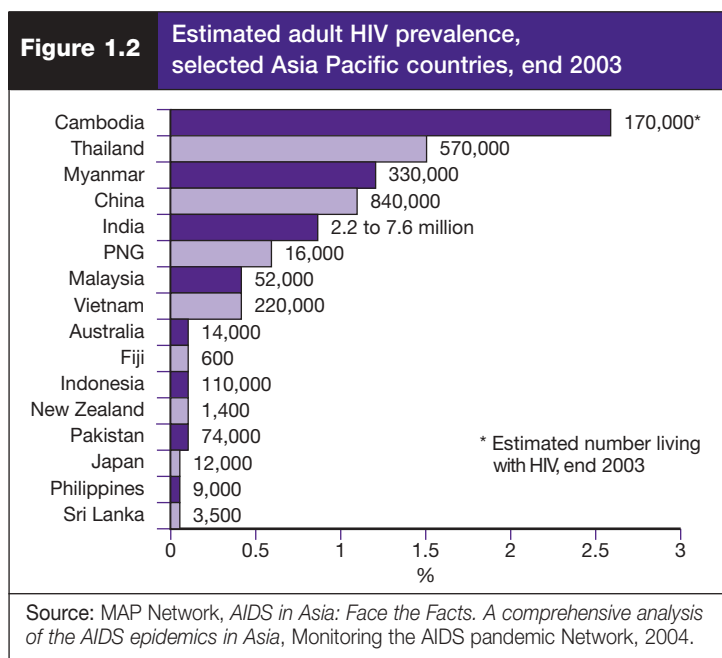
Myanmar: the third high prevalence country of the region

The epidemic of HIV infection in Myanmar has not been as comprehensively publicised as those in Thailand and Cambodia, but it does appear to share a number of their characteristics. These three countries are the only ones of the Asia Pacific region in which the estimated number of adults living with HIV infection clearly exceeds 1% (see Figure 1.2). Myanmar has not been recognised for implementing the same degree of preventive interventions as Thailand and Cambodia, but there are some recent signs of activity, particularly in relation to injecting drug use.

Epidemics driven by injecting drug use

A number of very different countries of the Asia Pacific region share the fate of having widespread epidemics of HIV infection among people who inject drugs. After Thailand, Malaysia was probably the first country of the region to report high levels of HIV prevalence in this population, through routine testing the authorities undertook among detainees in drug rehabilitation centres.

Vietnam detected an epidemic of injecting-related HIV infection, which was first seen at one end of the country, then quickly spread to all population centres where injecting took place (Figure 1.3). In China, Yunnan province was the early focus for its drug-related epidemics, but other parts of the country have been affected more recently.



Indonesia did not even recognise the widespread presence of the practice of drug injecting until the late 1990s, but by then HIV infection was insidiously working its way into populations of injectors, and reached levels of 40-50% in a number of cities by the early 2000s.

In all of these countries, sexual transmission of HIV infection appears to have been relatively limited so far, but there are signs of increasing prevalence among sex workers in several parts of Vietnam (primarily the south) and Indonesia (Papua in the east, Riau province in the west, and Jakarta more centrally).

India: concentrated and disseminated epidemics within one country

India, with its vast and diverse population, holds the dubious distinction of having the highest number of people living with HIV infection in the region (see Figure 1.2), and possibly competes with South Africa for this title globally. Although there is not, and cannot be a perfectly reliable way to estimate the number of people living with HIV infection in India (or elsewhere for that matter) the numbers in India are believed to be somewhere in the range of 2 to 8 million.

The first focal points of the epidemic in India were the north-eastern states, primarily Manipur, where an epidemic among drug-using men appeared practically overnight during the late 1980s. In other parts of the country, particularly Chennai and Mumbai, high levels of infection have been detected in female sex workers, and one or two states now record adult prevalence at levels comparable to that seen in Myanmar and Thailand.

On the other hand, Kolkata seems to have come through with so far very limited HIV transmission in either its sex working women or drug users. One possible contributing factor is the acclaimed Sonagachi program that has involved a range of health and welfare initiatives for female sex workers.

Papua New Guinea: another heterosexual epidemic emerging?

Limited surveillance in Papua New Guinea has long hinted at the possibility of a substantial heterosexual epidemic. The prevalence of HIV infection among pregnant women in Port Moresby has crept towards 1%, and the proportion of people presenting with tuberculosis who have HIV infection has been recently recorded at close to 20% in Port Moresby and Lae. Sex worker prevalence surveys have been very limited. Despite signs of an emerging epidemic, the country is still far from the long-predicted African scenario, and there clearly remains an opportunity and a need for large-scale preventive interventions.

Bangladesh, Japan, the Philippines, South Korea: very different low prevalence countries

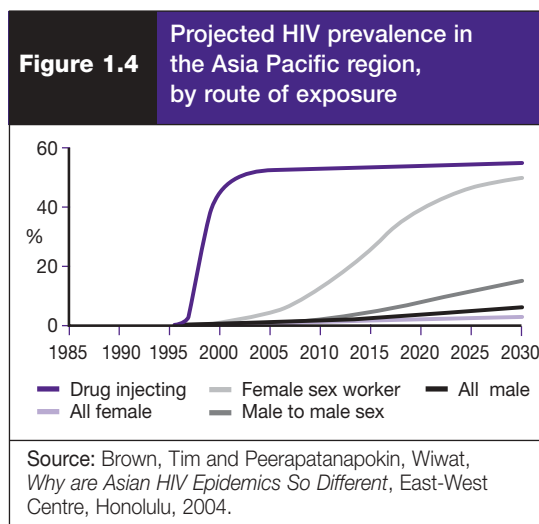
Of the Asia Pacific countries with populations above 10 million, there remain a few in which HIV does not appear to have made real inroads. Explanations vary, from the widespread use of condoms as contraception in Japan, to the male circumcision practised routinely in much of the Philippines. These factors may play a role, but a more important determinant may be the patterns of sexual networks. For example, although the Philippines appears to have an extensive sex industry, a much lower proportion of the male population participates as clients than in Thailand and Cambodia. The availability of sexual health services, including screening and treatment for sexually transmissible infections among female sex workers, may also have contributed to reducing the level of HIV transmission.

The Pacific Island countries: tiny populations of uncertain vulnerability

Apart from the French territories and Fiji, no Pacific Island nation has seen more than a handful of cases of HIV infection and some have still recorded none. Behavioural data are largely anecdotal and suggest risk potential, but must be utilised cautiously, not the least because of the potential to incite discrimination.

Future epidemics

Mathematical models have been used to try to understand the dynamics of the HIV epidemics that have emerged in the Asia Pacific region so far, and to predict their course under different intervention scenarios.



1 HIV infection and AIDS in the Asia Pacific region

Based on these models, which must be recognised as depending on a number of reasonable yet unverifiable assumptions, it appears that the Asia Pacific region still faces the threat of slow, long-term growth in the extent of the HIV epidemic. As Figure 1.4 shows, HIV prevalence under plausible assumptions could reach 5% in males and 2% in females by 2020, representing tens of millions of new infections across the region.

Several Asian countries, most notably Thailand, but also Cambodia, have shown that the sexual transmission of HIV infection via the sex industry can be slowed by well recognised interventions implemented on a large scale. In other countries (as diverse as Australia and Bangladesh) epidemics among people who inject drugs have been averted through the implementation of harm reduction strategies. Despite the fabulous advances in treatment over the past decade, HIV infection remains an incurable and often deadly disease, and one that is preventable by well-known means. Although the HIV epidemic has made inroads in many parts of the Asia Pacific region, the window of opportunity for prevention remains wide open.

John Kaldor is Deputy Director and Professor of Epidemiology at the National Centre in HIV Epidemiology and Clinical Research. The centre is funded by the Australian Government Department of Health and Ageing, and is affiliated with the Faculty of Medicine, University of New South Wales. The author is grateful to Elizabeth Pisani, Tim Brown and Melanie Middleton for their assistance in the preparation of this paper.

References and further reading

The information presented in this chapter has been compiled primarily from surveillance reports published by national ministries of health and technical organisations working under contract to donor agencies. For a few of the countries under consideration, epidemiological analyses of HIV prevalence and risk behaviour have been published in peer-reviewed medical journals.

A comprehensive analysis of the HIV epidemics and their determinants in the Asia Pacific region was published this year (MAP, *AIDS in Asia: Face the Facts. A comprehensive analysis of the AIDS epidemics in Asia*, Monitoring the AIDS pandemic Network, 2004). This volume also contains a large number of key references. The annual report published by UNAIDS (*2004 Report on the Global AIDS Epidemic: 4th global report*, UNAIDS, Geneva, 2004) presented key summary epidemiological statistics on HIV risk behaviour and prevalence by country.

WHO pares down HIV treatment guidelines for poor countries

by Anne-christine d'Adesky

In 2002, only 5% of those who required HIV therapy had access to it in developing countries. The World Health Organization wants to multiply that figure tenfold, so that three million people receive treatment by 2005. Its officials have issued draft treatment guidelines that provide a public health model for HIV disease management in resource-poor settings. Compared to US guidelines that stress an individually tailored approach to HIV therapy including protease inhibitors (PIs)¹ and sophisticated laboratory tests, the draft guidelines emphasise the simplicity, economy, and relative safety of non-protease regimens. They also encourage syndromic management of HIV, which emphasises careful tracking of physical symptoms, while limiting lab testing to the basics.

The WHO's bare-bones model stresses potent initial treatment regimens that do not require substantial improvements in health infrastructure. It is designed primarily for the senior policy-makers and treatment advisory boards that are establishing developing countries' AIDS treatment programs. It is sure to help frontline doctors as well.

The guidelines reflect sobering lessons learned from a decade of using protease inhibitors in richer countries. Today, serious side effects and drug resistance are linked to long-term use of HIV drug cocktails. Some patients no longer have any effective treatment options available while others have put off commencing treatment in the first place. Recent versions of the US Government's treatment guidelines reflect this trend. They no longer advocate a 'hit early, hit hard' approach to HIV treatment. Rather, they urge physicians and patients to carefully weigh the risks and benefits of therapy. The US guidelines also play up the critical role of patient education and emotional support to help individuals adhere to a taxing lifetime regimen. These issues pose even greater challenges in the developing world.

The WHO's guidelines reflect a collective awareness that economics, not science, drive health policy in developing countries. At the same time, the guideline drafters stress that their proposed guidelines should be read as a rough map for therapy, not a blueprint. There is considerable debate among the experts over many topics in AIDS care. One of the

strengths of the WHO document is that it pinpoints some of the minefields facing clinicians and patients. It also draws attention to steps that could be taken to fill in gaps in our knowledge.

Some critics have questioned the ethical issues underlying advocacy of a different therapeutic standard for poorer vs. richer countries. The guideline's authors defend their approach, noting that prior clinical guidelines for HIV therapy were developed for use in high- and middle-income countries. The guidelines are not meant to be a substitute for the necessary national AIDS treatment programs, but 'are meant to facilitate the dramatic scale-up that is needed in countries with limited infrastructure and significant resource limitations.'

'I was part of the committee that came up with the guidelines,' stated Dr. Mark Wainberg, an HIV specialist at McGill University and former president of the International AIDS Society. 'I don't think they are perfect, but I doubt whether any similarly constituted group would improve significantly on the recommendations. In spite of my bias, I think that the two NRTIs² plus an NNRTI³ concept is ethical as well as practical. Protease inhibitors were considered less reliable because of potentially non-monitored toxicities in resource-poor settings.'

Dr Sam Narasapa of Chennai, India agreed: 'I have no doubt that the [non-protease] regimen suggested will work. We need to be bold and ensure that this therapy will benefit individual patients. This will contribute to the reduction in viral burden transmission in the community. We must remember that these are guidelines and it is left to the individual physician as to how he will treat the patients. Training and hands-on experience is essential.'

Principles for minimalist therapy

The main topics covered in the WHO guidelines concern the initiation of anti-HIV therapy: when to start, what drugs to use, when to switch, how to monitor treatment, problems of toxicity and resistance. The guidelines also consider specific treatment issues concerning women (including pregnant women), children, drug users and other special groups. These also cover potency, dosing, drug interactions,

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managing HIV-tuberculosis coinfection, and the difficulties of distinguishing symptoms of HIV drug failure from immune restoration syndrome.

