

Access to treatment for HIV and AIDS in Resource Poor Settings:

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*“These guidelines [Scaling Up Antiretroviral Therapy in Resource-Limited Settings] offer a chance of hope to those who despaired. They affirm the human rights and dignity of people living with HIV. They represent an opportunity to build upon the solidarity and energy of the global movement against HIV/AIDS by redressing the inequalities between rich and poor in access to care.”*¹

¹ Tomris Türmen, [2002], *Family and Community Health*, World Health Organisation, Geneva.

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INTRODUCTION

This literature review was commissioned by Soul City. This review is part of the preparation for *Soul City Seven*.

The struggle to control the spread of HIV and save the lives of people living with the virus has been a turbulent one. The South African government's notorious position is well known. The battle by activists, challenging the AIDS policy of the Minister of Health and the Department of Health ended up both on the streets and in the courts.

There has been a significant development that has come about largely as a result of this pressure being brought to bear on policy makers by civil society. On the 8th August 2003 the South African cabinet issued a statement², which endorsed the use of antiretrovirals [ARV] in public health facilities. The government has also set up a task team to ensure the effective roll out of ARVs in public hospitals and clinics. The terms of reference for this task team are very comprehensive and if they are carried out with political will and commitment, we could be seeing the impact of treatment and proper management of HIV. Lives will be saved and the quality of lives of millions of people living with HIV will be improved. We will also soon be witnessing a significant decrease in numbers of new infections of the virus.

Between 5 and 7 million South Africans are expected to succumb to AIDS by 2010³ and the country is predicted to have more than 2 million orphans⁴ by the same year. This is the background against which this review is being drawn up. Within this context the review will focus on access to treatment for HIV and AIDS in resource poor settings by making reference to selected literature demonstrating how access to ARVs provide significant opportunities to impact on mortality and morbidity.

The key arguments that are presented supporting the provision of ART in the public health sector are:

1. Its impact on prevention – and thus on people who are HIV negative
2. That it is cost effective in the long run
3. Its positive impact on morbidity and mortality patterns.

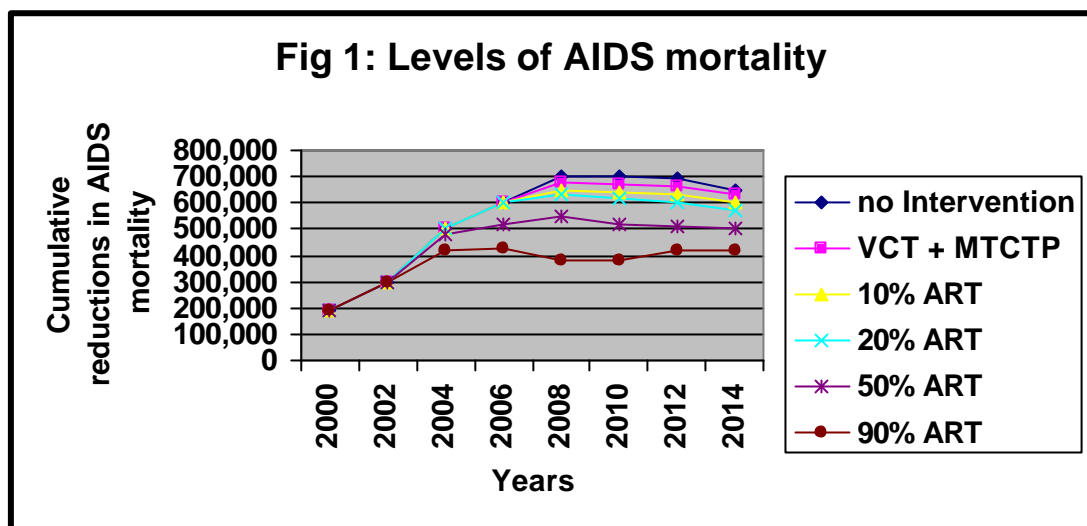
Figure one demonstrates the impact of a phased implementation of ARVs in South Africa on mortality⁵.

² South African Cabinet, (2003), "Cabinet Statement on HIV/AIDS – Programme on HIV and AIDS, 8th August 2003

³ Dorrington R, Bourne D, Bradshaw D, Laubscher R, Timaeus IM.[2001] *The Impact of HIV/AIDS on adult mortality in South Africa*, South African Medical Research Council.

⁴ Ibid

⁵ Ibid



Definition of treatment

Treatment can be given a narrow definition that limits treatment to therapy that attacks the virus and impacts on its ability to replicate in the body and limits the meaning to anti-retroviral therapy.

Or it can be given a broad definition, which includes access to quality pre- and post-test counselling, wellness management and the prevention and treatment of opportunistic infections.

There is a range of medical, social and psycho-social interventions available that can prolong health and slow down the immune suppression caused by HIV. According to guidelines produced by the Southern African HIV Clinicians Society⁶ for antiretroviral therapy in adults the primary goals of antiretroviral therapy are:

- Maximal and durable suppression of viral load;
- Restoration and/or preservation of immunological function;
- Improvement of quality of life;
- Reduction of HIV-related morbidity and mortality.

The Vaccine Initiative

The possibility of developing a vaccine to control the AIDS epidemic needs to be considered in the context of prevention and treatment of HIV. We need a tested and proven vaccine that is affordable and accessible to all and designed for the strain of HIV prevalent in Africa. Scientists predict that this will take at least ten years to finalise. With no other intervention in between, we can expect to see the continued and increasing numbers of premature deaths of young people on a scale unprecedented in the history of any epidemic. So treatment and the management of HIV and AIDS remain crucial as long as there is no cure for AIDS or a vaccine.

Alan Whiteside⁷ says that: “Many believe the best hope for controlling the epidemic is a vaccine. Such a vaccine seems a long way off and even if one were

⁶ Andrews S, Cotton M, Maartens G, Martin D, Miller S, Wood R, Spenser D, Venter F (2002), *Antiretroviral therapy in adults* – Southern African HIV Clinicians Society Clinical Guidelines

⁷ Barnett T, Whiteside A, (2002), *AIDS in the Twenty-First Century Disease and Globalisation*.

developed it would need a high level of efficacy. The danger is that a vaccine might give people a false sense of security and actually increase the spread of HIV. Vaccine development is resource intensive and most research is in the rich world. Such vaccines may not be appropriate or affordable for the poor world. The challenge is to find a solution that is acceptable, effective, affordable and deliverable.”

Making the argument for access to Highly Active Antiretroviral Therapy [HAART]

The overriding objective of the review is to present substantiated arguments supporting the view that access to Highly Active Antiretroviral Therapy [HAART] for people living with HIV and AIDS is a critical component in any policy being developed to address the AIDS epidemic. The scope of the topic is vast. The fact that access to treatment has become very politicised increases the scope of the issue even further. Each aspect of treatment and management of HIV and AIDS qualifies for a literature review of its own.

The format of the review is as follows. The issue of access to treatment is contextualised by presenting facts, figures and the impact of HIV and AIDS. This will include socio-economic inequalities, which further exacerbates the impact of the epidemic. It presents the arguments against the use of HAART often presented by AIDS denialists, and attempts to counter this with reference to specific literature based on practical experience and sound scientific practice.

Information supporting the argument that it is possible to implement a comprehensive country treatment plan in resource poor settings, which includes HAART will be provided. Real impediments to provision of treatment like, access to treatment in the context of globalisation, trade laws and monopoly of world markets by giant conglomerate pharmaceutical companies will be discussed. The review also presents information on how various countries faced with similar conditions have overcome these impediments. It provides an overview of guidelines developed by international bodies, on how to make ARVs accessible and effective in resource poor settings.

The case will be made as to why treatment and prevention of HIV and AIDS are two sides of the same coin. The argument for access to treatment will be made in the context of ending stigma and discrimination as well.

The review presents arguments demonstrating what the core components of access to treatment as a plan entails and the dangers of not having a policy with proper protocols and guidelines for the use of ARVs in place. Current policy of the Department of Health [DoH] on HIV/AIDS will be looked at and what is available but currently falls outside of government policy.

The review follows the format of presenting key arguments made in a range of literature. The arguments are often repeated in different papers presented. Given that each paper is based on experience and expertise in different parts of the developing world, it reinforces the argument for access to HAART and makes for a more compelling case.

The last section of the review then provides information on other aspects of the management and treatment of HIV and AIDS as appendices.

1. Appendix One -Guidelines And Policy Documents On Aspects Of The Management and Treatment of HIV (Not ARVs) produced by the DoH, SA Government
2. Appendix Two - Nutrition and management of HIV
3. Appendix Three - Campaigns on constitutional rights for decent health care; trade agreements impacting on access to treatment and local and international agreements.
4. Appendix Four - Trade agreements and access to cheap and affordable treatment.
5. Appendix Five - How communities are mobilising and campaigning to make access to treatment and decent health care a basic human right. A few case studies.

EPIDEMIOLOGY & IMPACT OF HIV AND AIDS

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organisation (WHO), the number of people living with HIV by the end of 2002 was estimated to be 42 million. In Sub-Saharan Africa, more than a quarter of young adults are infected with HIV.

The picture of the epidemic in Sub-Saharan Africa: HIV Prevalence

A global summary of the HIV/AIDS epidemic

Global summary of the HIV/AIDS epidemic December 2002 ⁸	
Number of people living with HIV/AIDS	Total 42 million
Adults	38.6 million
Women	19.2 million
Children under 15 years	3.2 million
People newly infected with HIV in 2002	Total 5 million
Adults	4.2 million
Women	2 million
Children under 15 years	800 000
AIDS deaths in 2002	Total 3.1 million
Adults	2.5 million
Women	1.2 million
Children under 15 years	610 000

The above information is available in the recently published document by the United Nations AIDS programme. The document provides a global summary of the HIV/AIDS epidemic, and has a chapter dealing with sub-Saharan Africa. This region is described as being the worst affected in terms of the epidemic, with a total of approximately 29.4 million people living with HIV/AIDS in sub-Saharan Africa. The epidemic is still growing in some countries and the entire region accounted for 3.5 million new infections in 2002. The total number of people who died of AIDS is estimated at being about 2.4 million Africans in 2002 alone. Ten million young people (aged 15-24) and almost 3 million children under 15 are living with HIV.

Recent estimates suggest that of all people living with HIV in the world, 6 out of every 10 men, 8 out of every 10 women, and 9 out of every 10 children are in Sub-Saharan Africa. These figures provide sufficient evidence to make HIV/AIDS a national, regional and continental priority.