The guidelines limit anti-HIV treatment to patients who are seriously ill, using the WHO staging criteria for HIV disease. Treatment is advised for individuals with WHO Stage IV disease (clinical AIDS), those with WHO Stage I, II and III HIV disease and CD4 T-cell counts below 200, and those with WHO Stage II and III HIV disease and a total lymphocyte count (TLC) below 1200. The recommended first- and second-line combination therapy contains a dual nucleoside analogue regimen of AZT/3TC combined with efavirenz, nevirapine or abacavir. Acceptable substitutions include d4T/3TC, d4T/ddI and AZT/ddI for the dual nucleoside analogue component. The guidelines duly note that cross-resistance to nucleoside analogues can develop, making adherence to dosing schedules critical. Some of the nucleoside analogues' side effects, such as lactic acidosis and liver enlargement, are of particular concern to pregnant women and children.

The guidelines promote a tiered scale for laboratory testing, starting with 'absolute minimum tests' that include an HIV antibody test and a blood test for haemoglobin and haematocrit level. 'Basic' testing includes a white blood cell count and differential that can pick up common treatment side effects such as low neutrophil count as well as providing a total lymphocyte count. In studies to date, the WHO working group notes that TLC correlates poorly with CD4 levels, but provides a good marker for prognosis and survival when used with WHO clinical disease staging criteria. Other 'basic' tests include blood sugar, liver and kidney function and pregnancy tests. 'Desirable' tests include bilirubin, amylase and serum lipids. These are particularly useful for monitoring drug toxicities as well. CD4 T-cell tests are also 'desirable', but viral load testing is merely optional.

Drug resistance tests do not make the list at all, being too costly. But resistance testing for sentinel purposes is needed to identify resistant viral strains in a given population. The WHO is setting up a Global HIV Drug Resistance Network to assist member states in this task. To help individuals adhere, the guidelines recommend a low-cost formula used in the US: patient education, continued counselling and when possible, involvement and support by the family or community. They also suggest a strategy of Directly Observed Therapy for HIV therapy borrowed from tuberculosis (TB) management.

What about the older and cheaper dual nucleoside analogue regimens? Avoid them if possible, say the WHO experts. Such regimens are less potent and lead to resistance. But what if there's no money for three drugs? Case studies show patients can still benefit from suboptimal therapy. Ethically, many

Asia Pacific NeuroAIDS Consortium



APNAC participants, Cairns, October 2003.

The Asia Pacific NeuroAIDS Consortium (APNAC) is comprised of clinicians, scientists, neuropsychologists, social researchers and neuropathologists from 12 countries within the Asia Pacific region. Members have a shared interest in the social, diagnostic, management and research aspects of HIV-related neurological diseases that occur in resource-poor settings in the region. The member countries are Australia, Cambodia, China, Fiji, Hong Kong, India, Indonesia, Malaysia, Myanmar, Papua New Guinea, Singapore and Thailand.

APNAC first met in Sydney at the 14th ASHM conference and spent the following year working on research projects and developing the consortium further. The second meeting, in Cairns in October 2003, allowed APNAC members to finalise a grant application to fund research into studying the epidemiology of HIV-related neurological disease in children and adults in the Asia Pacific region. In addition, the meeting allowed members to finalise guidelines for the diagnosis and treatment of NeuroAIDS opportunistic infections and diseases for those patients who present to a healthcare setting where there may not even be a CT scanner to help the diagnostic process. It is proposed that these guidelines will be published in 2004.

APNAC serves as a productive and workable model for bringing together clinicians and scientists from the region to focus and work on a specialised area of HIV/AIDS. The group has established a regular email forum to share clinical experience.

Photo source: ASHM

doctors choose to treat sick or dying patients with two drugs and grapple with resistance later. The WHO draft guidelines support this choice. If a two-drug regimen appears to be working, they suggest keeping a patient on the regimen and switching over to three drugs when possible. 'The concession regarding two drugs reflects reality and represents a dilemma since individuals have a right to benefit from such therapy, notwithstanding the problem of drug resistance,' acknowledged Wainberg.

Real world complications

How useful are these guidelines for doctors and patients? What is good in theory can be hard in practice. The guidelines pay little attention to food and nutrition, but doctors in the field say this is a critical aspect of managing HIV. Screening for sexually transmissible infections and treatment and prevention of opportunistic infection are also given short shrift. There is passing mention of complementary herbal therapies and traditional medicine used in different countries.

Non-medical and social issues also fall outside the scope of the guidelines that impact on access to care. Left unaddressed, for example, is the issue of public stigma that makes people reluctant to get tested for HIV and reluctant to seek care until they are quite sick. That includes discrimination by health professionals who fear exposure to the virus.

In the developing world, HIV is linked to poverty and rides on the coat-tails of endemic diseases such as TB, malaria, and parasitic or fungal infections. Treating HIV there requires managing these multiple infections. The draft guidelines note that coinfections like TB promote HIV disease progression and vice versa. Also, HIV drugs interact negatively with those for TB and other diseases. They suggest treating active TB cases first, to avoid stressing the liver and causing drug interactions. But that is not possible in persons with advanced HIV disease.

Immune restoration syndrome poses another challenge. Some patients have experienced serious flare-ups of hepatitis and other diseases after initiation of anti-HIV therapy. Such acute illness represents an intense inflammatory reaction to pre-existing indolent infections. Without comprehensive lab testing, it is difficult to determine whether these symptoms result from treatment success and immune recovery, treatment failure and HIV disease progression, or drug-induced toxicities. This issue is likely to be a particular problem in developing countries, where hepatitis is rampant.

Given their cheap cost and simplicity, there is no question that non-protease regimens make sense as universal therapy. But in the longer term, there are potential serious consequences. The long-term impact of specific drug toxicities on children and women of child-bearing age is critical; so is future resistance to HIV. In many developing countries, chronic and often improper use of drugs has led to multi-drug-resistant strains of TB and malaria. What are the odds of doctors doing better with HIV therapy?

India improvises

India provides a reality check and an early warning for the experts. The HIV epidemic there affects four to 12 million people. Heterosexual sex is the primary route of transmission. Around 10% of HIV-positive patients are so sick they need treatment now, but only a few thousand are receiving anti-HIV drugs. There is little public education about AIDS or HIV and their treatment, but there is a lot of stigma and discrimination, even by health professionals. Like many countries, India has excellent doctors, nurses and midwives, but not enough of them in rural areas where HIV has spread. Around 500 physicians are treating HIV in India, mostly in major cities. The majority are dermatologists who have become de facto HIV specialists because they see patients with sexually transmissible infections.

Dr Shashank Joshi is a US-trained infectious disease specialist in Bombay who has treated almost 500 HIV patients over nearly five years. He treats wealthy private patients and very poor patients at a public hospital. The rich ones get all the perks available in the US, including protease inhibitors and viral load testing. The poor make do with the non-protease regimens and syndromic management outlined in the WHO guidelines. So far, he has had remarkable success attacking HIV in both settings, but Joshi says that he is the exception rather than the rule.

'I think the overall health system in India is very bad,' Joshi remarked. 'The vast majority of doctors here practise bread and butter medicine. Very few are trained abroad as ID doctors. They are just handling patients as they come in with HIV disease and doing symptomatic treatment.'

Up to now, he said, HIV therapy has been erratic, unsupervised and often suboptimal. 'That's medicine in India. Everybody and anybody can prescribe antiretroviral drugs in India. So they make their own regimens, for their own convenience and their own pockets. It doesn't necessarily translate into quality of care. God save the patients who are on all these crazy protocols.'

Joshi often sees patients referred by other doctors. 'Most of their prescriptions are not up to the mark,' he remarked about his colleagues. 'They don't know what to combine with what. I can show you prescriptions where it's AZT plus d4T.' (As the WHO guidelines point out, AZT and d4T are antagonistic with each other and should never be taken concurrently.)

Joshi feels that Indian-based treatment guidelines coupled with continued medical education of physicians are the way forward. 'But that could take

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Laboratory Training



Seminar on Laboratory Development in Cairns, October 2003

The National Reference Laboratory in Australia (under a technical service agreement for the World Health Organization) has been involved in an external quality assessment scheme (EQAS) for those laboratories in the South-east Asian and Western Pacific that test for HIV, HBV and HCV. A workshop was held in 2002 to review the results of the scheme, to train participants in using EQAS information and to improve the quality of test results. The workshop also provided participants with a forum for exchange of information with an emphasis on issues and problems in testing in blood service and diagnostic laboratories specific to the regions. Twenty-three participants from fifteen countries attended. The NRL has since been involved in maintaining EQAS as an educational tool for laboratories in the regions.

In 2003, a laboratory technicians' seminar was held in Cairns as part of the ASHM annual conference. Participants from Cambodia, Nepal, the Maldives, Sri Lanka and Papua New Guinea attended. The idea for this seminar arose at the first International Roundtable on Access to HIV Treatments at the Australian National University in September 2002. At that forum a number of participants expressed frustrations with laboratory services and quality assurance standards that compromised the capacity and reliability of HIV testing and monitoring in their countries.

ASHM identified an opportunity to provide a short intensive program to address some of these issues. The objectives of the seminar were to:

- provide participants with an update on current technologies for HIV testing;
- review the selection and use of appropriate technologies in resource-poor settings;
- maintain laboratory safety and maximise quality assurance; and
- transfer information and train-the-trainer skills.

The seminar program included sessions devoted to testing strategies, Simple Test Kit (STK) applications, counselling and issues related to the uses of STK, understanding and using viral load testing and quality management in the laboratory.

Photo source: ASHM

some time – and money,' he acknowledged, 'We don't have much of either.'

He is also concerned about what he calls 'over-reliance' on non-protease regimens in populations which suffer from liver damage due to chronic use of drugs to treat TB or parasites. 'In Indians, liver toxicity is going to be a hundred-fold more because they are exposed to anti-TB drugs,' he predicted. Aside from liver problems, Joshi has also seen rashes from nevirapine and abacavir and neuropathy with some regimens.

'All the nukes are toxic, all the NNRTIs are toxic,' declared Joshi. 'It's done for convenience, compliance, cost – two pills twice a day. People are not prescribing PIs because they are inconvenient to take; they are large and they are bitter. But that is not always the right thing to do. There will be cases when all these non-PI regimens are defeated by drug resistance, and you have to use only salvage regimens.'

But Joshi certainly does not give the protease inhibitors an unqualified endorsement. He published his first report on treatment-related diabetes and lipodystrophy in patients using protease inhibitors. 'Among my elite cohort of 300 patients, there is a high incidence of lipodystrophy,' he noted.

One patient suffers from avascular necrosis resulting in deterioration of his hip bone. 'We are going to see that,' Joshi said. 'There is no way to prevent anything.' He has put a small number of patients on experimental cyclical treatment interruptions, mainly one month on therapy and one month off, to reduce toxicities and buy them time. 'I am extremely happy with my results,' Joshi remarked. 'The CD4 curve is either flat or up. The viral load is almost undetectable, but in a couple of cases we do get rebounds. In early disease,' he argued, 'I believe it should be standard of care. In later or chronic disease, I am not so sure. Our observations are very preliminary.'

Other Indian doctors share Joshi's improvising ways. Indian HIV patients often have very low baseline haemoglobin levels or anaemia due to chronic malnutrition. That rules out AZT for first-line regimens because this drug itself causes anaemia. 'I don't use much AZT because most of my patients have haemoglobins under 10 or 12 grams and AZT is a killer for them,' stated Dr Ishwar Gilada, a dermatologist turned HIV specialist with a thriving practice in Bombay.

Gilada treats most of his patients with generic non-protease regimens and has not seen many problems. Because his patients are often underweight, he deliberately lowers drug doses, using a dose-per-kilogram scale borrowed from paediatric medicine. 'This

works well for my patients and reduces toxicities,' he said. 'Many of our doctors are learning to do this.' Such steps deviate from the WHO guidelines and pose the risk that HIV will acquire drug resistance from exposure to suboptimal therapy.

In Indian patients, alcoholism is another common factor that increases the risk of liver toxicity. 'Liver monitoring is the most important test,' noted Gilada. His patients have their liver function monitored every two to three months. 'If it's OK, we increase the follow-up time.' Luckily, many can afford CD4 and viral load tests, so monitoring is easier. So far, Gilada said that 5% of his patients have had typical minor skin problems caused by non-protease drugs, and 1% to 2% have had serious problems.

In Chennai, Dr Narasapa has seen one patient with nevirapine-induced hepatitis, and hypersensitivity reactions in three women taking nevirapine-containing non-protease regimens. Narasapa worries about the potential consequences of non-protease regimens. He remarked, 'The only way to minimise long-term effects is to see that counselling is given more than once. And the training of physicians is important.'

Managing coinfections remains the biggest daily challenge for most doctors, said Joshi. 'Ninety percent of doctors here start people on anti-TB drugs without really diagnosing, based on weight and other symptoms. That is why India has the highest rate of multidrug resistant TB. INH [isoniazid] resistance is 40%, rifampin resistance is over 30%, and almost every second-line drug is resistant.' These statistics do not bode well for syndromic management of HIV, he feels. Joshi concluded, 'We need to be prepared to manage resistant HIV'.

Social and religious issues present other barriers to treating HIV, making some regimens and side effects more acceptable than others. The NNRTI efavirenz is a problem. 'In India, whenever we give efavirenz, we get tremendous sweating, fully wet, as if they've taken a bath. And that is socially unacceptable in India,' reported Joshi. His wealthier patients quickly abandon the drug. 'They will say to hell with it, even if I get a pot belly, even if I get diabetes, I don't care, I will take a PI.'

Diet is also a big issue in India. The typical Indian diet is oily, which makes it hard for patients to use PI-based regimens. Some people regularly fast, which affects adherence and absorption of drugs. 'My patients don't want to compromise on their eating habits,' Joshi shrugged. 'These are the realities we have to deal with every day.'

Like many Indian doctors, Joshi routinely uses Indian ayurvedic or herbal compounds, alongside standard Western medications. But he is aware that

little is known of potential drug-herb interactions. 'What I'm concentrating on are non-drug options to increase CD4 and decrease viral load,' he explained. 'In my patients who were failing salvage therapy, I began trying other things like de-worming agents. The viral load comes down. My whole aim is to develop cheap, cost-effective protocols for the Indian environment.'

Summing up the task at hand, Gilada said, 'We have to be creative and watchful, keeping in mind that the well-being of our patients comes first. We will make mistakes just as doctors in the US have made them. But we are learning as we go forward.'

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Notes

- 1 Protease inhibitors (PIs) currently include amprenavir (APV), indinavir (IDV), lopinavir (LPV), nelfinavir (NFV), ritonavir (RTV) and saquinavir (SQV).
- 2 Nucleoside reverse transcriptase inhibitors (NRTIs) include zidovudine (AZT), didanosine (ddI), stavudine (d4T), lamivudine (3TC), zalcitabine (ddC) and abacavir (ABC).
- 3 The non-nucleoside reverse transcriptase inhibitors (NNRTI) class includes nevirapine (NVP), efavirenz (EFZ) and delavirdine (DLV).

3

Challenges in balancing HIV prevention programs and treatments

by Don Baxter

For the first time in 20 years of the HIV epidemic we have developed over the last two years the real prospect of saving tens of millions of lives. As I see it there are two key challenges to maintaining HIV prevention in the current 'treatments-oriented' world. I shall explore them but also set them both in the wider, integrated context necessary to turn the epidemic around.

The two challenges I analyse are: seeing treatments as prevention, leading to a medical model coming to drive the HIV prevention agenda; and the diversion of leadership and the distortion of program directions that a predominant focus on treatments access can invoke.

A treatments-oriented world

Despite the sprawling, amorphous affairs that international AIDS conferences are, their biennial timing can provide useful time-pegs to provide perspective on developments. The two years between the Barcelona conference and the conference in Bangkok, July 2004, provided a useful reminder of just how fast we have moved to a 'treatments-oriented' world.

Those two years are particularly useful for analysing, reflecting on and assessing those less visible shifts in the foundations which underpin program development and changes to directions – often overlooked in the hurly-burly of program implementation.

The 2000 Durban Conference had provided the reality-jerk for much of the world about just how bad the HIV epidemic was – located right in the reality of 20 million impending deaths. The immorality of treatments access across the world was made unavoidably stark – and many in the comfortable rich west were shaken to begin addressing it.

But it was the Barcelona Conference in 2002 that really galvanised the world to action. The 'big politics equation' was widely agreed:

- namely, that the epidemic continues to grow exponentially, yet ...
- we have the prevention techniques; and

- we have the treatment drugs to prevent 20 million deaths and infections over the next five years.

We lack only:

- the political will at an international level and in many countries, and
- the US\$10 billion per annum necessary to save these lives.

This consensus was developed during that conference – and articulated in its closing plenary – along with a conditional rider: the Bangkok AIDS Conference in July 2004 will be the time for accountability on progress.

From Barcelona to Bangkok: the whirlwind of change

And what rapid change that galvanisation has brought!

- The production, pricing and distribution of antiretroviral drugs is being revolutionised.
- The Doha 'Paragraph 6' agreement within the World Trade Organisation provided a framework for nations to declare public health emergencies and take measures to provide pharmaceuticals to their populations. (See Chapter 5.)
- Pharmaceutical companies were shamed into lowering prices – undercut by generics manufacturers, and facilitated by Médecins Sans Frontières' comparative pricing tables.
- The Clinton Foundation established and negotiated major price reductions for both drugs and diagnostic tests.
- Drug regimens themselves have been simplified.
- Previously inert international agencies have been mobilised; especially the World Health Organization (WHO), the World Bank, and now the Asia Development Bank.
- The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria has emerged more quickly and stronger than many expected. (See Chapter 4.)
- Other major donors started to provide substantial funds: Gates Foundation, the UK's Department for International Development, the Bush Administration's US\$15 billion Presidential Emergency Plans for AIDS Relief (PEPFAR) program.

- WHO developed and launched its 3x5 program – aiming at getting three million people in developing countries onto antiretroviral treatment (ARVs) by 2005.
- Brazil emerged at the Barcelona Conference as the world's most dynamic policy leader, with treatments access as part of a comprehensive, integrated program – and broke the ice in threatening to issue compulsory licenses for a public health emergency.

The whole terrain is being transformed. Much of the framework for major improvements in access is falling into place, but still only about 250,000 people in developing countries are actually receiving ARVs.

Nonetheless, as I look back over my notes from Barcelona what strikes me now is the rapidity of this set of changes; a rapidity that left many feeling a little bewildered at times. The transformation has changed the focus of all countries – and the changes have been far more rapid than governments, health systems or the community sector in nearly all countries can assimilate and come to terms with. Perhaps the only exceptions are Brazil and Thailand – where the governments, the health sector and the community sector have all been working effectively together to bring these changes to fruition.

Challenge 1: 'medicine driving the prevention agenda'

Part of moving to a 'treatments-oriented' world has been the washing away of the previous rationales used by the pharmaceutical industry and medical/clinical sector for not providing access to HIV treatments to the developing world. The following have been exposed as rationalisations for inaction or for market protection.

- The drugs are too expensive to be cost-effective.
- Poor adherence will lead to a widespread HIV-resistance nightmare.
- The health care systems will never be able to deliver the drugs.

The result has been many medicos moving from scepticism about treatments access to 'boosterism' for it. This is a welcome shift – but such moves can involve evangelical approaches. Richard Horton, editor of *The Lancet*, captured the essence of the problem in his recent book *Second Opinion*:

Listening to doctors debate how they can tackle [communicable] diseases, one can be left feeling that the outstanding issues are largely technical.

If this were true, the burden of human disease would be straightforward to combat. It is not. What scientists have been less keen to investigate are the messier questions about the social, even behavioural, aspects of disease. These cannot be studied in a sterile laboratory or in a carefully controlled clinical trial. And because they are messy, such questions are frequently ignored. (Horton, 2003: 123)

And coming across with the 'boosterism' has been a medical model approach to HIV prevention. (Cohen, 2002) Many have seen behavioural prevention approaches as having 'failed' – citing the examples of India, Russia, China, South Africa – and have therefore focussed on 'treatments as prevention'.

What is being posited – often only implicitly – is a solution to the HIV epidemic focussed on what I characterise as 'pharmaceutical prevention'. (Perhaps 'caricature' is more accurate than 'characterisation'; I use the phrase only for the purposes of this discussion.)

This approach has several dangers. It will see medicine increasingly driving the prevention agenda – in unproductive directions – and it diverts political will and leadership away from the other essentials of a comprehensive, integrated HIV response – that is, away from success.

What do I mean by 'medicine driving prevention'?

Let me give you a couple of examples.

WHO's 3x5

The WHO 3x5 program was developed very rapidly. It was announced in November 2003 and now there are country-assessment teams in more than 20 countries. The assessment teams were initially intended to be inter-disciplinary teams working within a framework which incorporated a comprehensive HIV response.

Funding for 3x5, however, has fallen far short of expectations so those teams have been reduced and – not surprisingly – had to be largely restricted to the priority expertise areas of clinical and health system expertise, that is, no health education expertise, or community-based expertise, or people with HIV/AIDS themselves.

The outcome in a country such as Indonesia, for instance, is that targets for ARV treatment are set higher than the currently identified number of people with HIV – and some or many of these people would probably not benefit from ARV immediately.

As Wendy Holmes pointed out in *The Lancet* recently, this is likely to skew the voluntary counselling and testing program overwhelmingly towards

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identifying HIV-positive people in order to achieve the 3x5 treatment targets – and away from the support and prevention role that program is also intended to play. (Holmes, 2004) In a worst-case scenario it may lead to coercive or compulsory HIV testing of vulnerable populations, for example, in order to achieve the 3x5 targets.

The CDC ‘paradigm shift’

In a different way, the movement of clinical scientists into prevention strategy in the US has seen the Center for Disease Control (CDC) in Atlanta, Georgia, undergo a ‘paradigm shift’, switching its prevention focus onto to HIV-positive people and their partners. (CDC, 2003)

While not intended to *replace* the existing, community-focussed, health-promotion programs funded by the CDC, this is increasingly becoming the result. This distortion of prevention objectives is compounded in the context of the religious right’s influence on the Bush Administration’s ideologically-driven approach which pushes abstinence, anti-prostitution and war-on-drugs policies, intimidates innovation and decimates resources among many of the leading prevention agencies in the US.

A grave danger for the international HIV epidemic is that this ideological assault will increasingly be written into all contracts of the US\$15 billion PEPFAR Program and all USAID funding in the developing world.

The false dichotomy – ‘treatment versus prevention’

Part of this pressure comes from clinically-focussed scientists moving into prevention and seeing it as having failed. In light of the distressing list of spectacular failures – India, Southern Africa, China, Eastern Europe – this is an easy conclusion to reach, and many of these scientists see ‘pharmaceutical prevention’ as the only long-term solution. But this analysis is too simplistic, for two reasons. First, prevention does work and there is ample scientific and epidemiological evidence to prove it.

Where properly resourced and led, HIV prevention has not failed:

- Thailand turned its epidemic around.
- In some African countries (e.g. Uganda, Ethiopia and Rwanda), antenatal HIV prevalence demonstrates declines from the mid-1990s.
- In the early 1990s, the infection rates in most of the rich western nations plunged and have largely stayed at low levels.
- Brazil has demonstrated major reductions in rates of infection.

Second, the obverse in the proposed dichotomy is inaccurate. ‘Pharmaceutical prevention’ does not have a good success record in other diseases. We have an excellent measles vaccine – but three million children die from measles in Africa each year. We have effective tuberculosis treatments but millions die from it each year. Even in rich countries the record can be poor: look at hepatitis B vaccination rates among children in Australia, or hepatitis A vaccination among gay men.

An ‘interplay’ case study – the impact of ARVs on behaviour

The introduction of effective ARV treatments into Australia illuminates the complex interplay between pharmaco-clinical interventions and social behaviour. While their widespread introduction in 1995/96 did initially contribute to a reduction in HIV infections, it now seems clear that from 1998 onwards the rate of new infections gradually increased again – though this increase was masked in the overall surveillance data until 2002.

As the gay community came to understand the concept of reduced infectivity and community viral load and the reduced risk implied in that, we saw not an ‘abandonment of safe sex’ or a ‘complacency’ about it, as sometimes characterised, but an increase in occasional episodes of high-risk sex by an increasing number of men (though often not the same ones) ... another ‘messy result’ in Horton’s terms.

As there was a concomitant change of clinical management practice, the number of men with HIV actually taking ARV decreased (from around 70% to 50%) – in their own health interests – so the level of community viral load probably increased, undermining the assumptions of risk levels made by most HIV-negative gay men.

The recent modelling paper by Clements and others illustrates the potential for quite major increases in HIV infections – up to 50% in some scenarios – arising from the impact of ARV provision. (Clements, et al, 2004)

To say this illustrates a ‘failure of pharmaceutical prevention’ is facile – and it is not a claim I am making. But it is a salutary illustration of the complex interplay of pharmaceutical and clinical interventions with community perceptions and norms about the meaning of those interventions.