Impact of the AIDS Epidemic in South Africa

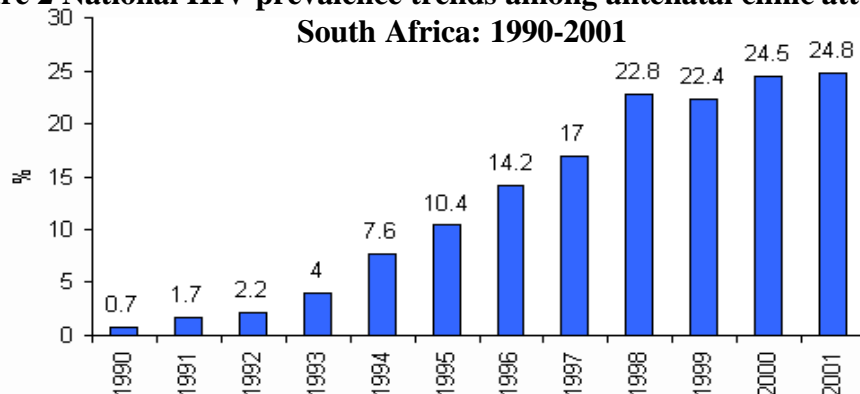
While many political parties have attempted to use the AIDS epidemic as a football to score points, we need to separate this opportunism from the fact that AIDS is a very political issue. It is political in the context of globalisation. AIDS is a poverty related illness and is exacerbated by social inequalities. In his book which looks at

⁸ Joint United National Programme on HIV/AIDS (UNAIDS) and World Health Organisation (WHO), (2002), "AIDS Epidemic Update 2002.

health and well being, Whiteside⁹ explains that these are not individual concerns, but are global issues. The book looks at the social and economic impact of the HIV and AIDS epidemic. It places the epidemic in the current South African context of denial, and then attempts to analyse the epidemic starting with the individual and broadening this out to look at Africa, and ultimately a global response.

Figure Two below is a graph reflecting data from the Department of Health's [DOH] annual National HIV Sero-Prevalence surveys¹⁰ of pregnant women attending antenatal clinics for the past 10 years and provides a good estimate of HIV prevalence and trends over time in South Africa. Based on the 16 730 blood samples tested for HIV during the survey in 2001, it is estimated that nationally, 24.8% of pregnant women were infected with HIV by the end of 2001. This is in comparison with a prevalence rate of 24.5% recorded for 2000. Whilst this rate of infection is high and presents us with a significant public health problem, the findings appear to indicate that there is not a statistically significant growth in the epidemic from the previous year. Figure 2 shows that the national prevalence rate of increase has slowed in its increase since 1998. This is referred to as a levelling off, plateau or stabilisation in growth.

Figure 2 National HIV prevalence trends among antenatal clinic attendees in South Africa: 1990-2001



It is estimated that by the year 2005, there will be 6 million South Africans infected with HIV and almost 1 million children under the age of 15 whose mothers will have died of AIDS.

The DoH should be providing a more comprehensive report based on an analysis of the information being collected nationally. This kind of data, based on statistics collected at primary health care level and including urban, rural, and informal geographic settlements, can assist in determining HIV and AIDS policy and priorities.

Also of concern is the fact that results of this prevalence study used to be provided in March of the following year, the 2001 results were only released in June 2002, and the 2002 results were not yet released by August 2003.

A study was commissioned by the Nelson Mandela Foundation and conducted by the Human Sciences Research Council¹¹. These findings were released in 2002. This is the first nationally representative study of HIV prevalence. Currently

⁹ Refer to footnote 7 above.

¹⁰ Department of Health: 1990-2001 "National HIV Sero-Prevalence Survey of Women Attending Public Antenatal Clinics in South Africa".

¹¹ Human Sciences Research Council (HSRC), (2002), "Nelson Mandela/HSRC Study of HIV/AIDS South African National HIV Prevalence, Behavioural Risks and Mass Media, Household Survey

government extrapolates national infections rates on the basis of results obtained from sero-prevalence surveys of women attending antenatal clinics¹²

One has to be cautious about research that draws conclusions based on surveys questioning behavioural responses as there is always an element of participants saying what they think is the right thing to say and not necessarily reflecting their own behaviour. In spite of this, this research provides useful insight into some trends and the impact of the epidemic in South Africa. Some of the key findings of the research include the following:

1. That 11.4% of South Africans (4.5 million people) are living with HIV/AIDS
2. That more people are practicing safer sex since the Demographic and Health Survey conducted in 1998.
3. While African women aged 25-29 who live in informal settlements are most at risk of HIV infection, the study shows that HIV/AIDS can affect anyone irrespective of race. Overall people living in urban informal settlements were most at risk of HIV, with a prevalence of 21.3%.
4. Breakdown on the basis of gender showed that 12.8% of females tested HIV positive, while 9.5% of males tested positive. Among the youth (15-24), double the number of females (12%) was infected as males (6%).

There is little empirical information about the impact of AIDS and there is an urgent need to improve surveillance of AIDS morbidity and mortality. In 2002 a survey of households affected by HIV/AIDS in South Africa was published which was commissioned by the Kaiser Foundation.¹³ The key findings of the report are that, while no sector of the population is unaffected by the HIV epidemic, it is the poorest South Africans who are most vulnerable to HIV/AIDS and for whom the consequences are inevitably most severe. The report also documents the impoverishing impact of HIV/AIDS on households and the inordinate burden of caring for AIDS-sick family members.

The findings confirm that children are worst affected. This was by way of increasing childhood malnutrition – almost half of the households in the survey reported having insufficient food at times and that the children in these households often went hungry. The longer-term ramifications of the HIV epidemic are deepening poverty among the already poor; disruption and premature termination of schooling for children, especially girls; increasing early childhood malnutrition; and increasing strain on extended family networks.

Both the surveys under review make compelling arguments for the provision of a comprehensive HIV/AIDS treatment and prevention programme. Steinberg's¹⁴ findings, for instance, reveal that 40% of households reported that the primary caregiver had taken time off from formal or informal employment or schooling to take care of the AIDS-sick person adding to the loss of household income and the under-schooling of girls. Forty four percent of the households in the survey had a monthly income of less than R1000. Two thirds of these households reported loss in income as a consequence of HIV/AIDS. Increased expenditure on medicines and

¹² refer to footnote 10 above.

¹³ Steinberg M, Johnson S, Schierhout G, Ndegwe D, (2002) *Hitting Home: How Households Cope with HIV/AIDS*, Health Systems Trust, Durban.

¹⁴ Ibid

medical care, and the high costs of funerals are also contributing to the financial burden.

“The recurring hospital visits and treatment are a direct consequence of a lack of a proper response to the epidemic through the public health care system. So people have to pay for the cost of travel, repeat treatment for opportunistic infections that keep coming back and other related costs.”¹⁵

This scenario can be reversed with a proper programme to manage HIV and AIDS which includes the provision of ART. The person living with HIV will be able to live a life of dignity and will be healthy and able to carry on with his or her normal life.

GOVERNMENT POLICY ON THE MANAGEMENT OF HIV AND AIDS

“TAC’s intervention in the PMA case, rather than attempting to emasculate state power, aimed to assist the government to defend its right to pass legislation to fulfil its constitutional obligations to progressively realize rights of access to health care services”¹⁶

In 2000 the Department of Health developed a 5-year strategic plan to deal with HIV and AIDS.¹⁷

The Strategic Plan is structured according to the following four areas:

- Prevention;
- Treatment, care and support;
- Human and legal rights; and
- Monitoring, research and surveillance.

Of relevance to this review is priority area number two “Treatment, Care and Support”. The goals of this priority area is to:

- Provide treatment, care and support services in health facilities
- Provide adequate treatment, care and support services in communities
- Develop and expand the provision of care to children and orphans

The section on Treatment Care and Support looks at the following as strategies to carry out the key objectives of this goal:

- Developing guidelines for the treatment and care of HIV/AIDS patients in health facilities and the community
- Ensure uninterrupted supply of appropriate drugs for the treatment of opportunistic infections and other related conditions
- Build capacity of health professionals to provide comprehensive HIV/AIDS/STD/TB treatment, care and support
- Establish strong links between health facilities and community-based support programmes

¹⁵ Ibid

¹⁶ Heywood, M (2001), *Debunking ‘Conglomo-talk’: A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation.*

¹⁷ Department of Health [2000]. *An Enhanced Response to HIV/AIDS and Tuberculosis in the Public Health Sector – Key Components – 2002/03 – 2004/05*

- Improve prevention and treatment of TB and other opportunistic infections
- No specific reference is made to the use of ARVs or developing appropriate protocols and guidelines for use and management in the public health sector. In a progress report entitled “Tracking Progress on the HIV/AIDS and STI

While all of these are vital components to a comprehensive HIV and AIDS Prevention and Treatment Strategy, the Government’s five year strategic plan for HIV and AIDS is lacking in the following crucial areas.

The most contentious point about this five-year strategic plan is that it excludes the provision of ARVs at primary health care level in South Africa. The most recently issued statement by the South African Cabinet¹⁸ marks a shift in this policy.

The key problem South Africa is experiencing with respect to the implementation of an AIDS policy is lack of political leadership starting at a national level. The other weakness is that there are very few mechanisms in place to monitor progress, collect data and use this to reform policy and programmes accordingly.

The last two years has witnesses a dramatic change in the face of the epidemic in our country. We are now in the AIDS phase of the epidemic. Official statistics put the number of deaths as a result of AIDS related illnesses at approximately 600 a day.¹⁹ According to a report issued by the Joint Health and Treasury Task Team²⁰ patients infected with HIV who have moved on to develop AIDS is currently estimated at between 400 000 and 500 000.

The face of the epidemic has also changed. At the onset of the epidemic people were referred to as AIDS sufferers and victims. The picture painted of someone who had HIV was one of a skeletal figure or one facing imminent death. Two things have changed this drastically. HAART has changed this reality and made HIV and AIDS a chronic illness as opposed to a death sentence. But this is only if you can afford the treatment. The other significant development in response to this is the growth of an international movement campaigning for quality of life, access to treatment and an end to profiteering on essential living saving drugs. This form of activism has resulted in critical victories in the struggle to combat the spread of the HI virus and save the lives of millions of people living with HIV.

The South African Government’s Response to the epidemic

Since 2002 to date three significant statements have been made by cabinet addressing the shortfalls of current policy on HIV and AIDS. The first was made in April 2002²¹, which for the first time acknowledged the use of ARVs in the management of HIV and AIDS. Of significance was the commitment by government to provide a comprehensive package of care for victims, including counselling, testing for HIV, and STIs for cases of sexual assault. The provision of

¹⁸ Report Of The Joint Health And Treasury Task Team Charged With Examining Options To Supplement Comprehensive HIV/AIDS Care In The Public Health Sector [2003]

¹⁹ Government Statistics indicating that 200 000 people are dying per annum of AIDs related illnesses.

²⁰ Joint health and treasury Task team charged with examining treatment options To supplement comprehensive care for HIV/AIDS in the Public health sector – issued by the Joint Health / Treasury task team – 01 August 2003 and its annexures available online at <http://www.gov.za/issues/hiv/ttr/index.html>. The 82-page report itself is at <http://www.gov.za/reports/2003/ttr010803final.pdf>.

²¹ South African Cabinet, (2002), “Cabinet Statement on HIV/AIDS, 17th April 2002

ARVs as post exposure prophylaxis (PEP) for rape survivors has been erratic and the provision of PEP varies from province to province.

Out of intensive battles on the street with pickets, and memorandums, government firstly was forced through a court battle to make ARV drugs available to prevent mother-to-child-transmission of HIV [PMTCTP]. For a more comprehensive summary of the various court battles and advocacy initiatives on access to treatment see Appendix Four.