So a critical question arises for the epidemic internationally: how this will play out in resource-poor settings where there are relatively low levels of HIV knowledge, high rates of stigma and discrimination and little political leadership. At this stage the answer is completely unknown, but it is unlikely to be simple. Yet we are moving to that situation very quickly in many countries.

And a second critical point: this case study illustrates the artificiality of a 'prevention' and 'treatment' dichotomy. Instead, as Sue Kippax and Kane Race (2004) recently pointed out in *Social Science & Medicine*, we need an approach to prevention that integrates the medical and the social narratives to re-establish a nexus, indeed, an alliance – and a genuine one – between medicine and social science.

Challenge 2: diverting political leadership

The second challenge brought by a predominant focus on treatments is the diversion of focus of political leadership. As we all now know, effective HIV responses require forthright political leadership from the highest levels. Just look at that list of failures I mentioned above: problematic leadership by President Mbeki, invisible leadership by Prime Minister Vajpayee, negligible leadership by President Putin, and culpable defensive 'head-in-the-sand' leadership in China. But all of the successes I listed had strong public leadership from the top.

Prevention needs political leadership because socially and politically difficult things have to be done. For example:

- engaging with ostracised communities,
- candidly and directly addressing intimate sexual behaviour and illicit drug use in the public domain, and
- creating enabling environments to provide rights and support for marginalised communities such as sex workers, injecting drug users, homosexually active men, and itinerant workers.

There is no 'natural' political constituency for HIV prevention in Asian and Pacific countries, indeed anywhere outside the rich west. In the west a confluence of HIV exploding in the recently-emerged gay communities, threatening those communities' very existence, stimulated a political, community-driven response which could be picked up and adapted by sex workers and injecting drug users. These conditions do not exist – in the sense of driving a political movement – in Asia and the Pacific.

Politicians in Asia, except those in Thailand and more recently, Cambodia, have been notoriously reluctant to exercise public leadership in favour of 'those icky people we don't really like'.

The problem with an overwhelming treatments focus for the HIV epidemic is its potential to allow this reluctant political leadership to appear to be responding effectively by focussing *only* on access to HIV treatments. For politicians anywhere, it is much

easier to introduce and lead a program focussed on caring for the sick than one engaging with and defending 'the aberrant'.

The danger is that treatments access is the *only* major HIV program that is introduced and supported. The prevention programs will languish (if they ever started); affected communities are not mobilised; stigma and discrimination will remain ignored; the enabling environment simply left unaddressed; and a multi-sectoral 'whole-of-government' mobilisation avoided.

Unfortunately, and perhaps ironically, such a narrow focus on treatments access will guarantee that the treatment program itself fails. Susan Paxton has recently given us some solid insight into the extent of discrimination against people living with HIV/AIDS across a range of Asian and Pacific countries. (2003) And much of that discrimination is within the health systems of those countries. So access to treatments may well be thwarted at the local level of service provision – notwithstanding the central government's intention.

My community colleagues in Thailand – where a treatments access program is being successfully rolled out – have found that the *only* way to combat this discrimination is to insert a local community presence of people living with HIV/AIDS directly within each of the 800 hospitals involved in the program.

Political leadership can also falter over time. Brazil currently provides the best model for a national HIV response. (Oliveira-Cruz, 2004) Australia used to, but now we model a faltering response, particularly on the question of political commitment to prevention.

The government took more than a year to review its overall HIV program – and then another year to respond to that review's recommendations. It established a new advisory committee to the Minister which has met just once in six months and which compromises Australia's partnership approach by not including HIV community representatives. Yet, during this period, we have seen a fundamental change in the direction of Australia's HIV epidemic – rises in HIV infections across the country.

Conclusions

So what outcomes are desirable coming out of the Bangkok AIDS Conference? The pendulum has swung too far towards treatments access. That focus needs to shift back – but not just back to prevention programs. This oft-repeated dichotomy can be misleading.

3 Challenges in balancing HIV prevention programs and treatments

I hope I have illustrated that pharmaco-clinical interventions are inextricably bound up with social and community understandings of the meaning of them. The treatments/prevention nexus needs to be a genuine partnership – but the interdisciplinary forums for discussing and debating these interactions have declined, almost disappearing in the treatments access ‘whirlwind’. I hope Bangkok helps to re-establish the spaces necessary for that dialogue.

But treatment and prevention programs – even when they are integrated and work closely together – are only two of the six elements of successful responses. Access to treatments programs will fail in countries where we do not achieve *all* of the following:

- forthright political leadership for a comprehensive response;
- mobilisation of affected communities;
- comprehensive and co-ordinated prevention and treatments programs;
- stigma and discrimination challenged and eliminated;
- creating an enabling environment with a rights-based foundation; and
- mobilising a co-ordinated multi-sectoral response of effort and resources.

This is an edited version of a paper given in Melbourne at the 18th World Conference on Health Promotion and Health Education by Don Baxter, Executive Director, Australian Federation of AIDS Organisations (AFAO) and Board Member, Asia Pacific Council of AIDS Service Organisations (APCASO). A version of this paper was published in the May 2004 issue of ASHMNews.

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The Global Fund to Fight AIDS, Tuberculosis and Malaria

by Edward Reis

The Global Fund to Fight AIDS, Tuberculosis and Malaria was established in June 2001 at the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS and was operational in January of 2002. The sole purpose of the fund is to attract and disburse additional financial assistance from governments and the private sector worldwide to strengthen local responses to HIV/AIDS, TB and malaria in developing countries.

While around 60% of the fund's portfolio is allocated to HIV/AIDS, tuberculosis and malaria, each attract around 20% of funding allocation. Why does the fund focus on these three diseases? In terms of global disease burden and mortality, these are the 'Big Three'. In 2002, HIV/AIDS accounted for more than three million deaths; TB killed over two million people and malaria cost the lives of between one and two million people. (UNAIDS, 2002)

The fund recognised that without a massive increase in resources to support prevention, treatment, care and support for people in developing countries living with these illnesses, the global death rate would rise inexorably. The social, economic and political consequences of this rise are untenable. It is important to note that the fund sets out to attract additional financial support from its donors. From the outset, the fund has acknowledged that current levels of donor aid – bilateral and multilateral – are insufficient to address the scale of these epidemics. Support for the fund is not a means of channelling already committed aid, but rather a means of extending the amount and reach of aid.

This chapter will briefly consider the structure and history of the fund to date, Australia's participation in the fund and the state of the fund today.

Structure and process

The structure of the fund is intended to reflect its focus on mobilising resources, managing portfolios, and monitoring and evaluating disbursed grants. It is also intended to be as streamlined and cost-efficient as possible. The Global Fund is governed by a board that approves grants and lobbies for financial

donations to support the fund's activities. This board is advised by four ad hoc committees that focus on particular areas of expertise: governance and partnership; monitoring, evaluation, finance and audit; portfolio management and procurement; and resource mobilisation and communications.

The board is supported by a Geneva-based secretariat of around 70 people. The fund assesses, approves and resources project applications that are lodged by independent agencies from around the world. Those applications are assessed by a Technical Review Panel that considers the technical and scientific merit of all funding proposals, based on current understandings of global best practice. Recommendations are then made to the board, under four categories: fund; fund if further information is provided; encourage re-submission; and do not fund.

Individual countries wishing to receive Global Fund grants are required to set up a Country Coordinating Mechanism (CCM) to develop and submit grant applications. Applications must be consistent with and informed by national strategies that are in place to address HIV/AIDS, TB and/or malaria. They must also reflect the priorities of national stakeholders and address gaps in funding from other sources. If an application is successful, the CCM is then responsible for managing and reporting on the implementation of the funded programs. CCMs are seen as fundamental to the Global Fund's principle of local partnerships owning and managing their projects. There are guidelines for the composition of CCMs which stipulate membership from private and public sectors, government and non-government organisations, people living with the diseases, academic and research institutions, and bilateral and multilateral donor agencies.

Principal recipients are identified in each grant application and are accountable for the management of a grant and must supervise project implementation. Together with the secretariat in Geneva, they design program goals and determine a calendar of performance-based grant disbursements for the duration of the program. Local Fund Agents are identified by the secretariat to assess the capacity of principal recipients to administer funds, manage programs and report on all aspects of program implementation. The Local Fund Agent is also responsible for verifying annual audits of grant disbursements.

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It is important to note that the fund is a financial institution and not an implementing agency. The fund does not provide technical assistance or direct capacity-building assistance to applicants or recipients of grants. This work is left to existing agencies already working in these areas. Chief amongst these are the Joint United Nations Program on HIV/AIDS (UNAIDS), the World Health Organization (WHO), World Bank, bilateral aid agencies and non-government organisations. As noted previously, many of these organisations may be involved as members of CCMs as well.

The submission process starts with the fund's secretariat calling for funding proposals, which are then prepared and submitted by the CCMs. Each submission must have identified one or more principal recipient/s. Proposals are reviewed by the secretariat. The Technical Review Panel then makes its recommendations, and the board makes grants based on availability of funds. The secretariat then contracts the services of a Local Fund Agent to verify the administrative capacity of the principal recipient/s and the grant conditions are drawn up.

Once funds are provided and programs implemented, a system of monitoring, reporting and periodic disbursement requests begins. This system involves close cooperation between principal recipients, Local Fund Agents and the secretariat to ensure that fund disbursements are made on demonstrated performance measures throughout an initial two-year grant commitment from the fund. At the end of the first two years, and subject to satisfactory reporting and implementation, CCMs can then apply for additional funding to complete the full term of their programs.

In its first 18 months of operation the Global Fund disbursed US\$1.5 billion for two years to 154 programs in 93 countries. By November 2003, Round 3 grant approvals brought total grants to US\$2.1 billion across 121 countries. To date, all recommended projects have been funded.

While this is an impressive record of performance, by any measure, undoubtedly the greatest challenge the Global Fund faces is continuing financial support from western countries and donor organisations.

Funding renewals for projects that received support in the first round of grants will commence at the end of 2004. If the fund does not receive extra financial support from new and existing sources it will not be able to finance any new rounds of projects. The fund generally issues a round of calls for proposals every eight months. It may be anticipated that the number of new applications in Round 5 will increase as a result of programs to scale up treatment – such as the WHO's 3x5. It is estimated that

US\$4.9 billion is needed to cover funding requirements for 2004 and existing program renewals in 2005. Extra money will be needed to cover new funding rounds in 2005. In November 2003, pledges for 2004 amounted to just over US\$1 billion.

While this is cause for concern, many countries make their pledges through protracted internal processes and to date the fund has been confident of meeting the required goals. Major donors, in particular the United States, have been slow to facilitate the flow of assured donations to enable the fund to be confident of meeting its future commitments. While the current US administration has committed substantial funds to HIV/AIDS in developing countries, much of this aid is channelled through US agencies, rather than the Global Fund, and conforms to an ideological policy that does not account for local cultural and social norms in recipient countries.

Thankfully, the US Congress has proven to be the fund's ally by appropriating substantially larger funding allocations than the US government has been prepared to commit for fund activities. A real cost to the fund, however, is the allocation of personnel and resources for the lobbying required to get those pledges from Congress. This is all the more important as the US is the single largest donor to the fund and has pledged to meet a maximum of 33% of the fund's resources if other countries can meet the remaining 66%. Consequently, the fund must lobby on all fronts to ensure that the US is obliged to meet its pledges.

Australia's approach

What of Australia's role in the Global Fund? Until February 2004, Australia had made no contributions to the fund. This stance was based on three major concerns. Firstly, the Australian Government opted for a 'wait and see' position to assess the fund's capacity and effectiveness. Secondly, the government argued that Australia has considerable bilateral programs in place that are supporting HIV/AIDS initiatives in regional countries. Finally, there were concerns about the degree to which the fund would direct grants to the Asia-Pacific region.

Arguably, concerns regarding the fund's capacity and effectiveness became somewhat redundant in a relatively short period of time. As noted earlier, within the first 18 months of the fund's existence, over US\$1.5 billion had been allocated to projects in 93 countries and the fund was able to meet the requirements of all recommended projects. However, it is not only in the form of successful grants that the fund's effectiveness is measured. The process of establishing CCMs and developing grant applications

Clinical Placements



Dr Evy Yuniastuti.