The most updated position of government on the issue of provision of ARVs in the public health sector was a statement issued on the 8th August 2003²². The statement refers to the Report of the Joint Health and Treasury Task Team on treatment options to enhance comprehensive care for HIV/AIDS in the public sector. The Report²³ deals with various challenges, including in particular, a programme to administer anti-retrovirals. The statement goes further to state that the cabinet meeting reiterated government's principled approach that antiretroviral drugs do help improve the quality of life of those at a certain stage of the development of AIDS, if administered properly. Finally the statement reports that Cabinet has instructed the Department of Health, as matter of urgency, to develop a detailed operational plan on an antiretroviral treatment programme. It is expected that this detailed work would be completed by the end of September 2003.

DEBUNKING THE MYTH THAT HIV DOES NOT CAUSE AIDS.

The public debate, controversy and speculation about the science of HIV and AIDS has been a major setback to the struggle to contain the AIDS epidemic and to save the lives of thousands of people in South Africa.

This debate impacted on South Africa as the President of the country and the Minister of Health directly and indirectly showed support for the theory that dissident scientists were putting forward refuting the existence of the HI virus, and subsequently claiming that it was poverty that was causing people to die of a compromised immune system. Linked to this argument was the question raised around the use of antiretroviral medicines and the toxicity associated with these drugs. Scientists supporting dissident views claim that ARVs are killing people and not HIV. They also question whether the HI virus was ever isolated to prove its existence, and claim that the HIV blood tests are inaccurate and unreliable.

Inadequate infrastructure and lack of resources to implement a policy, which includes the provision of antiretroviral drugs, are some of the other reasons being put forward as to why ARVs cannot be made available in the public health sector in South Africa. Subsequently many scientists, activists and academics have written articles, made submissions about making ARVs available in resource poor settings. Organisations like the TAC were forced to embark on acts of civil disobedience in its effort to get government to include access to ARVS in the public health sector as part of its HIV and AIDS policy.

²² Refer to footnote 2 above

²³ refer to footnote 20 above.

AIDS denialists:

Below is a summary of the arguments presented by AIDS denialists – people who do not believe that there is a link between HIV and AIDS.

- No animal model exists for AIDS; it is said to be impossible to inject an animal with HIV and cause AIDS;
- Viruses are said to cause disease quickly or never;
- Antibodies are usually protective, so why is it only HIV-positive people who develop AIDS?
- Many cases of AIDS without HIV are claimed to exist, casting doubt on the role of HIV in the development of AIDS;
- The failure of AIDS to spread outside the high risk groups is said to cast doubt on whether it is really an infectious disease;
- HIV is claimed to be present in such low levels in the blood of people who are HIV- positive that it can't possibly cause disease. Furthermore, if it is so difficult to isolate, how come it's transmissible?
- The variance in the incubation period between infection with HIV and the development of AIDS is said to cast doubt on the link between HIV and AIDS
- The accuracy of tests for HIV is questioned.”²⁴

There are many scientific articles and literature to counter and answer these questions.²⁵

How HIV causes AIDS:

By leading to the destruction and/or functional impairment of cells of the immune system, notably CD4+ T cells, HIV progressively destroys the body's ability to fight infections and certain cancers, ultimately resulting in a totally compromised immune system – if the person does not get any anti-AIDS treatment.

Epidemiological Association: the suspected cause must be strongly associated with the disease. This being that as of the end of 2000, an estimated 36.1 million people worldwide – 34.7 million adults and 1.4 million children younger than 15 years – were living with HIV/AIDS. Through 2000, cumulative HIV/AIDS-associated deaths worldwide numbered approximately 21.8 million – 17.5 million adults and 4.3 million children younger than 15 years.

Isolation: the suspected pathogen can be isolated - and propagated - outside the host. **Transmission pathogenesis:** transfer of the suspected pathogen to an uninfected host, man or animal, produces the disease in that host.

Science Of HIV And Efficacy Of Anti-Retroviral Treatment:

The debate about the link between HIV and AIDS has impacted on the lives of people living with HIV and has undermined prevention work done by NGOs and the government itself. Academics and AIDS activists have since ensured that more information is available on the science of HIV and AIDS in an attempt to address the confusion.

²⁴ AIDS MAP website - www.aidsmap.com

²⁵ Links Showing That HIV Causes AIDS – taken from the Treatment Action Campaign website – www.tac.org.za; <http://www.niaid.nih.gov/factsheets/evidhiv.htm>; http://my.webmd.com/content/dmk/dmk_article_5462570

This part of the review provides references to abstracts and papers demonstrating the efficacy of antiretroviral treatment in extending peoples' lives and managing HIV infection. It also provides statistics and research findings of the efficacy of ARVs and implementation in resource poor countries.

Research and information dating back to 1998 demonstrate the impact of ARVs on morbidity [indicative of diseases] and mortality²⁶. This research confirms that the use of ARVS has made a marked impact in reducing morbidity by reducing the occurrence of AIDS related illnesses and ultimately mortality. It confirms that ARVs are cost effective as far as they result in a drastic decline in the incidence of most opportunistic infections associated with HIV and a compromised immune system.

Coovadia et al provide factual information on key aspects of how the virus 'works', information on the fact that the virus exists, and other relevant scientific information in an easily accessible form without compromising the facts, by being too simplistic.

Central to the debate as presented by AIDS denialists is whether AIDS is caused by poverty or by a virus. Coovadia et al state that poverty makes AIDS worse, but it does not cause AIDS. Poverty places people at greater risk of acquiring HIV in many ways. Socio-economic inequalities existing predominantly in developing countries make people and women in particular more vulnerable to HIV infection. This is a major contributing factor to premature death.

Statistics show that there is a much higher prevalence of HIV in informal settlements, compared to both urban and rural areas.²⁷ Lets take the example of lack of proper housing. With access to a decent home, a person has the privacy of his bedroom and possibly a supply of electricity. Both these factors increase his or her chances of being able to practice safer sex. Living in a shack, which is often shared by children and members of the extended family makes having sex difficult enough let alone having the space to put on a condom. Further, the ability to put on a condom, in the dark, is more cumbersome than being able to do so with light.

Coovadia et al²⁸ deals very effectively with questions of resistance and toxicity and whether ARVs work or not in a booklet dealing with the science of HIV and AIDS. The case for the use of HAART is made by referring to extensive international research, which confirms that HAART works in Brazil, United States and Europe amongst other countries.

In answering the question as to whether antiretroviral treatment works or not, Coovadia et al refer to medical articles that present research findings confirming that HAART works. Based on a survey of 1 255 patients on ARV medicines in the US, the use of ARVs significantly reduced the number of deaths and disease among people living with HIV, irrespective of race, age or how HIV was contracted.²⁹

²⁶ <http://www.hivatis.org/trtgdlns.html>, New England Journal (1998): "Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection"

²⁷ Refer to footnote 11 above

²⁸ Coovadia H, Daitz V, Karim QA, Usdin S, Molefe J, Japhet G, Ntuli A, (2002): "AIDS Know the Facts, Soul City, Health Systems Trust, University of Natal, TAC.

²⁹ Pellela et al. New England Journal of Medicine 1998 338(13): 853-60.

NATIONAL AND INTERNATIONAL AGREEMENTS AND GUIDELINES ON THE EFFECTIVE USE OF ART

The year 2001 was marked by Government raising public debate on the efficacy of ART side effects and toxicity. In an attempt to counter this and try and address some of the damage caused by these misleading statements, the TAC hosted an expert consultation of doctors, scientists, nurses, policy specialists and activists to discuss the benefits of using antiretroviral therapy (ART) for treatment of HIV and AIDS in South Africa. *The Bredell Consensus Statement*³⁰ was issued and deals with the imperative to expand access to ARV medicines for adults and children with HIV and AIDS.

Aside from speaking about the key components of a treatment programme that includes the provision of ARVs, the statement also calls for more clinical research into ART in South Africa to be grant driven-research as opposed to being funded by pharmaceuticals, as is currently the case. The key motivation for this is to set the agenda for the research programme, which according to the document must include the following components:

- Determining the most appropriate and well-tolerated combinations of medicines taking into “account the needs of women and children as well as conditions that exist in developing countries such as South Africa”;
- Improved clinical algorithms or simple laboratory markers that can replace some expensive current laboratory monitoring;
- Long-term cohort studies investigating adverse drug events; and the
- Interactions between TB and HIV therapies.

These are the debates and issues that need to be addressed, which will contribute towards the development of a complete, comprehensive plan and programme to control the spread of HIV and save the lives of those already living with HIV.

Guidelines for Use of ARVs

The TAC reprinted guidelines on antiretroviral therapy in adults – which was developed by the Southern African HIV Clinicians Society. The scientific information provided in the booklet on ARV treatment is presented through an introductory paragraph. It is stated that the scale on which impoverished communities are denied access to desperately needed antiretroviral treatment is unparalleled in the history of infectious diseases.³¹

In summary the introduction identifies exorbitant costs of taking a lifetimes course of antiretroviral treatment and political intransigence as the current key obstacles to ensuring that adequate management of HIV infection is available in many developing countries including in particular South Africa. The rest of the booklet takes the reader through a thorough breakdown of the key aspects of going on to antiretroviral treatment for the rest of ones life. As stated these guidelines are not cast in stone but need to be updated as new scientific breakthroughs are made on management of HIV and AIDS.

³⁰ Treatment Action Campaign, (2001), “*Bredell Consensus Statement on the Imperative to Expand Access to Anti-Retroviral (ARV) Medicines For Adults and Children with HIV/AIDS in South Africa.*”

³¹ Refer to footnote 6 above.

Useful information is provided on clinical indications for starting ARV therapy. Once again, in the context of a country that has no formal policy or guidelines for use of ARVs, many doctors prescribe ARVs as soon as the person is diagnosed with the disease. As stated by the guidelines under review- there are many requirements that need to be complied with before a person can go onto to ARVs. This includes the patients being prepared to commit themselves to long-term treatment and to maintaining good adherence to the therapy. Understandably within the climate of denial of the existence of HIV and related arguments about toxicity of these drugs, many people are confused and this does impact on adherence and even uptake- aside from the fact that most people cannot afford ARVs in under-developed countries, even at reduced prices.

Another initiative that was pioneered by civil society in South Africa and which then brought on board other role players, including government and the private sector, is the National Economic Development and Labour Council [NEDLAC] *Framework Agreement on a National Prevention and Treatment Plan for Combating HIV/AIDS*.³² Negotiations reached an advanced stage at NEDLAC with all four sectors represented, including Community, Labour, Business and Government. Unfortunately when the frame work agreed to by the negotiators had to be signed by heads of the various sectors, negotiations broke down and the document remained unsigned by July 2003. While labour and community were ready to sign off on the document, business and government began dragging their feet. As of July 2003, business has indicated a willingness to sign the document, and government needed to get approval from Cabinet.

The following is a summary of the key elements of the proposed NPTP. The objective was to get agreement on key issues related to a framework for a national treatment and prevention plan. A critical component of the agreement was to get the sectors to commit to combine and use their resources and efforts to provide an effective HIV/AIDS prevention and treatment plan for the country. Something which the current 5 year Strategic HIV/AIDS plan of government does not do.

This agreement was drawn up in the following context:

Recognition of the importance of eradicating poverty to combat the spread of HIV, as well as the impact of poverty on people already infected with HIV. All plans to prevent and treat HIV must be complemented by plans to alleviate and eradicate poverty, including building the economy, creating jobs, improving access to clean water, better housing, access to improved nutrition, welfare grants and other measures.

This framework agreement was not intended to replace or duplicate the existing Strategic Plan to address the HIV/AIDS epidemic produced by the national department of health. It was aimed at recognizing and building on the ongoing work of government both in the areas of prevention as well as in treatment care and support. But it is intended to address the key weakness of current government policy –this being the exclusion of ARVs, and a plan that involves all sectors of society with targets and deadlines for delivery.

³² Nedlac Framework Agreement on a National Prevention and Treatment Plan for Combating HIV/AIDS (2002)

The framework agreement is set within the context of the Cabinet statement of April 17th 2002³³ and makes specific reference to the following international agreements that have been signed by our government on addressing HIV and AIDS. In this instance the framework agreement makes reference to the Abuja Declaration³⁴. Countries pledged to set a target of allocating at least 15% of their annual budget to the improvement of the health sector and to make available the necessary resources for the improvement of the comprehensive multi-sectoral response to the HIV/AIDS epidemic. The agreement is also placed in the context of The UNGASS *Declaration of Commitment on HIV/AIDS* (June 2001).³⁵

The key paragraph of this framework³⁶ agreement is a clause committing the four parties to the following:

“The development of a comprehensive plan that addresses the different components of an effective strategy, including education, awareness and prevention; procurement and production of medicines, treatment, support and care; and issues relating to discrimination and stigmatisation, and that addresses the policy, resource, organisational and legal dimensions required to ensure successful outcomes”

This is spelt out as follows:

- A strong focus on education, awareness and prevention, to stem the infection rate, with measurable targets and timeframes;
- A universal roll-out to prevent mother to child HIV transmission,
- A comprehensive package of care for rape survivors, including counselling, testing for HIV, pregnancy and STI and access to anti-retroviral drugs in public health institutions for those who chose them;
- A program that allows people living with HIV/AIDS to come forward without fear of stigmatisation or discrimination and allows access to:
- All necessary information in an understandable form;
- Clinics that provide information on health, regular monitoring;
- Treatment of opportunistic infections;
- Access to ARV according to national standards
- Recognition and prioritisation of vulnerable groups in access to information, prevention, treatment and care.

The revised UNAIDS guidelines on HIV and human rights³⁷ provide relevant and up-to-date policy guidance based on the current state of international law and on best practice experiences at the country level. It is based upon the following key premises:

- Access to HIV/AIDS –related treatment is fundamental to realising the right to health;
- Prevention, treatment, care and support are a continuum;

³³ Refer to footnote 21 above.

³⁴ The Abuja Declaration and Framework for Action for the Fight Against HIV/ AIDS, Tuberculosis and other Related Infectious Diseases in Africa, 27 April 2001;

³⁵ Resolution adopted by the General Assembly- [2 August 2001]- S-26/2. *Declaration of Commitment on HIV/AIDS*

³⁶ Refer to foot note 32 above

³⁷ *HIV/AIDS and Human Rights – International Guidelines* – UNAIDS Geneva July 2002. Revised Guidelines 6: commentary and recommendations for implementation

- Access to medication is one element of comprehensive treatment, care and support
- Ensuring sustainable access to medication requires action on numerous fronts; and
- International cooperation is vital in realising equitable access to care, treatment and support to all in need.

A critical component of the guidelines deals with the role of the State and political leadership. It states that States should develop and implement national plans to progressively realise universal access to comprehensive treatment, care and support for all persons living with HIV/AIDS, as well as universal access to a full range of goods, services and information for HIV prevention. National plans should be developed in consultation with nongovernmental organisations to ensure the active participation of people living with HIV/AIDS and vulnerable groups.

In this vein the document outlines what are states obligations in terms of ensuring that through legal strategies, and budgetary allocations universal access to HIV and AIDS prevention, treatment, care and support is provided. It states that this is necessary to respect, protect and fulfil human rights related to health, including the right to enjoy the highest attainable standard of health. The document is sober and realistic in that it does acknowledge that this will be progressively realised, but nonetheless States need to have a plan, and need to review and amend and adopt laws, policies, programmes and plans to realise universal and equal access to medicines, diagnostic and related technologies.

MAKING THE CASE FOR HAART

What follows will be a review of various important pieces of literature explaining why it is imperative that we treat HIV and AIDS. In doing so it provides responses to many of the impediments and excuses that are put forward by government officials and policy makers, especially in South Africa, as to why ARVs should not be provided as part of this treatment programme. They also provide sound arguments proving how it is possible to provide HAART in under-resourced settings including South Africa and all other developing countries.

Some of the articles provide extensive information on known effective interventions that can also serve as a model best practice intervention using HAART, in under-resourced settings. Most articles make the case for HAART in the context of treatment and prevention being part of a continuum of care.

Policy makers in South Africa have presented the following arguments as reasons for not being able to make ARVs available in the public health sector. Firstly, lack of infrastructure –As was found with the pilot PMTCT sites, mainstreaming effective HIV/AIDS care and treatment requires an in-depth analysis of the personnel and infrastructure currently in place. As is already widely known, there are improvements that should be made to the health system: staff need to be recruited and trained, monitoring structures need to be put in place or further developed, and communication systems need to be better utilized. South Africa, however, has a strong foundation, with an effective network of laboratory services

(the National Health Laboratory Services, NHLS), a solid regulatory body (the Medicines Control Council, MCC), and extensive physical infrastructure.³⁸

Government also speaks about issues of toxicity, which is often quoted by the Minister of Health as a reason for not providing ARVs in the public health sector. The client's choice, after having been confronted with their peers under treatment, is the best indicator of the acceptability of ARVs, as it is based on real life experience.³⁹ In the MSF pilot project in Khayelitsha (with 177 patients on treatment), most patients experienced side effects in the beginning of treatment (usually dizziness and some headaches), but in the majority of cases, these side effects disappeared after two weeks on treatment. In the early months of the programme, some patients demonstrated reluctance to take ARVs as they were afraid of side effects. After 18 months of experience, clinicians were confronted with overwhelming pressure from patients wanting to access treatment, based in part on the progress that their peers had made under treatment.

In assessing the challenges to provision of ARVs in settings where medical and economic resources are limited the paper written by Reynolds et al⁴⁰ argues that simply providing affordable access to highly active antiretroviral therapy [HAART] is insufficient. It goes on to say that the global objective should be to combine prevention with access to clinical care that clearly helps patients to live longer, healthier lives. This is the key objective of the Global Fund to Fight AIDS, Tuberculosis, and Malaria⁴¹. The purpose of the Fund is to attract, manage and disburse additional resources through a new public-private partnership that will make a sustainable and significant contribution to the reduction of infections, illness and death, thereby mitigating the impact caused by HIV/AIDS, tuberculosis and malaria in countries in need, and contributing to poverty reduction. The fund provides an opportunity to address a number of challenges to ensure that when antiretroviral drugs are more accessible, they will be used in a rational and beneficial way for patients.

Reynolds et al⁴² states that guidelines need to ensure that health care providers need to know how to incorporate antiretroviral therapies into comprehensive clinical care plans. Other key issues that must be put in place as part of a comprehensive plan include affordable access to laboratory monitoring necessary for the safe and effective use of antiretroviral therapies. Underdeveloped countries can draw on the experience of developed countries experience with the use of ARVs in identifying which are the most effective regimens. It is recommended that all HAART initiatives be incorporated into primary care programmes, as part of HIV-prevention, education, and counselling activities.

On infrastructure requirements, Reynolds et al recommends that low-cost methods for monitoring patients receiving HAART must become a public priority. The

³⁸ MacLean, E, Darder, M, Berger, J, Goemaere, E, (2002), *Why Treat HIV/AIDS? A Medical, Social, Economic, and Moral Imperative*. Médecins Sans Frontières, South Africa.

³⁹ Ibid

⁴⁰ Steven J. Reynolds, MD; MPH.; John G. Bartlett, MD., Thomas C. Quinn, M.D., Chris Beyrer, M.D., M.P.H., and Robert C. Bollinger, M.D., M.P.H. *Antiretroviral Therapy Where Resources are Limited*. The New England Journal of Medicine – Vol 248:1806; May 1 2003, Number 18:

⁴¹The Global Fund to Fight AIDS, Tuberculosis & Malaria Funding the fight against the diseases of poverty <http://www.globalfundatm.org/>

⁴² See footnote 40 above

document demonstrates that for all the challenges posed to under-resourced countries, there are solutions. But these require political will and strong leadership.

Other key factors that are critical for the effective provision of HAART include ensuring sustainable drug supply to avoid ARV resistance. In order to improve treatment guidelines the paper recommends that efforts to provide access to drugs should be coordinated with other support to developing countries, in order to assist in the generation of country specific data to validate and modify guidelines for the use of HAART. The other important area for support is to provide developing countries with the resources to measure their clinical effect through the provision of ARVs.

The paper stresses the need to ensure that provision of affordable HAART must also incorporate other cost-effective interventions like measles vaccinations, pneumonia vaccinations, or provision of clean water, which should be part of a comprehensive primary care plan.

An important point made by Reynolds et al is that programmes to expand access to HAART will provide a unique opportunity to improve overall health care delivery systems. Entire communities will benefit from the improved delivery of primary care, the integration of care and prevention programmes and the availability of trained experienced health care providers.

Good literature exists to demonstrate how treatment and a national plan can stem the tide of the epidemic.⁴³ Clinton makes similar arguments as Reynolds et al. Of note is the following argument. “Prevention efforts cannot be effective unless people agree to be tested. People will not agree to be tested until the results provide them with more than just a death sentence. Less than 1% of those who need treatment in Africa are receiving it and there is little hope that people will line up for testing until medicines are widely available. As your [physicians and health professional] work in the United States and elsewhere has shown, prevention care and treatment are all part of the same package.”

Medecins Sans Frontieres [MSF] explains in a well researched paper⁴⁴ how it has developed nine treatment pilot projects in seven countries, treating approximately 1000 patients with antiretroviral therapy, with impressive results: after six months of therapy, patients had a 93% survival rate, an average weight gain of three kilos, and, where viral load was tested, 82% of patients had undetectable viral loads.⁴⁵ In one of these projects, in the Western Cape township of Khayelitsha, dedicated HIV clinics have been providing treatment for opportunistic infections, counselling, and antiretroviral medicines.” The paper makes reference to the Medical Research Council [MRC] report on the impact of HIV/AIDS on adult mortality which provides sober statistics on what will happen if we do not provide treatment for HIV and AIDS⁴⁶:

⁴³ Clinton. WJ, *Turning the Tide on the AIDS Pandemic* – The New England Journal of Medicine Volume 348: 1800-1802 May 1 2003 Number 18.

⁴⁴ Refer to foot note 38 above

⁴⁵ Campaign for Access to Essential Medicines, *Overcoming the Treatment Deficit*. July 2002.