ASHM hosted a clinical placement for Dr Evy Yuniastuti in 2004, through a scheme managed by Family Health International. Dr Evy won the first-ever David Bary Memorial Award for her work with people living with HIV/AIDS at the Cipto Mangunkusumo Hospital in Jakarta. She has a special interest in mother-to-child transmission, is the author of *HIV and Pregnancy* and a member of the Indonesian Association of Physicians in AIDS Care. Her trip was a whirlwind month of clinical placements, laboratory visits and exchanges with community and medical leaders in Sydney and Melbourne. She is pictured here with Edward Reis, ASHM's Education and International Programs Manager.

Photo source: ASHM

has helped to develop valuable skills and experience and to forge a partnership approach to tackling HIV/AIDS in many countries where this did not previously exist. As Australia's own response to HIV/AIDS has consistently endorsed and reflected a partnership system that has resulted in highly successful prevention and care programs, it is fitting that we recognise the value of this in other settings.

The argument that Australia has effective HIV/AIDS bilateral programs in place and so does not need to contribute to the Global Fund was spurious from the start. As noted earlier, the fund was set up to attract additional financial support from donor countries and organisations. The UNGASS forum recognised that such a fund was needed to address a global problem that could not, and would not, be halted through existing multilateral and bilateral aid programs.

Bilateral programs only target certain, and often strategic, countries for aid assistance. Countries deemed to be of no economic or strategic relevance to donors miss out. These inevitably include the poorest and most needy countries. AIDS, TB and malaria are pandemics that cannot be addressed with piecemeal bilateral approaches. Scaling up can only

happen through a coordinated global approach. It is disingenuous to withhold support to the Global Fund on the basis of effective bilateral programs.

Nevertheless, the fund itself has recognised the value and importance of Australia's bilateral programs. Australia has been instrumental in establishing the Asia Pacific Leadership Forum on HIV/AIDS and Development. In 2000, Australia committed A\$200 million over six years towards a global AIDS initiative and established itself as the leading donor in East Asia and the Pacific. This was recently increased to A\$600 million by 2010.

Finally, concerns about the fund's contribution in the region have also proven to be unfounded. Cambodia, China, India, Indonesia, Lao People's Democratic Republic, Sri Lanka, Thailand and Vietnam all received grants in the fund's first round. In the second grant round many of these countries were again successful and Bangladesh, East Timor, the Western Pacific Islands (a multi-country group of eleven island nation states), Myanmar, Nepal and the Philippines all received grants. In Round 3 grants, Papua New Guinea received US\$6.1 million for malaria programs over two years. In Round 4, US\$8.4 million was received for HIV/AIDS programs.

In all, about 20% of the fund's grants have gone to the Asia Pacific region. The fund has committed itself to regional support at least until the beginning of 2005, as these grants cover an initial period of two years.

After considerable lobbying and on the occasion of the fund's Executive Director visiting Australia, a commitment of A\$25 million over three years was announced in February 2004. Australia's commitment to the fund, while criticised for being considerably less than the contributions of similar-sized economies, is welcome and brings a number of benefits.

Global Fund programs and Australia's bilateral programs can now be complementary and coordinated to reduce duplication and address program gaps. Australia's bilateral programs have until recently not supported HIV treatments access. Through support of the fund, Australia is better placed to contribute to the urgent need for treatments in resource-poor countries.

Contributions to the fund mean that Australia has input to Global Fund operations. Given the considerable expertise in Australia in the development, implementation and evaluation of HIV/AIDS programs in developing countries, this stands to complement fund activities.

The fund is already providing vital support to countries in this region. As security concerns escalate due to social and political instability, increased efforts to address the social and economic impacts of HIV/AIDS contribute to the region's stability. It is to

be hoped that future Australian governments will continue to support the fund and review the amounts pledged.

Future

While the fund's achievements have been considerable, it is not without its critics. The ability of the board to raise and guarantee continued financial support has real consequences for the fund's future. At a board meeting in Geneva in late June 2004 the launch of a fifth round of grant applications was postponed. Critics have been quick to accuse the donor countries that sit on the board of suspending the next funding round in order to delay (or suspend indefinitely) their donations to the fund. While Round 4 applications were approved at the June meeting, a consequence of delaying Round 5 grants is that this round contained the fund's largest commitment to treatment scale up programs and the opportunity for millions more people to receive HIV treatments.

Another criticism of the fund has been the slowness with which it has instituted one of the key forums in its structure, the Partnership Forum. This forum was identified as a core structure of the fund in its by-laws. However, its first meeting did not take place until July 2004, adjacent to the World AIDS Congress in Bangkok. The membership, role and functions of the Partnership Forum are considered to be a crucial mechanism for the contributions of people living with HIV/AIDS, tuberculosis and malaria and for increasing accountability and transparency in the fund's decision-making processes.

A further criticism has been that CCMs have not always adhered to or reflected the principles they are intended to follow. The idea of a cooperative partnership between government and non-government organisations is often new to many developing country regimes – if not an anathema. Representation on a CCM does not necessarily translate into full partnership or meaningful dialogue. In many places, government agencies are overly directive towards CCMs at the same time as they are the principal recipients for fund grants in those countries. The fund has recently been instrumental in dispatching Secretariat staff to a number of countries to review CCMs before further grant disbursements are approved.

It is not surprising that a venture as grand in scale and scope as the Global Fund should encounter difficulties in its operations. However, the achievements and potential of the fund far outweigh those difficulties. The successes to date should be seen as testament to the credentials and capacity of the fund

to deliver a global response to a global problem. However, it is only with the continued and expanded support of the world's wealthy nations, organisations and individuals that the fund can succeed. If these pandemics are to be stopped, such entities must be prepared to subvert their own strategic use of development aid, their own cultural constraints and the sponsorship of their own aid industries to allow the considerable amounts of money that are needed to be directed to the Global Fund.

Edward Reis, Education and International Programs Manager at ASHM, has 10 years experience in managing development projects in south-east Asia, was team leader for the AusAID Indonesia HIV/AIDS and STD Prevention and Care Project review of the Indonesian National AIDS Committee and National AIDS Committee Secretariat in 2002, and was lead consultant to USAIDS Indonesia on the development of the Indonesian National HIV/AIDS Strategy 2003-2007.

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Trade negotiations and treatment access

by Marina Carman

The impact of trade negotiations on access to affordable drugs in the developing world was brought into the spotlight when a number of US pharmaceutical companies took the South African government to court in 2001 over a government bill which aimed to increase access to cheaper essential medicines in certain circumstances. The companies argued that the bill contravened international patent rules as laid out in agreements within the World Trade Organisation (WTO). However, in the face of an international outcry, due to the disastrous impact of HIV in South Africa, the pharmaceutical companies backed down.

Despite subsequent moves within the WTO to address concerns about the impact of its negotiations on affordability of desperately needed medicines, unresolved issues remain.

The purpose of this chapter is to outline the agreements within the WTO which impact on access to affordable drugs and public healthcare services. These issues are of great importance in terms of HIV, due to the expense of the medication, the wide range of opportunistic infections requiring treatment, and the comprehensive and coordinated care which is needed. This chapter also covers the impact of mushrooming bilateral and regional trade negotiations outside of the WTO framework (including the US/Australia Free Trade Agreement).

TRIPS

The main international framework for patent law is the agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) within the WTO.

Patents give brand name companies exclusive control over the use of their product for a defined period – and have been justified as a way of compensating and encouraging investment in research and development. Patents became an issue in terms of HIV because of the massive gap between the price of brand name antiretroviral medicines (initially US\$10,000 to US\$15,000 per person per year) and the ability of those who most needed them to pay. The pricing of drugs needed to treat opportunistic infections, and diagnostic tests, also put these out of

reach in many countries. The return being demanded by pharmaceutical companies was considered by many to be unreasonable – especially given that the industry is the most profitable in the world¹.

A hugely important factor in bringing prices down has been competition with generic antiretrovirals – most of which come from countries such as India and Brazil which started out with minimal patent law. Where a patent has expired or in countries where one doesn't exist, generic versions can be manufactured and sold – generally at a much lower price.

Despite price reductions of brand name anti-retrovirals, generic versions are still much cheaper. Generic fixed-dose combinations (numerous anti-retrovirals combined in pills taken twice daily) now sell for as little as US\$140 a person per year. The same combination of brand name drugs (taken as six pills a day) costs five times as much.

Patents allow companies control over the price at which their product will be sold, and restrict competition with generic products. For this reason, increased patent protection has been sought through international trade negotiations.

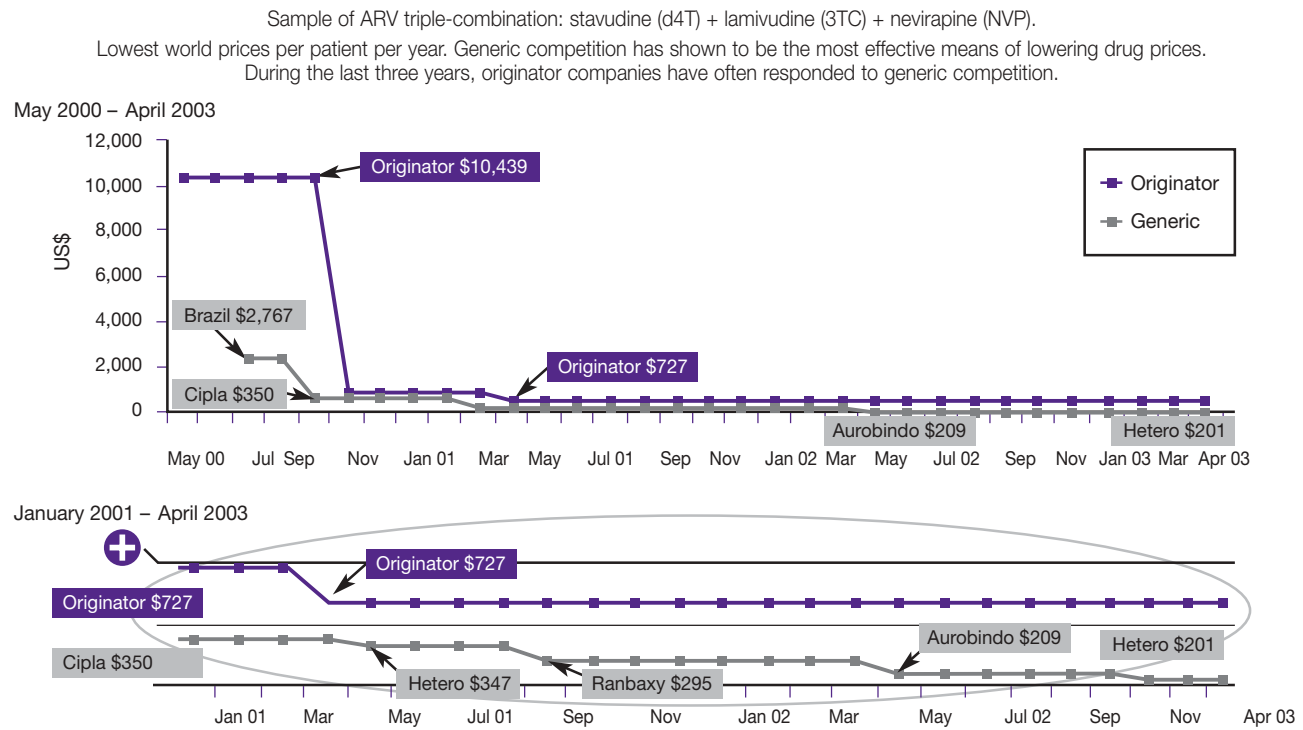
Throughout the Uruguay Round of General Agreement on Tariffs and Trade – a series of trade liberalisation talks which started in 1986 and which resulted in the formation of the WTO in 1994 – developed countries and pharmaceutical companies lobbied for stronger patent law. This resulted in the TRIPS agreement – which included measures such as extending patents from 10 to 20 years, increasing the range of patents, and strengthening punitive measures. All members are bound to implement laws in compliance with TRIPS – or face trade sanctions.

At the WTO ministerial meeting in Doha, Qatar in November 2001, the developed world responded to developing countries' concerns about access to medicines by delaying the deadline for least-developed countries to implement patent law consistent with TRIPS to 2016, officially recognising that nothing in the agreement should be interpreted to prevent members taking action to defend public health objectives, and reconfirming the ability of countries to use compulsory licensing. (WTO, 2001)

Compulsory licensing is domestic legislation which allows for the use of patented material within the country (outside of that permitted by the right holder) under certain circumstances. It can therefore

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Figure 5.1 The effects of generic competition



Source: Médecins Sans Frontières, *Untangling the Web of Price Reductions: a pricing guide for the purchase of ARVs for developing countries*, Geneva, May 2003. Used with permission.

be used to permit the manufacture or registration of cheaper generic versions of patented drugs.