⁴⁶ Medical Research Council. *The Impact of HIV/AIDS on Adult Mortality in South Africa*, September 2001, p6. The MRC report uses a model developed by the Actuarial Society of South Africa and compares it with other relevant models.

“[W]ithout treatment to prevent AIDS, the number of AIDS deaths can be expected to grow, within the next 10 years, to more than double the number of deaths due to all other causes, resulting in 5 to 7 million cumulative AIDS deaths in South Africa by 2010.”

The MRC report states that AIDS has “become the single biggest cause of death in South Africa.”⁴⁷ It speaks about a medical crisis that will only become more catastrophic in the coming decades unless significant political commitment unequivocally supports prevention, care, and treatment efforts.

The MRC’s projected AIDS-related and non-AIDS related mortality in 2010 show that if the course of HIV/AIDS policy is not changed dramatically, both men and women are significantly more likely to die of HIV/AIDS in their young adulthood than to die in old age or of any other cause.

Looking at the impact of HIV and AIDS on the Health Sector, Maclean et al⁴⁸ make reference to research commissioned by the Department of Health⁴⁹. The study of the impact of HIV/AIDS on the health sector predicts more than 3 million cumulative AIDS-related deaths by 2010. The impact of such high—and rapidly increasing—levels of morbidity and mortality strains an already overwhelmed and under-resourced health sector. It estimates that approximately 500,000 hospital admissions in 2000 were HIV/AIDS-related. This figure stands to increase to more than two million annual hospital admissions by 2010, unless a significant decrease in the number of new HIV infections and HIV/AIDS-related opportunistic infections halts the trend. The inpatient facilities of public hospitals will be most-affected, as increasingly immuno-suppressed patients require more frequent hospitalisations.⁵⁰

In addition to the loss of medical professionals due to illness and death, doctors and nurses are said to be experiencing psychological burnout due to the impact of watching a growing number of young patients getting sick and dying while the health system has nothing to offer them aside from increasingly overcrowded facilities and temporary treatment for opportunistic infections.^{51, 52}

MacLean et al provides graphical data showing the incidence rates for opportunistic infections without and with HAART, based on the experience of doctors during year one of the programme at Khayelitsha HIV clinics.

An important point made by MacLean et al and also contained in the *Bredell Consensus statement*⁵³, is that “an estimated 20,000 people are already using antiretroviral therapy in South Africa currently. All these patients are either in the private sector or are getting ARVs through funded treatment projects. As long as the government refuses to make ART available in the public sector, and especially with prices of ARVs dropping, the number of people who find ways to

⁴⁷ Ibid

⁴⁸ Refer to footnote 44 above

⁴⁹ Abt Associates. *The impact of the HIV epidemic on the health sector in South Africa*. 2000.

⁵⁰ Ibid.

⁵¹ Goemaere E and Parisel A. *Report on an exploratory visit in Kwa-Zulu Natal. March 2002. Conversations with health staff.*

⁵² Modiba. P, Schneider.H, Weiner.R, Blaauw.D, Gilson.L, Zondi.T, Kunene.X, Brown.K, [2002]:*The Integration of HIV/AIDS Care and Support into Primary Health Care in Gauteng Province*, Centre For Health Policy, Wits. University

⁵³ See footnote 30 above.

independently access these lifesaving drugs will continue to increase. Yet, the growing use of antiretroviral drugs without national standards, sufficient training of health professionals, or prices compatible with long-term affordability can have a deleterious effect for individual patients and national public health. The unsystematic provision of ART can increase the likelihood of individual resistance and the development of drug-resistant strains of the virus.”

This is a compelling argument for supporting the provision of ARVs in the public health sector, under strict protocol and guidelines. The Bredell Statement concludes with the following statement: “The choice is not a choice between providing and not providing antiretrovirals. Rather, it is a choice between the systematic scaling up of ART provision and antiretroviral anarchy.”

MacLean et al provides detailed information dealing with Constitutional Rights and access to treatment. This section details the exact clauses in the South African Constitution and Bill of Rights, which protect the right to access to decent health care for all. It also provides detailed information on legal battles involving organisations like the Treatment Action Campaign, in its struggle to get access to affordable treatment for all people living with HIV and AIDS. See Appendix Three for more literature references on this topic.

Two sides of the same coin: the link between treatment and prevention

The section entitled “Two sides of the same coin: the link between treatment and prevention”⁵⁴ – goes to the heart of the question addressing the issue of access to treatment. Current government policy juxtaposes the question of access to treatment for HIV and AIDS with prevention of the spread of HIV and AIDS. This is not an either/or question, or one which must be presented as a choice between the two options. Treatment cannot be separated from prevention. The paper argues that besides being ethically inexcusable to entirely disregard the 40 million people worldwide who are *already* infected with HIV, focusing solely on prevention without a treatment option undermines the benefits of prevention messages. This is substantiated as follows:

- Treatment as an option provides a motivation for HIV-positive people to be aware of their status: without treatment as an option, knowledge that one is HIV-positive can be seen as offering little more than stigmatisation.
- Treatment as an option promotes openness and reduces stigma as HIV is no longer an inevitable death sentence.
- Treatment programmes can fuel educational initiatives supported by a pool of HIV-positive people open about their status.
- Treatment as an option improves the efficacy and psychological health of health care workers who are able to offer something beyond temporary treatment for opportunistic infections.
- Treatment for HIV-positive people helps to keep families intact and economically stable, thereby minimizing at-risk populations such as orphans and commercial sex workers.
- Treatment for HIV-infected people minimises clinical risks of transmission at each unprotected sexual intercourse. (Long-term benefits of this are unclear though, as patients under treatment live longer and may change risk behaviours.)

⁵⁴ Refer to footnote 44 above

Ultimately treatment is an incentive for people to test. Currently, as confirmed by the HSRC household survey⁵⁵, very few people are testing voluntarily for HIV. Most people who know their status, according to this survey, found out their status by applying for a home loan or life insurance policy and were compelled to have an HIV test.

Treatment turns voluntary counselling and testing [VCT] into a powerful prevention tool. Once a person has found out his or her status, if it is positive, their post test counselling must deal with how to prevent the further spread of HIV and equally importantly must counsel the person on management of HIV and AIDS. If a person tests negative, then the person must be counselled on how to stay negative. This is not happening at the moment, so everyone assumes they are negative, and it is largely those people who do not know their status that are spreading HIV.

McLean et al, draws on the experience in Khayelitsha to demonstrate the point of how treatment addresses stigma and is critical as a prevention tool. The relevant paragraph reads: “While scant research has focused on this link, an analysis of the clinics in Khayelitsha provides some insight into the powerful relationship between treatment and prevention. In 1999, a provincial prevention of mother-to-child transmission (PMTCT) initiative in the Western Cape led to a dramatic increase in the number of women aware of their HIV status. Before the existence of PMTCT programmes in the province, few were aware of their status and even fewer were willing to disclose. PMTCT, for the first time, provided a motivation for pregnant women to be tested for HIV: the health of their babies depended on it. In 2000, three clinics began to provide treatment for opportunistic infections and, for those in the late stages of HIV/AIDS, antiretroviral therapy. These clinics likewise provided an incentive for others to be tested: their own health depended on an acknowledgement that their recurring illnesses were linked to a larger disease.”⁵⁶

Clinically, the World Health Organization (WHO) differentiates four stages in the natural history of HIV infection. The *stages* are numbered according to the degree of evolution of the disease—Stage One being the initial stage of infection and IV the most advanced (AIDS). The number of CD4 T-cells in plasma (*CD4 count*) is the hallmark of disease progression; it is this figure that is generally used to mark the appropriate initiation of ART. Recommendations vary to accommodate different settings. The World Health Organization’s guidelines for scaling up ART in resource-limited settings cite 200 as the suggested CD4 count (or clinical stage IV) at which to start treatment. The revised recommendations of the South African HIV Clinicians Society are consistent with the WHO document.⁵⁷ In resource-poor settings where treatment is less readily available, a significant number of patients have started treatment with CD4 counts below 50 or even 10 with some success.”⁵⁸

Early in 2001, individual members of the faculty of Harvard University issued what was referred to as the “*Consensus Statement on Antiretroviral Treatment for AIDS in Poor Countries*, signed by 148 academics⁵⁹. This document provides parameters for making antiretroviral therapy immediately available to poor countries. This

⁵⁵ Refer to footnote 11 above

⁵⁶ refer to footnote 44 above

⁵⁷ Refer to footnote 6 above

⁵⁸ Medecins Sans Frontieres and University of Cape Town Department of Public Health, *Antiretroviral Therapy in Resource-Poor Settings: One-Year Report*. September 2002.

⁵⁹ Individual Members of the Faculty of Harvard University, [2001], *Consensus Statement on Antiretroviral Treatment for AIDS in Poor Countries*

document lists some of the commonly quoted reasons for not providing ARVs in resource poor settings: + That poor countries lack adequate medical infrastructure to provide AIDS treatment safely and effectively. + In settings of high illiteracy patients would not take their antiretroviral drugs correctly, thus promoting and spreading drug resistance. + The cost of antiretroviral drugs is too high for the United States and other rich countries to finance, without siphoning resources away from HIV prevention programmes and other worthy development goals; and + political leadership in Africa and other poor regions is not sufficiently committed to underpin a major international effort towards AIDS treatment.

At the same time the review has attempted to demonstrate the economic and social impact of HIV/AIDS. This was shown in terms of premature deaths and devastation of the public health care system, dealing with an influx of sick young people, with recurring illnesses. Just at an emotionally tragic level, AIDS has taken 22 million lives and created more than 13 million orphans.⁶⁰ An estimated 16,000 new infections occur every day worldwide, and based on current trends, AIDS deaths will exceed those associated with the Black Plague of the 14th century by the year 2004. In the end, no country will escape the disaster. The disease not only has weakened the social, political, and economic fabric on local, regional, and national levels but also promises to fundamentally destabilize this fabric worldwide.⁶¹

The significant point about the HIV epidemic is that unlike other chronic illnesses like sugar diabetes and heart disease which affects mostly older people, HIV and AIDS is killing people in the prime of their lives and is depleting the economically active section of our population.

With soaring death rates from HIV/AIDS in low-income countries, both the prevention of transmission of the virus and the treatment of those already infected must be global public health priorities.⁶²

Prices of drugs have dropped over the last 4 years. Public mobilisation and activism has resulted in major changes to international trade agreements. Presenting infrastructure as an excuse is unacceptable. The recently launched Global Fund to treat HIV/AIDS, Tuberculosis and Malaria⁶³, should enjoy the financial support of all developed countries, and this money can be allocated for the development of infrastructure where this is lacking.

A considerable body of evidence suggests that effective AIDS treatment is now possible in low-income countries.⁶⁴ Through large-scale, scientifically monitored programs, the development and sustainability of highly effective AIDS treatment strategies remains promising in settings of poverty and high AIDS prevalence.