A deadline was set for the end of 2002 to find a solution to the problems countries without adequate domestic manufacturing capacity faced in making use of compulsory licensing. TRIPS was ambiguous on whether generics could be imported/exported in such cases.

During subsequent negotiations, developed countries, and the US in particular, expressed concerns that cheaper drugs made available through compulsory licensing in such cases would be diverted to markets in developed countries – leading to price reductions. Parallel importing in general – the purchase of patented drugs from another country where they are cheaper, rather than from the manufacturer – is actually permitted under the Doha declaration. However, there is very little evidence of diversions so far.

Nearly a year later, negotiations eventually resulted in a ‘solution’ – with numerous conditions attached. A draft declaration was released by the chairman of the TRIPS council, Eduardo Perez Motta on 16 December 2002. The US blocked consensus on the ‘Motta text’ by continuing to insist on more conditions, such as limiting compulsory licenses to a set list of diseases.

Although the WTO is formally based on consensus decision-making, the eventual agreement was brokered during talks with only five countries: the United States, Brazil, India, South Africa and Kenya. On 30 August 2003, a draft agreement was released – based on the Motta text, with the addition of a statement from the Chairman of the TRIPS Council.

- 1) The agreement lists 23 relatively rich countries which have agreed not to issue compulsory licenses for importation under any circumstances. The text leaves open the space for identifying other countries to opt out. Under TRIPS previously, any country could issue compulsory licenses in particular circumstances, provided that they went through various procedures.
- 2) The agreement includes a general statement that the provisions not be used for ‘industrial or commercial objectives’. However, generic manufacturing in developing countries is generally undertaken by private corporations.
- 3) The importing country has to inform the WTO why it needs to buy the drug from another country (i.e. prove and defend it has insufficient manufacturing capacity). The country is also required to give full details of all imports.

4) The exporter can only manufacture the set amount it will export, and must inform the WTO of all details before hand. The drugs should have sizes, shapes and packaging that make them distinct from patented medicines. This limits the ability of generic manufacturers to make use of economies of scale. There are doubts as to what this new agreement will deliver. (Joint NGO statement, 2003) Fear of litigation and inexperience in contesting patent law may limit the ability of countries to make use of these provisions. The increased conditions on reporting open the door to disputes at the WTO, which are expensive and time-consuming. The current decision is only a temporary waiver. A permanent amendment to TRIPS is scheduled for 2004.

Beyond this agreement, however, there are broader concerns about the future impact of TRIPS – as more countries become compliant with strengthened patent law, and new, patented drugs come onto the market. India must become TRIPS-compliant by 2005, raising concerns about those countries which are dependent on its generics industry for cheap medicines and the active constituents needed in the manufacture of antiretroviral drugs. The vast majority of domestic manufacturers worldwide rely on India for the latter.

Greater competition with generics is important in bringing down prices, but on its own it will not ensure treatment access for developing countries. This is because newer medicines, and the widest range of medicines, will not always be available in generic form. For these reasons, and because competition with generics is still restricted, a system of differential pricing of medicines is sometimes proposed.

Pricing

In October 2002, the European Commission recommended a system which would allow developing countries access to drugs across the board at 80% of the normal price. Some pharmaceutical companies have raised concerns that this would encourage parallel importing and reference pricing – i.e. countries would trade the discounted medicines, and developed countries would also demand lower prices. (Oxfam, et. al., 2002)

These sorts of proposals have arisen because existing arrangements have not produced price reductions that are significant enough or generalised enough. Under the Accelerated Access Initiative launched by UNAIDS in 2000, developing countries were encouraged to negotiate special prices with the pharmaceutical companies. Results have been modest, and unevenly distributed across products and countries. The scheme did not include generic medicines, which were generally still cheaper than offers negotiated through the scheme.

In these circumstances, many countries have opted for a combined approach of negotiations through multilateral bodies, and direct negotiations with brand name/generic companies. Other significant deals have been brokered through the Clinton Foundation – securing cut-price medicines and diagnostic tests from brand name companies.

However, the overall problem with current pricing negotiations is that offers apply to specific products, and can run out or be withdrawn in the future. Some countries and organisations are in a better position to negotiate discounting than others. In addition, one-off offers do not encourage or assist long-term, sustainable healthcare planning in developing countries.

The best market mechanism for bringing prices down is to allow competition with generics. However, this is being restricted – not only under TRIPS, but through recent US challenges to the World Health Organization's pre-qualification program. (This program expedites the registration and use of drugs such as generic fixed-dose combination antiretrovirals and use in developing countries.) So, many are promoting the need for a generalised system which allows developing countries access to discounted medicines.

Beyond trade negotiations centred around patents, other concerns have been raised about the liberalisation of trade in services.

GATS

In both developing and developed countries, a strong public healthcare system is essential in ensuring: adequate access to care and treatment for poorer patients or marginalised population groups who suffer from HIV; the coordinated care needed for patients with HIV; the formulation of adequate public responses in terms of prevention, treatment and legal/ethical concerns; and the promotion of coordinated clinical and public health research. Experience has shown that adequately addressing the epidemic requires a long-term, coordinated approach aimed at treatment, prevention, education, poverty-reduction and improvements in general healthcare – which is likely to occur only with strong public sector involvement.

The General Agreement on Trade in Services (GATS) was also included in the initial brief of the WTO. GATS aims to liberalise trade in services through the gradual phasing out of government controls on international competition. GATS applies to all WTO members, with countries being liable for trade sanctions if they discriminate against an outside supplier. This could include such things as

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labour laws, consumer protection, local content laws, licensing standards or social equity requirements. At present, few services have been listed under GATS by member governments. The aim of negotiations is to gradually increase the number of services listed.

At the moment, GATS does not apply directly to public services, but it does apply to services which are provided on a commercial or competitive basis. The increased corporatisation of public services, and the existence of a parallel public/private health system, means that it is possible that in the case of a dispute, GATS could be interpreted to cover public healthcare. (Ranald and Southalan, 2003) Public services could be brought into GATS in the future by defining government payments to organisations (like public hospitals) as a subsidy, which should be open to competitive tender.

This has potentially significant implications for public healthcare in Australia. GATS could mean further steps towards a privatised health system, such as exists in the US. Under this system many cannot afford health insurance or access to healthcare, and the price of basic medicines is three to ten times the price of those in Australia. (Lokuge and Dennis, 2003)

The Australian government made its initial GATS offer public for the first time in April 2003. However, this initial offer could be changed at any time – with no guarantee of public discussion. The government has not agreed to calls to specifically quarantine public healthcare from GATS.

FTAs

Partly because negotiations within the WTO have stalled due to developing country dissatisfaction over the lack of movement on significant liberalisation in areas such as agriculture, the US and Australia are pursuing a range of bilateral negotiations. These are a means of pursuing an agenda of trade and investment liberalisation – and potentially pushing forward multilateral talks in the WTO.

Australia has signed free trade agreements (FTAs) with Singapore and Thailand, is pursuing negotiations with Japan, and considering a deal with China. The US has recently signed a Central America FTA, and FTAs with Singapore and Chile. In 2003 it launched bilateral free trade negotiations with twelve countries and announced its intention to begin negotiations with eight others. It continues to pursue a Free Trade Area of the Americas, and other agreements in southeast Asia, the middle east and southern Africa. (USTR, 2004)

A number of concerns have been raised about the impact of these agreements on public control of healthcare and access to affordable treatment – particularly where agreements are brokered between developing and developed countries. Opening up trade in these circumstances generally presents more benefits to the more economically powerful partner, and creates pressure on the less powerful partner to bargain away important public policies.

For example, the US and Australia have pursued the removal of certain restrictions on trade and investment in relation to services (including health), and tighter patent regulation through these agreements. The latter includes measures which have been termed ‘TRIPS-plus’. (For a detailed explanation of these see: MSF, 2004.) It is not surprising then that these agendas were replicated in an FTA deal between Australia and the US which was reached in February 2004. (For the full text of the deal, see: DFAT, 2003.) However, it is important to note that Australia is the less powerful partner in this case.

Despite the fact that many experts predict negligible economic gain or a net loss, the government has argued that greater economic integration with the US will benefit Australia. The original study commissioned by the government assumed totally free trade in agriculture yet predicted gains for the Australian economy of A\$4 billion a year, or only 0.3% of GDP after 10 years. (Australian APEC Study Centre, 2001) A later study by the same group released in May predicted a gain of A\$5.6 billion a year, or about 0.7% of GNP – yet the deal made little progress on agriculture. The increased estimate was based on modelling using a number of questionable technical assumptions. (Quiggin, 2004) In addition, concerns have been raised about the impact of the deal on numerous public services and policies. Most prominent amongst these has been health.

PBS

During negotiations, US pharmaceutical companies lobbied strongly in relation to the price control mechanisms of the Pharmaceutical Benefits Scheme (PBS). (Burton, 2003) At present the PBS includes a review process for medicines to be listed for public subsidy. The Pharmaceutical Benefits Advisory Committee provides an independent and evidence-based assessment of the relative efficacy and cost-effectiveness of medicines to be listed for public subsidy. The system allows for comparison between brand name medicines and relatively cheaper generic versions of drugs where patents have expired. It also maximises market power through a centralised buying system. (Harvey, 2004)

The FTA deal includes changes to the PBS review mechanism by allowing more right to appeal if a

product is rejected for subsidy. This allows more opportunity for US pharmaceutical companies to exert pressure to have their products listed – through lobbying and their massive legal and PR machines. It opens up the possibility of drugs being listed at higher prices than the PBAC originally recommended. The agreement also allows opportunities for pharmaceutical manufacturers to apply for an upward adjustment to PBS prices over time. There is, however, no provision for adjustment downwards.

In addition, a number of measures relating to intellectual property which were included in the deal potentially delay the entry of generic products onto the market after a patent expires. This limits the competition and price reduction which could occur – both within the PBS and with over the counter medicines. Relative price increases are a concern in relation to the latter because these are bought without government subsidies, concessional discounts or safety-nets.

The general objective stated in the deal is a harmonisation of intellectual property laws between Australia and the US. The US believes that Australia's laws are inadequate. However, Australia already has patent law which exceeds standards set out in TRIPS, and is amongst the strongest of all developed countries.

The FTA reaffirms Australia's voluntary restriction on compulsory licenses and parallel imports. It also reaffirms Australian provisions for the extension of patents by up to five years as compensation for the time taken to grant a patent. (This is not included in TRIPS.)

The deal sets a bad example in terms of undermining the use of 'bolar provisions', which were included in TRIPS and allow for the immediate release of generic products upon the expiration of a patent. Under this legislation, generic manufacturers can complete the marketing approval process before the expiration of a patent, and have access to test results for patented drugs provided to regulatory bodies while the patent is in force. Generic manufacturers can also argue for the registration of a drug based on bioequivalence – and thus do not have to repeat test and trial results.

The FTA reaffirms five years of data exclusivity – i.e. test results provided to regulatory bodies cannot be disclosed to a third party. (TRIPS requires general protection against unfair commercial use, but does not specify a period.) The deal also provides for more measures to ensure that generic drugs are not released onto the market before a patent expires – such as a stronger linkage between patent and regulatory bodies. Under the deal, patent holders will be notified when a generic manufacturer seeks marketing approval prior to the end of a patent. This all provides more opportunities for brand name

companies to legally challenge generic products – which may delay or prevent such products from being marketed.

Despite Australian government assurances that the PBS would remain intact, US Trade Representative, Bob Zoellick, has stated that prices of medicines would rise under the deal. (Garnaut, 2004) In a submission to the Senate Inquiry on the agreement, Drahos et. al. write:

Because most of the measures in the FTA apply to new drugs rather than existing ones, and because legislation will need to be enacted, regulations changed and new procedures put in place ... the full effect of the FTA on the pharmaceutical market is therefore unlikely to be felt for about five years. By that time, however, it is plausible that the gap between US and Australian drug prices could be cut in half. We estimate, very conservatively, that Australia's PBS will have to pay at least one third more for its drugs with the FTA than without it. (2004)

While this may not immediately be passed onto consumers, it will raise the cost of the PBS overall. Over time this could add to pressure to undermine the PBS or pass on more costs.