“We believe that on moral, health, social and economic grounds the international community should provide the scientific and financial leadership for a rapid scaling-up of AIDS treatment in the poorest and hardest-hit countries of the world. Initial efforts should be focused on those with more advanced HIV infection, with a target of at least 1 million AIDS patients in Africa in treatment within 3 years as a first objective, and indeed more if feasible, and with a proportionate scaling up in

⁶⁰ UNAIDS. Report on the global HIV/AIDS epidemic. Geneva: UNAIDS, 2000. Available at http://www.unaids.org/epidemic_update/report/Epi_report.pdf.

⁶¹ Refer to footnote 59 above.

⁶² Ibid

⁶³ Refer to footnote 41 above

⁶⁴ Refer to footnote 59 above

hard-hit countries in other parts of the world. Africa accounts for around 80 percent of all HIV-infections in low income or high prevalence countries.”⁶⁵

There are at least 4 compelling reasons for combining AIDS prevention and treatment⁶⁶:

1. Treatment is essential to the 36 million people already infected with HIV, the vast majority of whom will die of AIDS without it. This is the immediate humanitarian rationale for treatment. The pandemic has already claimed 22 million lives, including 17 million in Africa.

2. Treatment is necessary to optimize prevention efforts. It is only when HIV testing is coupled with treatment that people have an incentive to be tested, thus enabling a rational response to AIDS: primary prevention for those who are HIV uninfected, and antiretroviral treatment for those who are HIV infected. Effective antiretroviral treatment of HIV-positive people also lowers the viral load within infected individuals, which in turn has a major effect in reducing the likelihood that they will transmit HIV infection to others.^{67, 68, 69} Ultimately, then, appropriate treatment of infected individuals may become a major tool in AIDS prevention.

3. Treatment is necessary to save the children -- and fabric -- of societies. Without treatment, the number of adult deaths expected from AIDS is so great that the currently catastrophic figure of 13.2 million AIDS orphans will grow into an even more socially devastating wave in coming years (by some estimates, 44 million orphans of all kinds by 2010).⁷⁰ Without family support, these children often can not attend school, suffer from poverty and malnutrition, and become victims of violent and sexual crimes—all of which places them at high risk for acquiring AIDS and which threatens to mire them in increasingly desperate conditions. If the current lack of treatment continues, a demographic shift is predicted in the most severely afflicted parts of Africa such that teenagers will outnumber their elders by 2020.⁷¹

Scaling up Antiretroviral therapy in resource poor settings

A very significant development in 2002 was the document issued by the World Health Organisation. This was in the form of guidelines for a public health approach entitled: *Scaling up Antiretroviral Therapy in Resource Limited Settings*.⁷²

In just under ten years, the face of the HIV/AIDS epidemic has changed completely, from being a disease that resulted in premature and painful death, to one that can be managed like any other chronic illness. The introduction of

⁶⁵ Ibid

⁶⁶ Ibid

⁶⁷ UNAIDS (1999). HIV/AIDS prevention in the context of new therapies. (UNAIDS, Geneva)

⁶⁸ C. Hart *et al.* (1999). Correlation of human immunodeficiency virus type 1 RNA levels in blood and the female genital tract. *J Infect Dis* 179:871-882.

⁶⁹ P. Vernazza *et al.* (2000). Potent antiretroviral treatment of HIV infection results in suppression of the seminal shedding of HIV: the Swiss Cohort Study. *AIDS* 28:117-121.

⁷⁰ USAID. Children on the Brink: Updated estimates & recommendations for intervention. USAID: 2000. Available at <http://www.usaid.gov/press/releases/2000/childrenreport.pdf>.

⁷¹ Monitoring the AIDS Pandemic Network. The Status and Trends of the HIV/AIDS Epidemics in the World, 2000. U.S. Census Bureau, 2000.

⁷² Hammer.S, Gibb. D, Havlir. D, Mofenson, L, Beek. I, Vella. S. (eds) [2002] *Scaling Up Antiretroviral Therapy in Resource Limited Settings*. World Health Organisation.

antiretroviral treatment has marked this turning point in the mid 1990s. But, this depends on which part of the world you come from. Unfortunately the scenario painted above related to those countries where people have access to a functioning and efficient health care system, or are rich enough to afford such quality health care. With the drop in prices of ARVs, the question of access to treatment in poor and underdeveloped countries is becoming a reality.

It is precisely for this reason that policies and guidelines for the use of ARVs is very important. Without this we are experiencing a situation where doctors are recommending mono therapy and dual therapy as opposed to HAART. This will lead to resistance, as the virus is able to develop resistant strains. Once this strain of HIV resistant to certain antiretroviral drugs is spread through the population, then it has a huge impact on the efficiency of ARV therapy. ARVs are toxic and need careful monitoring with laboratory tests of CD4 counts, viral loads, liver functioning and levels of acidity. Only a proper programme that addresses all these issues with a clear policy and guidelines on the use of ARVs will ensure that these problems are avoided. As illustrated by both the experience in Brazil and the experience of MSF in Khayelitsha, these problems are not insurmountable.

The WHO guidelines make a very important point in relation to this issue. It states that “scaling up will not be possible in the absence of a clear public health approach that promotes the rational and safe use of these powerful precious medicines. These technical guidelines developed with the support of the US National Institute of Health, present such an approach, promoting the use of standardised regimens and simplified monitoring. They recommend standards for the large-scale introduction of ARVs that prevent misuse.”

The document also reinforces the view that through the scaling up of access to ARVs, millions of people will be granted a new lease on life, wider access to treatment will stimulate prevention and there will be positive impacts on social and economic development as people living with HIV live longer and more productive lives.

These guidelines provide very useful information aimed at policy makers and health care workers working in the public health sector. It anticipates all the problems associated with scaling up access as opposed to management for individuals on ARVs.

Gayle et al. looks at how treatment and a comprehensive programme contribute to dealing with the epidemic and saving lives.⁷³ Helen et al also looks at prevention in the era of treatment and speaks about how treatment can enhance prevention methods. “In addition to greatly improving lives and delaying illness, enhanced access to treatment could bolster prevention efforts. A realistic prospect of obtaining treatment would provide persons at risk for infection with greater incentive to seek counselling and treatment. By implicitly valuing the lives and health of persons infected with HIV, treatment initiatives may reduce the stigma that poses a major impediment to prevention. Given that the risk of sexual transmission of HIV is closely correlated with the plasma viral RNA level in the infected person, some have hypothesised that the decline in viral load typically associated with HAART could reduce population-wide rates of HIV transmission. With substantial additional funding and a more strategic and timely approach to

⁷³ Helene D. Gayle, M.D., M.P.H. *Curbing the Global AIDS Epidemic* The New England Journal of Medicine. Volume 348: 1800-1802, May 1 2003, Number 18.

HIV prevention, a sustained reversal of the global spread of AIDS is achievable. This effort is urgently needed in Southern Africa, where up to one in three adults is already infected.”

Overwhelming evidence exist to prove that overall, ART is a critical component of an effective HIV/AIDS treatment and prevention strategy.

BARRIERS TO ACCESS TO TREATMENT

Price

Only 5% of the six million people in the developing world who need antiretroviral drugs are receiving them and only around 10,000 of Africa’s 25 million HIV-positive individuals receive HAART. “The doctor's role goes from caregiver to undertaker. You talk to them about the cheapest method of burial. Telling them about the drugs is always kind of a cruel joke,” said Dr Chris Ouma of Kenya, where 2.5 million people are infected with HIV, and most cannot afford AIDS drugs.”⁷⁴

A large percentage of the review has dealt with the fact that current government policy in South Africa excludes the provision of ARVs in the public health sector. It is also important to note that in terms of a global picture aside from lack of political will and leadership from many governments on the issue of HIV and AIDS, the multinational drug companies have a lot to answer for as well.

The World Trade Organisation's meeting in Seattle in December 1999 raised the issue of access to essential drugs for people living in poor countries. The inequalities of the world became the focus of major demonstrations, exposing that multinational drug companies have become the fat cats of the world while millions of people living in poor undeveloped countries are dying of treatable and curable diseases.

It must be recognised that since the victory of the PMA court case⁷⁵ the price of ARVs in particular have come down significantly. But the problem is that this is on the basis of special deals to governments in certain developing countries and excludes the private sector, like medical schemes for example. On the 1st December 2002, Médecins Sans Frontière produced the third edition of a paper entitled: “Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries.”⁷⁶

Prices of anti-AIDS drugs, in this instance, on the international market are a significant barrier to improving access to essential medicines in developing countries.

The document points out that the target audience of special offers made by big drug companies are governments, non-profit procurement agencies like MSF as well as other bulk purchasers of ARVs, including health facilities and NGOs. Useful information on pricing and what drugs are available on paediatric formulations for

⁷⁴Ford Nathan, *Statement on Access to ARVs in poor countries*, [2003] Médecins Sans Frontières, London EC1N 8QX

⁷⁵ Editorial, *South Africa's moral victory* Lancet , [2001], Volume 357

⁷⁶Médecins Sans Frontière (2002), *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*.

children is also provided. Of particular importance for us in South Africa is the information provided on the effects of generic competition on price levels.

There is currently a debate in South Africa about the cost effectiveness of providing ARV treatment. Antiretroviral drugs are "affordable" and launching a program to deliver the medicines to HIV-positive people throughout South Africa is "feasible," according to a cost study⁷⁷ completed by the country's national health and finance ministries. The research commissioned by the South African Government on this issue, makes strong recommendations on the roll out of ARVs in the public health sector at primary health care level, and demonstrates how it will be cost effective and will save the lives of millions of people. Unofficial reports state that the report makes the following argument in support of the roll out of ARVs: "Many deaths could be deferred until after 2010". The report states that on the conservative assumption that ARV therapy leads to 4-5 additional years of "relatively illness-free life": At 50%, people receiving ARV therapy 733 000 deaths would be deferred.

Generic ARVs vs Patented ARVs

In South Africa, buying the drugs in a pharmacy costs each patient about R16, 000 per year for a common first-line regimen (Combivir® plus Viramune® or Stocrin®), a price unaffordable for the great majority of the population, and virtually impossible to subsidize in public services. It is, however, important to note that international activism and the introduction of competition into the otherwise monopolized industry of HIV/AIDS medicines have brought about significant gains in the affordability of these drugs. In 1999 triple therapy treatment for ARVs cost around R4000 per month, today the price stands at around R1, 300 a month for patented first line regimen.

The use of generic ARVs, brings down the cost of provision of HAART dramatically. Other important cost factors include laboratory costs, which includes regular blood tests to monitor viral loads and CD4 or T-cell counts. These are vital statistics in the management of HIV and AIDS, especially for people on ARVs.