In general, the detail in the document is vague and open to interpretation. Drahos, et al., write:

Often, when trade negotiators cannot finalise contentious points of detail, they produce a text that is deliberately unclear on these matters and that can be sorted out later ... These ambiguous clauses allow each side to claim a 'win' ... But further consultation and dispute resolution processes will be put in place to sort these matters out later, outside of public and parliamentary scrutiny. (2004)

The deal establishes a Joint US-Australia Medicines Working Group 'to further promote the agreement's public health principles through an ongoing dialogue between the United States and Australia'. (Office of the United States Trade Representative 2004, p. 4) However, the agreement does not include the key principle of the Doha declaration, namely that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all. Instead, this group has been established along the lines of clearly commercial principles.

The disputes process established in the deal allows a government to argue that a law or policy contravenes the FTA, or is preventing it from getting the expected benefits from the FTA. Deliberations will be undertaken by a Joint Committee of governments, and then by a three-person panel of trade law

experts. It has not been made clear whether deliberations leading up to a decision will be public, or open to public comment. Decisions may not be appealed. This represents a restriction on the ability of citizens to decide on and influence public policy.

One further concern is that all laws and policies on investment and services at all levels of government are affected by the agreement unless they are listed as reservations. The only exceptions are existing (but not future) state government measures, primary education, and social services (but only insofar as they are 'established or maintained for a public purpose'). This raises the same problem outlined above in relation to GATS – potentially opening up a way for the US to force privatisation or request compensation.

Conclusion

TRIPS, GATS and FTAs have potentially significant implications for the future of affordable medicines and public healthcare. Yet these agreements are brokered behind closed doors and there is limited public consultation over the negotiating stance of governments. The South African case in 2001 had a major impact in increasing in public awareness around the issue of trade negotiations and HIV treatment access. Concerned professionals and organisations are continuing to pressure for increased transparency and maintaining health as a priority in trade negotiations.

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Notes

- 1 There is a questionable link between patent protection and increased research and development in relation to infectious diseases. Most of these diseases predominantly affect the developing world, which accounts for only a fraction of the global market in pharmaceuticals. Only 10% of global health research investigates the causes of 90% of the world's disease burden. (MSF, 2001: 10)

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Ethics, human rights and HIV

by Elizabeth Reid

This chapter explores the ethical and human rights issues associated with the HIV epidemic, especially those that arise in generalised epidemics and when the HIV epidemic spreads in situations of poverty or of limited resources.

Human rights discourses permeate activism and literature on the HIV epidemic. The Special Session of the General Assembly on HIV and AIDS in 2001 stated that:

Respecting, protecting and fulfilling the human rights of all individuals is indispensable to reducing the rates of infection, expanding access to care and treatment and mitigating the impact of the epidemic. (UN, 2001)

The complexity of claims to human rights

Disease-control measures have not traditionally been so firmly based on a recognition of human rights and fundamental freedoms. Public health policy prior to the HIV epidemic had often been founded on the belief that, if a danger to public health and safety could be proven to exist, then policies could be implemented overriding individual rights. The forced sterilisation of women, the isolation of lepers, mandatory contact tracing, quarantine, detention and exile have all been practised. The justification for such coercive measures has, at times, been only the fear of a danger.

The nature of the HIV epidemic brought the discussion of such measures into the foreground and created often strong divisions between those advocating compulsive strategies and those advocating educative or persuasive strategies. However, it should be noted that both sides had a common and humane goal: to lessen the toll in human suffering and death.

These differences were clear in the early days of the epidemic in Australia, where although some authorities advocated the mandatory detention of those infected, this curtailment of people's rights was rejected by the state. Discussion also persists in the international arena, most notably in terms of the

policies adopted by Cuba, where the government used the power of the state to advance what they defined as the collective good: the slowing down of the spread of the epidemic by limiting a small set of clearly defined civil liberties of those infected. Cuba has by far the lowest rate of infection in its region. This is an ethically complex issue.

It has been recognised that the curtailment of human rights to achieve a public health goal must be justified and, if such policies are adopted, the limitations should be of restricted duration and subject to regular review. The conditions under which such a limitation can occur are set out in the Siracusa Principles (WHO, 2002) and include, for example, that there are no less intrusive and restrictive means available to achieve the same objective, and that the restriction is provided for and carried out in accordance with the law. On the whole, the recent SARS outbreak honoured these conditions.

An extensive set of rights has been claimed for those infected with HIV: to marry, to bear children, to antiretroviral treatment, to equal protection under the law, to privacy, to life, to representation, to go to school, to non-discrimination, to work, to participate, to health and many more.

Claims for rights have also been made by what is often referred to as the 'general population': the right not to be infected, for example. At the time when Australia was developing its first national strategy on HIV and AIDS, the claim was often made that a balance needed to be achieved between the rights of those infected and of the general population.

Ethics and human rights

The ethical framework developed to guide the national response in Australia resisted this particular application of a human rights discourse. (Commonwealth Department of Health and Aged Care, 1989) In its place, the guiding principles state that each person is responsible for protecting themselves from HIV infection and for ensuring that they do not transmit the virus. This move from claims to human rights to a language of responsibility refused the division of the Australian community into those infected and the general population, and refused therefore the embedded accusation of blame and of pollution.

Instead, it developed a discourse of a shared, unifying responsibility; that each member of the Australian community bore a responsibility. It was acknowledged that this was a flawed or inadequate principle with respect to women and others who suffer rape and sexual abuse, but its enunciation was important to prevent the locating of this responsibility outside of the self in the marginalised 'other'.

This was an occasion when it was found that a human rights discourse was a less appropriate discourse for the situation.

The right to health

Let us look a little more closely at rights claims in the context of the HIV epidemic in settings of poverty.

Although often cited as the right to health, the full form of the right, as enshrined in international human rights law, is the right of everyone to the highest attainable standard of physical and mental health. Thus, this is not an absolute right. Mary Robinson, the former United Nations High Commissioner for Human Rights, states: "The right to health does not mean the right to be healthy, nor does it mean that poor governments must put in place expensive health services for which they have no resources".

The right is thus a claim to a set of policies, norms, institutions, laws, etc. – that is, to the constituents of an enabling environment that can best lead to the enjoyment of this right. (WHO, 2002: 11) It is an inclusive right, extending beyond healthcare to the determinants of health, such as access to drinking water, adequate sanitation, essential drugs, food security, freedom from violence, torture, slavery, discrimination and harmful customary practices, and access to information and education.

It is a right to be progressively realised. Mary Robinson continues: "it does require governments and public authorities to put in place policies and action plans which will lead to available and accessible health care for all in the shortest possible time".

The right to health is often broken down into more specific entitlements. One recent example is the right to access to antiretroviral therapy for HIV infection in resource-poor settings, contained in a resolution of the Commission on Human Rights on 22 April 2002. The Special Rapporteur of the Commission on Human Rights reporting on the right to health has also argued that the imbalance of research and drug development between the diseases of the poor and the diseases of the rich is a human rights issue.

Claims in a context of poverty

What sense can be made of claims to life or to health in the context of the HIV epidemic in situations of poverty or limited resources? Often these claims are reduced to a claim for treatment. But such reductionism needs to be resisted for it masks complex realities.

In order to more fully understand this, let us visit a small health facility dedicated to people with HIV in a low-income country. The HIV care centre is in the north of the country and is the only HIV-dedicated facility in a large area. It draws people from hundreds of kilometres away. Its fifteen beds are consistently full and its outpatients' clinics overflowing. It could accommodate more patients but the government would withdraw its funding if it did so, for the government has decided that non-government organisations (NGOs) should not run facilities larger than 15 beds. There are government health centres and hospitals in the region but there is a widespread refusal of care to those suspected or known to be HIV-infected, or hostile or denigrating attitudes on the part of the staff.

The official national figure for HIV prevalence is 0.7% of the adult population. In the districts in the north, the testing of antenatal women shows an average HIV prevalence rate for the region of 6%, with some areas showing 13%. It is a newly established epidemic and people are just beginning to fall sick in increasing numbers.

The HIV counsellor at the centre has been well trained and has continuing on-the-job supervision and training. However, he does not recommend condom use to the patients, for his parish priest told him that the virus can penetrate through the condom. The high regard in which he holds his parish priest as a source of information, coupled with his concern for his patients, has had a stronger effect on his behaviour than his counselling training.

Eighty per cent of new patients say that they heard about the centre by word-of-mouth. People who have been to the centre as patients, been cared for and healed, are returning to their neighbourhoods and villages and talking to others. They are breaking the silence and the social shame of the epidemic to reach out to others who they see are sick in similar ways, to tell them where to go and so to give them a message of hope.

The neighbours are not only 'referring' them to the centre, they are telling them exactly what would happen when they arrived and, if admitted, who to turn to, (i.e. staff roles and responsibilities). People arrive at the centre with the assurance of familiarity. Compare this to the uncertainty or bewilderment that can arise when the referral is a brief recommendation in a doctor's surgery.

Collaboration for Health in PNG



PNG participants at the ASHM conference 2003

Over 20 nurses and counsellors took part in a training course held in Mingende, Papua New Guinea, in March 2004. The course went for five days and included sessions on elements of quality comprehensive care, safety in the workplace, understanding the epidemic, natural history, building a care team, discrimination, language/questioning/counselling, grief and loss, and management of case studies (rape, cough, diarrhoea, neurological impairment). ASHM contributed to this training through a grant from the Pfizer Foundation and Pfizer Australia, under the aegis of a collaboration of pharmaceutical companies (the Collaboration for Health in PNG). Courses are planned in the future for other healthcare workers.

This project was developed in conjunction with a project to support people living with HIV to better understand the benefits to themselves of the habits of care, self-care and treatment adherence, and of working together to achieve their health and well-being goals. This project was funded by Merck Sharp and Dohme (under the aegis of the Collaboration for Health in PNG) and implemented by the National Association of People Living with HIV/AIDS.

Participants to the ASHM annual conference and associated training courses have been supported by the CHPNG over the last two years.

Photo source: ASHM

Few people arrive at the centre with illnesses not associated with HIV. This means that the symptoms are well-known by those who have been in care, if not by the larger community.

It is said that people in this country who know that they are infected are silenced and isolated from one another by their fear of disclosure and its social consequences. Yet here we have loops and flows of accurate, often complex, and often life-saving information within which disclosure essentially occurs. This is issue-centred confidentiality, rather than person-centred confidentiality – the sharing of significant information in situations shaped by shared concerns.

In this setting, the right to confidentiality becomes transmuted into a right to confidentiality beyond the immediate circle of family or community, what is sometimes called a right to shared confidentiality.

About 80% of those attending the care centre are men. HIV infection rates and morbidity are as high in women as in men. So there are forces at work here which determine that significantly more sick men reach the only HIV care facility in the region. One of these forces is that the referral flows are gendered: they flow amongst men but not to women in the same way.

There is no doctor at the centre. A local general practitioner, who has attended an HIV training course, makes ward rounds each day and attends the outpatients clinics. He, and the nursing staff, are supported by telephone consultations available any time, with an HIV specialist in the capital city, a seven-hour train ride away. The specialist provides these services free of charge as the NGO could not afford to pay him.

The centre has some drugs for most opportunistic conditions, except for tuberculosis (TB), where government policy requires that people receive treatment from its Directly Observed Therapy program, a requirement of which is that the person receive treatment in their village or town of origin. In its lack of respect for people's privacy, this requirement can deprive them of treatment. The centre cannot afford to provide antiretroviral treatment nor are its staff trained to administer and monitor these drugs.

Although the centre does not have antiretroviral drugs available, the doctors in its catchment area have begun prescribing monotherapy, and endemic poverty means that the treatment is often intermittent. Sometimes dual therapy is prescribed. The centre has had to strengthen its ability to deal with the consequences of these practices.

The centre is unable to carry out most diagnostic procedures other than clinical diagnosis. For this, the patient must take the train ride to the capital city, which means that he must be able to afford the cost of transport, lodging and treatment, and have a family member to accompany him, if he is too weak.

Thus, culture, household poverty, national poverty, prejudice, and many similar factors influence who has access to scarce health resources.

What does it mean to claim a right to life and to health in these circumstances? Is it a claim against the state to be pursued in a court of law? How can what constitutes the highest attainable standard of health be determined? How can the adequacy of its progressive realisation be assessed?

Or is the claim to a right to health a claim that decisions about the allocation of scarce resources need to be based on considerations beyond the analysis of health as a commodity, to health as a human right?