*"We have upside-down access to AIDS drugs in this world. The drugs are where the disease is not, and the disease is where the drugs are not."*⁷⁸

MSF has produced important research data based on operational experience. In its paper dealing with antiretroviral therapy in resource-poor settings, MSF addresses the question of costs effectiveness of providing ART. In summary the paper states that for the management (prophylaxis and treatment) of opportunistic infections, costs of drugs and tests are usually less expensive than ART. The frequency of clinical visits, however, is significantly higher in AIDS patients only receiving care for opportunistic infections.⁷⁹

Brazilian experience on cost of drugs

Brazil provides a good case study to answer this question as it shares similar socio-economic problems as those faced by South Africa. In the mid-1990s, the Brazilian Ministry of Health (MoH) adopted a policy of universal free access to antiretroviral

⁷⁷ Refer to footnote 18 above

⁷⁸ Dr. Peter Mugenyi, Joint Clinical Research Centre, Kampala, Uganda

⁷⁹ Ibid

(ARV) drugs for people with HIV. 113,000 patients now receive ARVs through the public health system. The scheme has improved patients' quality of life, produced a six-fold reduction in hospitalisation rates and is cost-effective - saving the government around US\$ 1 billion over five years.⁸⁰ What was also reported is that since 1996, the rate of HIV-related infections has fallen by up to 80 percent and 358,000 AIDS-related hospital admissions were avoided from 1997 to 2001.

A major concern for most governments with respect to the provision of ARVs in the public health sector is the question of sustainability. Once a person takes ARV therapy, they have to keep on this treatment for the rest of their lives. One of the problems of accepting offers and “donations” from drug companies is exactly the problem of sustainability. Many companies make price reduction offers for a limited period of time. When this period expires poor countries struggle to maintain the treatment programmes.

The key to the problem is to drive the prices of drugs down in the market. The best way to do this is to break the monopoly that patent holders have in terms of brand name drugs for essential life extending treatment. As mentioned above TRIPS allows for this. The other key factor is competition from generic drug companies. This is how Brazil has managed to sustain its programme together. The annual cost of ARVs is US\$ 235 million - 1.6 percent of the total MoH budget. Treatment for each patient is now 50 percent cheaper than in 1997, because 63 percent of ARVs used are generic versions produced by six Brazilian pharmaceutical companies. The prices of locally produced drugs have fallen by 82 percent over five years. One local producer, established by the MoH, produces almost half of all ARVs used in Brazil. The MoH negotiated with foreign pharmaceutical companies to reduce the cost of certain imported drugs by 60 percent. They avoided the use of compulsory licensing by agreeing tiered or differentiated pricing schemes.

A well-designed and supported international effort to reduce drug prices and improve health infrastructure could overcome many obstacles even in poorer countries. This should incorporate some of the successful elements of the Brazilian scheme, including a concerted governmental response, strong and effective civil society participation multisectoral mobilisation, balanced prevention and treatment approaches, advocacy of human rights, reflected in Brazil's policy of universal access to treatment.⁸¹

Are International trade agreements an impediment to access to treatment?

On the 14 November 2001 at a World Trade Organisation [WTO] ministerial meeting a Declaration on the TRIPS agreement and public health was adopted.⁸² Point 4 states that: “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.”

⁸⁰ Insights Health Issue, [2002], Model of success Universal access to treatment in Brazil, No. 2

⁸¹ Ibid

⁸² World Trade Organisation, [2001], *Declaration on Trips Agreement and Public Health*, WT/MIN(01)/DEC/2

This together with national laws regulating intellectual property rights, like the patent act in South Africa, makes adequate provision to allow for countries to override patent rights in the interest of national health and emergency situation as presented by the current AIDS pandemic.⁸³

In 2002 the WHO and WTO issued a joint study on WTO agreements and public health.⁸⁴ The key objective of the document is to attempt to strike a balance between relevant WTO agreements and the way they may influence health and health policies. The WTO Agreement and public health—paragraph 7 states that the TRIPS Agreement also covers some areas that are relevant to health. The issue of patent protection for pharmaceutical products is particularly critical. This is an area where it is very important to find a proper balance between two complementary public health goals that of providing incentives for future inventions of new drugs and that of ensuring affordable access to existing drugs. The document also makes reference to Infectious disease control and states that the World today has witnessed the emergence of new global health threats, for which control measures are still evolving (for example HIV/AIDS). It also covers other issues related to HIV and AIDS – including a section on Access to drugs and vaccines, Health services, Food Security and nutrition and concludes with an important paragraph entitled “Towards Health and Trade Coherence.

For a more comprehensive summary of the various national laws that allow for government to access cheap generic drugs, and a list of international trade agreements making this possible see Appendix Three.

Compliance –Can Africans take their drugs consistently

In October 2001, Andrew Natsios, US administrator for foreign aid, made the outrageous racist statement that administering AIDS treatment in Africa would be extremely difficult because of a paucity of health infrastructure and because most Africans don't have clocks or watches and thus could not take medication at specific times.⁸⁵

Compliance is critical to prevent patients from developing drug resistance and of the increased risk of spreading drug resistant strains of HIV. What has been some of the recorded experiences of programmes providing ARVs in resource poor settings?

The most successful intervention in South Africa to date has been the experience of Médecins Sans Frontières (MSF) together with the School of Public Health and Primary Health Care, University of Cape Town.⁸⁶ The programme applies strict criteria for qualification to go onto HAART. This includes regular attendance to the HIV clinic in Khayelitsha, adherence criteria including disclosure of ones status to at least one family member or friend, social criteria, and a doctor assesses the stage of disease. Only patients with a CD4 count of less than 200/mm² are eligible. From their experience promotion of adherence was based on a patient centred programme. Patients have access to trained counsellors for any questions related to HAART. Each patient is requested to identify a “treatment assistant” with home visits from the clinic. The centre has pioneered the development of support groups

⁸³ Patents Amendment Act, 2002

⁸⁴ World Trade Organisation [WTO] and World Health Organisation [WHO], (2002), *WTO Agreement & Public Health – A joint study by the WHO and WTO Secretariat*

⁸⁵ Donnelly. J, [2001], *Natsios called racist; firing sought*, The Boston Globe

⁸⁶ Refer to footnote 58

for people on HAART. Treatment literacy plays an important role, with patients being provided with information and pillboxes and other such support systems to help the patient monitor his or her drug programme.

Response to HAART is recorded through monitoring of CD4 counts, viral loads and weight gain. As an example, 54% of all patients registered on the programme started with a CD4 cell count of less than 50, and at 6 months only 2% have CD4 counts below 50, and 53% of patients have CD4 cell counts above 200.

Some of the lessons learnt is that if one analyses the survival of patients on the basis of their CD4 count at the time they started on ARVs, the pattern that emerged was that patients with CD4 levels below 10 were less likely to survive one year on HAART. The essential components of such a programme based on this experience include: careful selection of patients to go onto HAART, treatment adherence support and treatment literacy. This programme also demonstrates that the significant drop in the incidence of opportunistic infections as a consequence of HAART has important implications for costs and management of health care delivery.

Finally, this programme made an application to the Medicines Control Council [MCC] for a Section 21 exemption, which allowed them to buy generic ARV drugs from Brazil for the programme. The results after a year of using generic ARVs was that the generic drugs achieve the same health benefits as the brand name products for a significantly cheaper price. Once again this is of enormous significance in informing a national policy to provide HAART at primary health care level, and its implications for sustainability of such a programme.

Can ARVs be administered at Primary Health Care level?

A book produced by Dr Clive Evian provides useful information for both health care workers and the general public on how this is possible.⁸⁷ If the pace of this change and discovery continues, HIV/AIDS will soon become a manageable, chronic, clinical condition, especially if the financial barriers to this care can be reduced in the years ahead.

The section dealing with Primary care for early HIV infection and Primary care for advanced HIV disease is of critical importance and can be used to inform current official policy on HIV and AIDS management in the public health sector. Other sections of relevance include a section on: Recognising and managing HIV-associated and AIDS conditions, AIDS and the health care worker, The care of people who are in pain, or are dying. This book contains key information presented as guidelines in an accessible interesting format and attempts to be all-inclusive. Given the focus of the review, appendix Two will provide a brief summary of material and information available on nutrition, recognising the important role that access to proper nutrition plays in any illness, and particularly one resulting in a comprised immune system, like HIV.

WHY IS ACCESS TO TREATMENT AND CARE A HUMAN RIGHTS ISSUE?

The UNAIDS⁸⁸ guidelines is based on the following international commitments made by governments:

⁸⁷ Evian C, (2002), *Primary AIDS Care- Third Updated Edition*.

⁸⁸ *HIV/AIDS and Human Rights – International Guidelines – UNAIDS Geneva July 2002*. Revised Guidelines 6: commentary and recommendations for implementation

- The Commission on Human Rights in 2001 and again in 2002 confirmed that access to AIDS medication is a key component of the right to the highest attainable standard of health, enshrined in the Universal Declaration of Human Rights
- The International Covenant on Economic, Social and Cultural rights and the Convention on the Rights of the Child
- The Committee on Economic, Social and Cultural Rights, which monitors the Covenant, in 2000 made clear that the right to health included inter alia access to treatment and to HIV-related education.

The revised International Guidelines on HIV/AIDS and Human Rights, produced by UNAIDS, is premised on the fact that human rights promotion and protection is central to the response to HIV/AIDS. According to the statistics made available in 2002, across the globe more than 40 million people were living with HIV, half of whom were women, and half the new infections were occurring in young people under 25. It is also explained that these guidelines were being revisited to ensure that the revision of the Guidelines updates them to reflect new standards in HIV treatment and evolving international law on the right to health.

In making the case for access to treatment as a basic human right, the revised International Guidelines on HIV/AIDS and Human Rights, produced by UNAIDS, is critical reading.⁸⁹

These guidelines as with those issued by the Southern African HIV Clinicians Society⁹⁰, endorses the following fact. It states that: “Over the past six years, antiretroviral treatment for AIDS, while falling short of a cure, has slashed HIV death rates in high-income countries. But in developing countries, despite major decreases since 2000 in the prices at which these drugs have been available, they still reach fewer than 5% of those whose lives they would save. At the same time, human rights violations, including stigma and discrimination faced by people living with or affected by HIV/AIDS, still constitute a major barrier both to prevention efforts and access to care.

Poverty, discrimination, and gender inequalities are the engines of the 21st-century HIV epidemic-and who has access to what service.⁹¹ The poor and the disempowered have been blamed for their own misfortune. Why is it that in this context, the burden of proof regarding the need for effective care has in both instances fallen squarely on the shoulders of the destitute sick and their allies? Can we show that comprehensive HIV services are “sustainable” in the hardest-hit communities? Can we demonstrate that they are “cost effective” and a “ranking priority” in the face of other competing demands?⁹²

The commonly espoused excuses for not providing ARVs in resource poor settings, include the following: acquired resistance to these drugs, thievery and sale on the black market, adverse drug effects, diversion of resources from higher-priority projects, the obstacle of stigma, etc. But in answering the question as to why access to treatment is a human rights issue, Paul Farmer provides a succinct answer:⁹³

⁸⁹ Ibid.

⁹⁰ Refer to footnote 6 above

⁹¹ Farmer, P.E., Connors. M, Simmons. J, (eds). [1996]. Women, Poverty, and AIDS: Sex, Drugs, and Structural Violence.

⁹² Farmer. P, [2002], Introducing ARVs in Resource-poor Settings: Expected and Unexpected Challenges and Consequences, Harvard Medical School.

⁹³ Ibid

“One positive effect of integrating treatment should not be ignored: for over a decade, those living with both poverty and HIV (they are tens of millions strong, even if they have no acronym) have been demanding access to effective therapy. Thus merely introducing donor-supported HIV treatment efforts is positive because it shows we are listening, at long last, to these voices. Such novel efforts strike a blow for equity, no matter what the naysayers may say- and no matter how uncomfortable the public health and scientific communities may feel about the language of social justice or about social justice itself.”

Paul Farmer provides a very useful paper on challenges that a very poor country confronts in providing access to treatment. Paul Farmer⁹⁴ endorses the view that has been expressed by organisations like the World Health Organisation and MSF, that full participation of community health workers will be required if HIV prevention and care are to reach the poorest and most vulnerable communities. The Framework Agreement for a National Treatment and Prevention Plan⁹⁵ addresses this issue as well, and sees the role of the community as critical to ensure that we save the lives of those people living with HIV and equally importantly that we control the spread of HIV.

There is still a limited understanding and acceptance of the argument that access to treatment is not just about the basic human rights of people living with HIV and AIDS, but is linked to prevention efforts in resource poor settings as well. A contributing factor to this weakness is the fact that, relevant operational research has not been done because the projects do not exist. To do operational research, there must first be operations.⁹⁶ “Africa cannot afford to wait two decades to tackle AIDS” notes Ariel Pablos-Mendes. “Yet, the required research has been scant, owing to reservations about the feasibility of HAART, clinical overconfidence and ethical paralysis.”⁹⁷

We need to ask the question, why? Why is it that there is so much of dithering when it comes to making HAART and other social services necessary for an effective treatment and prevention programme available in resource poor settings, yet the impact of HAART in the United States, Europe, Australia, and Brazil has been profound⁹⁸. There exists evidence based on the experience of these countries that HAART impacts on reducing mortality and even expenditures, often dramatically.⁹⁹ Aside from just the impact on the disease itself, evidence exists, gathered from the above-mentioned countries providing evidence of decreased HIV transmission.

ART AND DRUG RESISTANCE

On drug resistance, for example, a very novice proposal is made to try and monitor internationally the spread of resistant strains of the virus. Who, in collaboration with the International AIDS Society, is instituting a Global HIV Drug Resistance

⁹⁴ Ibid

⁹⁵ Refer to footnote 32 above

⁹⁶ Refer to footnote 92 above

⁹⁷ Pablos-Mendez, A. 2001. “AIDS Care is Learnt by Doing It.” *Bulletin of the World Health Organization* 79(12): 1153-1154; p. 1154.

⁹⁸ Refer to footnote 92 above

⁹⁹ McNaghten, A.D., D.L. Hanson, J.L. Jones, et al. 1999. “Effects of antiretroviral therapy and opportunistic illness primary chemoprophylaxis on survival after AIDS diagnosis.” *AIDS* 13:1687-95;

Surveillance Network. The goals of this programme are to establish a network of institutions, laboratories and investigators in order to monitor the epidemiology of drug resistance prospectively on a global basis. This information will be made available through a web site and published reports and will be a resource for public health officials, clinicians and researchers in order to assist them with the development of regional and country-specific antiretroviral guidelines and strategies aimed at preventing the further spread of drug resistance.

These guidelines speak about what contributes to the spread of resistance strains of HIV and to the development of these strains in the first place. It also provides a very comprehensive section on ARV during pregnancy including what should happen if you fell pregnant while on ARV therapy. It looks at ARVs for children, tuberculosis and other HIV-related conditions, drug adherence, monitoring and antiretroviral drug toxicity.

Bower et al¹⁰⁰ state that mathematical models have been developed to show how ARVs prevent substantial number of HIV infections, significantly reduce HIV prevalence. And ARVs should be viewed as a non-conventional prevention tool and not simply as a therapeutic tool. This point is qualified by emphasising the dangers of providing ARVs without clear guidelines and support systems. One of the biggest challenges that ART poses is that ARVs could also increase the transmission and prevalence of drug-resistant strains of HIV. Blower et al shows that if substantial increases in risky sexual behaviour occur then antiretroviral-induced decreases in transmission will be masked.¹⁰¹

The issue of drug resistance and toxicity associated with the use of ARVs cannot be taken lightly. The review has already commented on the key components of a national programme to address the HIV/AIDS epidemic including the provision of ART. As mentioned, criteria must be developed to select people who should go on to ARVs. Especially under the current climate of stigma and discrimination, the experience of the MSF project in Khayalitsha¹⁰² shows that it is critical for the person to have disclosed his or her HIV status to one other person. A comprehensive policy on the use of ARVs will include issues of criteria and other basic requirements all of which are aimed at ensuring that the patient on ART takes their treatment regularly ensuring compliance. Other aspects of a good policy include facilities being carefully selected. Sites where HAART is offered need skilled staff and a certain level of order and efficiency. The presence of a doctor is essential for the provision of this service and the facility must have a track record of being able to ensure regular and timeous drug supplies.

In the absence of a clear policy on the use of antiretroviral drugs there is already widespread misuse of individual antiretroviral drugs as they bring short term relief for individual patients. Doctors may be prescribing these drugs without a full appreciation of the negative effects of incorrect use of these drugs. A clear policy will ensure that antiretroviral drugs are used appropriately in both public and private sectors.

¹⁰⁰ Blowe S, Farmer P, [2003] Predicting the public health impact of antiretrovirals: preventing HIV in developing countries. AIDS Science Vol. 3, No. 11.

¹⁰¹ Ibid

¹⁰² Refer to footnote 44 above.

Equally important is the need for proper support services and parallel programmes linked to the provision of ART. This is what is addressed by the National Treatment and Prevention plan under discussion for agreement at NEDLAC.¹⁰³

PUBLIC HEALTH MESSAGES & TREATMENT LITERACY

Presently, government's prevention programme focuses on promoting a sexist message: Abstain, Be Faithful or Condomise [ABC]. This message is loaded with moral pressure without considering the psychology of the target audience. It also assumes that all people, both men and women can practice and imbibe these messages. Good public health messages will include all aspects of sexuality. It will try and understand why people risk unprotected sex, what is it that prevents them from using a condom, and will then address these problems to remove the barriers. The key point to a successful campaign to promote good public health messages is to put people into a position where they are able to make informed choices. This will mean addressing socio-economic issues that hamper ones ability to exercise their choices. We also need to engage openly, honestly and frankly with people about sex. This will include providing simple effective messages targeting young people. For example, explaining to a 12 year old why having a baby would be physically harmful to her body, or encouraging young people to delay sexual penetration, while speaking about other safe non-penetrative ways of deriving sexual pleasure including masturbation. It is only by dealing with the HIV epidemic in a holistic manner, that we will address all the challenges presented to us by this epidemic.

Treatment literacy

Linked to access to treatment is the question of management systems to monitor individuals on ARV therapy in particular. This as mentioned earlier is critical to ensure compliance and identifying possible side-effects associated with ARC therapy, on time. The Treatment Action Campaign [TAC] has pioneered the concept of treatment literacy and the setting up of support groups for people who are on ARVs. The TAC is currently producing a manual aimed at training trainers for treatment literacy.¹⁰⁴ As the title suggest, the manual is aimed at firstly empowering people living with HIV and AIDS but is also aimed at people affected by HIV and AIDS. Treatment literacy and the information provided is intended to empower the user, and to dispel myths and fears associated with HIV and AIDS which has resulted in the high levels of stigma and discrimination associated with HIV infection.

¹⁰³ Refer to footnote 32 above

¹⁰⁴ Mthathi, S et al, (2003), Empowa - Education Manual For PLWHAs, Organisations, Workers & Activists – Treatment Action Campaign

MSF SA also provides training materials and works closely with the community to provide comprehensive education on HIV and AIDS prevention and treatment. This resource is available in CD format and targets nurses, other health care workers and is aimed at being a tool for public education.¹⁰⁵ The CD dedicates a module looking at issues of toxicity, and side effects associated with ARVs. It provides good information on when a person should consider changing their regimen and why. It also provides a quick overview of the different classes of ARVs, which is the deciding factor in determining what regimen a person will go on to. This table is useful in that it gives you an indication of all the choices available should your body react in a negative way to a particular drug.

HAART: classes of antiretrovirals

2 NRTIs	+	1 NNRTI or	1 PI = HAART
Nucleoside Analog Reverse Transcriptase Inhibitors (nukes/ NRTIs)		Non-Nucleoside Analog Reverse Transcriptase Inhibitors (non-nukes/NNRTIs)	Protease Inhibitors (PIs)
<ul style="list-style-type: none"> ● abacavir (ABC) ● didanosine (ddI) ● lamivudine (3TC) ● stavudine (d4T) ● zidovudine (AZT) 		<ul style="list-style-type: none"> ● delavirdine ● efavirenz ● nevirapine 	<ul style="list-style-type: none"> ● amprenavir ● indinavir ● lopinavir ● nelfinavir ● ritonavir ● saquinavir

105 MSF SA Training Materials [CD Rom] (2002) Nurse Practitioner Management of HIV Related Illnesses, PMTCT Training, Introduction too Antiretroviral Therapy, Counsellors Training in Antiretroviral Therapy, MSF Resource Centre Series.

CONCLUSION

The objective of this review is to provide arguments in favour of access to treatment. At the same time, the review has attempted to present common arguments against the provision of access to treatment and to counter these arguments. Finally it would be incomplete if the review did not present the real challenges to providing ARVs in resource poor settings. Paul Farmer¹⁰⁶ -

Anticipating Unanticipated Challenges: The Haiti Experience

- Managing concurrent health problems, including OIs common in poor communities
- Assessing generic drug quality
- Assuring uninterrupted drug supply (forecasting demand) and storage
- Maintenance/servicing of laboratory equipment
- Drug-resistant HIV; second –line regimens
- Use of fixed-dose combinations of ARVs
- Training for and monitoring rational use of ARVs
- Managing/referring HIV among patients from distant regions
- Management of scarce resources in settings of extreme poverty
- Effective integration of traditional healers, including birth attendants
- Responding to unemployment, lack of food, housing, and clean water.

But if this is juxtaposed with the consequences of not providing access to treatment for people living with HIV, we have a public health system that is all but crumbling from the burden of dealing with the epidemic. This has dire consequences for old people and children who do not have HIV but need access to health care, as current capacity cannot cope. The other sad consequence aside from the economic impact and the impact on mortality is measured by new HIV infections and AIDS deaths.

A comprehensive programme will include a plan to progressively address all the problems and ensure that timeframes are set to monitor progress in terms of ensuring that the above issues are all addressed.

Dr Richard Feachem – the current Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria – in response to the call for setting up pilot projects which will seek to “scale-up” services to larger populations, Richard Feachem said that: “These sites would achieve three things. First, they would bring HAART to tens of thousands of infected people in an effective way. Second, they would be islands of good practice where new drugs and new delivery techniques are continually being applied and evaluated and a major learning experience is going on. Third, they would provide powerful demonstration sites where the cost, impact and feasibility of using HAART in resource-poor settings could be clearly seen.”¹⁰⁷

¹⁰⁶ Above footnote 92

¹⁰⁷ Feachem, R. 2001. “HAART— the Need for Strategically Focused Investments.” *Bulletin of the World Health Organization* 79(12): 1152-1153. (p. 1153).

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