Or is it a claim for an ethical response to the situation of these women and men? Is it a claim for social justice, a claim for solidarity, what Paul Farmer calls a pragmatic solidarity (2003), a commitment to action.

Human rights law

Human rights law sets up the relationship between individuals and states in terms of claims or entitlements. Human rights are considered to be legally guaranteed by human rights law, protecting individuals and groups against actions that interfere with fundamental freedoms and human dignity. (UN, 1999: 3) Government obligations with regard to human rights are to respect, protect and fulfil, where the obligation to fulfil includes to facilitate, provide and promote. (UN, 2000)

The seminal documents for human rights law are the Charter of the United Nations, adopted in 1945, and the Universal Declaration on Human Rights, adopted in 1948.

The two major human rights treaties were adopted in 1966: the International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights. Since then numerous treaties, declarations and other legal instruments have been adopted and it is these that encapsulate human rights law. International human rights treaties are binding on governments that ratify them.

The rights enshrined in these treaties include the rights to: equality before the law and non-discrimination, privacy, life, health, education, work, and development.

Human rights law provides an opportunity to use the institution of the law to achieve one's ends. It also forces us to think about the areas in which one would want judges to intervene and make laws relating to HIV, given its sensitivities and complexities?

For example, is the claim of the right of HIV-infected persons to marry a matter on which we would want a judge to rule or is it a matter to be discussed, argued and worked out within families and communities? In societies with strong customary law traditions, this is an issue that would come before the council of elders or a similar body rather than the modern law court. Discussions within community fora can lead to the questioning of community attitudes and norms and to a greater under-

PNG Prescribers' course

The Prescribers' Course in HIV Medicine and Antiretroviral Prescribing, staged in Madang, Papua New Guinea from 6 to 8 February 2004, was planned by the PNG National Department of Health, the PNG National AIDS Council Secretariat, and the National HIV/AIDS Support Project and was funded by AusAID. Over 40 attended. Assistance in the development and delivery of the course was supplied by ASHM and by the HIV & HCV Education Projects of the School of Medicine, University of Queensland. The course was planned to assist medical practitioners in PNG in prescribing HIV antiretroviral therapies in accordance with the newly formulated *Guidelines for the Use of Antiretroviral Therapy in PNG* (November 2003).

standing of the impact of stigma and humiliation on the lives of those infected.

Another example is the claim made to a right to bear children. In situations where people do not have access to antiretroviral treatment, and so their life span might be limited, how do we think through such a claim? Do we use the language of rights and argue that the right of the adult to bear children needs to be balanced against the right of children to have parents during their formative years? Do we leave it to a judge to determine how to balance such rights? Or is this something that couples work through in the settings of their relationships? For if it is the latter, the language of rights might be less helpful than the language of responsibilities: If we wish to bring a child into the world, what are our responsibilities to that child? How can we plan a future in which he or she would be protected and nourished?

These two examples show that often the use of a language of rights is an advocacy tool, a way of drawing attention to a difficult issue, a way of creating community discussion of a complex situation, rather than a reference to a body of human rights law.

However, there are three key areas where a resort to human rights law would provide an effective instrument:

- the right of HIV-infected and affected persons to protection from unlawful discrimination;
- the right of HIV-infected and affected persons to privacy, where this right guarantees bodily integrity; and
- the national right to be able to protect public health and provide access to medicines for all.

These HIV-relevant human rights need to be entrenched in national legislation. They are policy areas that appropriately fall within the ambit of a court to determine.

A human rights-based approach

As well as a discourse of claims of human rights, there is another discourse of a human rights-based approach to health or to HIV. This discourse applies the notion of human rights to particular contexts. This approach is a set of practices, rather than principles or laws.

It argues the links between health, or HIV, and human rights: that violation of human rights can cause serious health problems; that health policies can promote or violate human rights; and that vulnerability and the impact of ill health can be reduced by taking steps to fulfil human rights.

The approach identifies the strategic principles which must be honoured. These include: respect for human dignity; attention to those populations most vulnerable to ill health; ensuring that health systems are accessible without discrimination; ensuring gender equitable services and outcomes. These strategic principles are explicitly linked to international human rights norms and standards.

Thus a human rights-based approach to health can be contrasted to a conception of health as a commodity, amenable to free market forces, where cost-effectiveness provides the algorithm for decision-making. The health priorities and practices determined by each approach would be significantly different, if only because the provision of care for the destitute, the socially dysfunctional, and the scorned comes with a higher price tag than the provision of services on a user pays basis, for example.

In the case study above of access to HIV care and treatment in an impoverished rural area, a human rights-based approach provides a way of structuring our understanding of the situation, but also of seeking strategic entry points for change.

An ethical discourse

There is also an ethical discourse on the difficult issues raised by the HIV epidemic. Let us look at the complex issues surrounding the prevention of transmission from mother to child. This discussion is often couched in a language of rights, in particular the right to life of the child. Let us see what an ethical approach might reveal.

The first thing to question is the term used to describe the intervention – which could in itself be an instrument for blaming the woman for the infection of her child. This is especially problematic given that the majority of women are infected through the behaviour of their husbands or regular partners. It is

in response to a growing sensitivity to this that the intervention is now widely called ‘parent to child transmission’.

There is agreement that the birth of a child infected with HIV is a tragedy to be avoided wherever possible. There is not agreement as to the best use of scarce resources in these circumstances.

Should the resources be used to prevent as many children as possible from being infected? Or should consideration be given to the likely life that a child will lead if it is born uninfected only to lose its parents in early childhood? Some of these children may well be taken into the extended family or fostered, but this will vary from culture to culture. Many will end up on the streets, faced with the likelihood of starvation or coping by being recruited into prostitution, banditry or as child soldiers.

Who should make the decision about how the resources get used? In one small programme in the suburbs of Blantyre in Malawi, the mothers thought this through and asked the programme directors whether they could be treated so that they could stay alive to take care of their children. They then thought further and returned to ask whether their husbands and other infected children could also be treated.

The community thought through the consequences of a programme to save their children’s lives and argued for radical change. They applied a contextual analysis, one that took a longer time-frame than just the birthing, one that looked into the consequences of the intervention especially in terms of the pain and suffering of the orphans, and came up with a different proposal. So, in that suburb now, instead of, let us say, 1,000 children being born with a significant chance of being uninfected, about 300 families are receiving treatment so that they can survive as a family unit, providing care and support to their children so that they have some chance of a better life.

The community decided what sort of future it wanted for itself, what values it wanted to live by. It then used that vision to determine how the scarce resources be allocated. They did this in the full knowledge that only some of them would be able to access treatment. There was no discussion of rights.

These considerations have led many to replace programmes to interrupt transmission to the child with programmes to treat families, sometimes called ‘parent to child transmission plus’.

At the heart of an ethical discourse lies the question of the kind of society that we want to live in, of the values by which we want it structured. Often the language of rights is not a claim to a legal entitlement but rather a way of evoking the values of social justice, equity and solidarity.

An ethical approach in settings of poverty

This can be seen most clearly, perhaps, in the case of access to treatment in resource-poor settings. This is a situation where even an accepted right to treatment can only be progressively realised. How are scarce resources to be allocated? Different approaches have been advocated with often quite different ethical principles underlying them.

In all resource-poor settings, there are those who can afford treatment. Often little is required to expand access to treatment in this group. Should any opportunity to make treatment more available be seized, even where this would worsen already-existing inequities?

It might be argued that anything that enables even one more person with HIV to have access to treatment is ethically justifiable. However, making treatment available to those already relatively well endowed may result in injustice to the many others who are not so fortunate.

Many different criteria have been considered or adopted for the allocation of scarce treatment drugs. Some have given priority to widows and children. Others have given priority to healthcare workers, to HIV educators and advocates, to the rural poor. Some have argued that people in positions key to the continuing functioning of the state should be given priority. On what grounds can such decisions be made? And who should make them? What will happen to those without access?

There are no easy answers to these questions with which people all over the resource-poor world are grappling.

Compassion and social justice

Perhaps once again the problem lies with the technological focus of the question. Drugs exist; they can be used. However, the contextual factors need to be included in the analysis. People are embedded in dense networks of social and power relationships: gender, class, caste, ethnicity, opportunity, wealth, education, etc. To talk about giving the poor priority access, or women access, is to reduce them to a single determining influence on their lives.

Could an approach be developed based on people's respect for the principles of social justice and compassion?

One proposal that has been made is that treatment access programs should be started in those hospitals or health care centres where good-quality care is already being given to people with HIV, care which respects the dignity of the person, which

draws their family and social support networks into the provision of care, which improves in multiple ways the quality and length of their lives. One remarkable characteristic of this epidemic is that it has drawn into its ambit quite remarkable people, people dedicated to working with others, in a spirit of commonality and support.

Perhaps the complexity of these issues can be simplified by working with these committed people. Thus other criteria are replaced by the proven capacity for empathetic and effective service delivery. This is another way of putting people at the heart of the response to the epidemic.

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Notes

- 1 Another approach argues that a first generation of rights flow from the American Declaration of Independence of 1776 and the French Declaration of the Rights of Man in 1789. See, for example, Rich (2002: 23). It is also argued that the modern human rights movement began with the Nuremberg trials, or the mobilisation against Leopold's exploitation of the Congo, or the campaigns against slavery.

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- UN [United Nations], General Comment 14, Section II.33, Footnote 23, Committee on Economic, Social and Cultural Rights, May 2000. (E/C.12/2000/4. CESCR, dated 4 July 2000)
- UN [United Nations], General Assembly document A/S-26/RT.2, Special session of the General Assembly on HIV/AIDS, Geneva, June 2001.
- WHO [World Health Organization], *25 Questions & Answers on Health and Human Rights*, WHO Health and Human Rights Publication Series, Issue No. 1, July 2002.

Web links to international resources

Note: ASHM makes no claims or warranties as to the validity of the information found on these pages and cannot be held responsible for the content. The links found below are a service only – not an endorsement – and are provided by ASHM in the hope that they may be useful to some readers.

AIDS Info [A service of the US Department of Health and Human Services]

<http://www.aidsinfo.nih.gov>

US national guidelines.

AIDSmap

<http://www.aidsmap.com>

News, publications, training materials, email lists, database of international organisations.

AIDS Education and Training Centers – National Resource Center

<http://www.aids-ed.org>

Training tools and clinical resources – based on US national guidelines.

AusAID

http://www.ausaid.gov.au/hottopics/topic.cfm?Id=2188_6118_4743_4010_8545

Australia's International response to HIV/AIDS July 2004.

Coalition of Asia Pacific Regional Network on HIV/AIDS

<http://www.7sisters.org>

The 'Seven Sisters' is a broad-based alliance bringing together seven regional networks. See the primary ASHM links page for details of similar and allied organisations.

Consumer Project on Technology

<http://www.cptech.org/ip/wto/index.html>

Page on intellectual property issues in the World Trade Organisation. Email list.

Family Health International

<http://www.fhi.org/en/HIVAIDS/Publications/manualsguidebooks>

Training resources and manuals.

Global Fund to fight HIV/AIDS, Tuberculosis and Malaria

<http://www.theglobalfund.org/en/links>

Toolkit for access to medicines and diagnostics for HIV/AIDS, TB and malaria.

HIV Insite – Center for HIV Information

<http://hivinsite.ucsf.edu/global?page=cr-00-04>

Listing of all international treatment guidelines.

International HIV/AIDS Alliance

<http://www.aidsalliance.org>

Amongst other publications and resources, this site hosts the HIV/AIDS NGO/CBO Support Toolkit – a website and CD-Rom with over 500 downloadable resources and supporting information.

Joint United Nations Program on HIV/AIDS

<http://www.unaids.org/en/resources/publications.asp>

Search facility for all HIV/AIDS-related titles published by UNAIDS and other organisations in the UN system.

Médecins Sans Frontières

<http://www.accessmed.msf.org/>

Information on treatment access campaign; resources on clinical care and drug pricing comparisons.

The Forum for Collaborative HIV Research

<http://www.hivforum.org>

Information on projects.

TREAT Asia [Therapeutics Research, Education, and AIDS Training in Asia]

<http://www.amfar.org/cgi-bin/iowa/asia/index.html>

Information on the initiative. Hosted on the site of the American Foundation for AIDS Research, which also includes publications and training materials.

World Health Organization – 3x5

<http://www.who.int/3by5/en>

WHO treatment guidelines for resource-poor settings; the 3x5 initiative; various publications and training resources.

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