

# Bredell Consensus Statement on the Imperative to Expand Access to Anti-Retroviral (ART) Medicines for Adults and Children with HIV/AIDS in South Africa

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On October 18<sup>th</sup> and 19<sup>th</sup> 2001 the Treatment Action Campaign (TAC) hosted an expert consultation of doctors, scientists, nurses, policy specialists and activists to discuss the benefits of using anti-retroviral therapies (ART) for the treatment of HIV and AIDS in South Africa. Participants included specialist clinicians and nurses who treat people with HIV and AIDS and who prescribe or study anti-retroviral medications. Included were representatives from diverse backgrounds, including the public and private health sectors, academic medicine, tertiary hospitals, urban, peri-urban and rural clinics. Several internationally respected scientists from South Africa and elsewhere made presentations. Religious bodies, trade unions, government and AIDS organizations also participated.

## The following consensus emerged:

1. The AIDS epidemic is one of the greatest challenges confronting South Africans. In facing up to the epidemic we confront not only a crisis of illness and death and a crisis of action, but a challenge to accept the truth, to tell the truth and to act on the truth.
2. Very large numbers of people are dying of AIDS or are sick with AIDS-related illnesses. The Department of Health estimates that last year 628 000 (25%) public hospital admissions were for AIDS-related illnesses. The Consultation also heard that AIDS-related illnesses are the most common causes of death in the medical wards among adults aged 19-49 at teaching hospitals affiliated to the Universities of Cape Town, Natal and Witwatersrand. The first aim of ART is therefore to decrease HIV associated illness (morbidity) and death (mortality). This goal can be achieved.
3. Access to anti-retroviral therapy is a vital and indispensable complement to both treatment of HIV disease and effective HIV prevention. It can restore hope to both health professionals and patients, and can assist us in regaining control of this epidemic. Therefore treatment for HIV and AIDS that includes anti-retroviral medicines should no longer be withheld as a result of government policy. ART in the public sector is necessary and possible, and a start must be made to implementing it as a matter of urgency in the interests of millions of lives.
4. As with any potent and effective medication there are side-effects and toxicities experienced by some patients taking ART. However, registered anti-retroviral medicines are effective and safe when they are appropriately prescribed and monitored. ART significantly improves the quality and length of life of men, women and children with AIDS. In South Africa this has been convincingly demonstrated in managed health care programmes, mainly in the private sector. It is estimated that 20 000 people are now using ART in South Africa. Extending access to these life-saving medications has become a moral, political, social and economic imperative.
5. Further delays in standardizing anti-retroviral use in the midst of a severe AIDS epidemic will undermine public health. Absence of appropriate standards is already leading to widespread inappropriate prescription and misuse – mainly by medical practitioners operating without training outside the framework of protocols and guidelines.
6. 'Anti-retroviral drug anarchy' may become a danger as more people need access to ART, prices come down, and untrained doctors prescribe the medicines. This threatens patient health, public health and the efficacy of the medicines themselves because of the possible development of resistant strains of HIV. In some cases, current prices have resulted in the prescription of sub-optimal drug combinations with the likelihood that this will result in the emergence of drug resistance. In view of this, there is a need for:
  - a. respect for patients' rights to information and to fully-informed consent before starting treatment;
  - b. comprehensive and urgent training of nurses, doctors and community health care workers in ART in the public and private sectors throughout South Africa;
  - c. establishing networks for sharing experience between all health care professionals;
  - d. clear and strictly maintained criteria for ART access;
  - e. standardized but flexible protocols about when to start therapy and the optimum choice of initial treatment regimens;
  - f. a minimum of three drugs as the standard of ART care;
  - g. guidelines for anti-retroviral management of patients with HIV who also have TB;
  - h. guidelines for anti-retroviral management of pregnant women;
  - i. health systems ensuring patient care and support, efficient delivery of medicines, adherence monitoring and staff support; and
  - j. public information and education that creates a culture of openness about HIV and AIDS and awareness that it can now be medically managed with ART.
7. Adherence to treatment requires informed and motivated patients together with an enabling clinical care environment. These conditions are practical and feasible. Research and ongoing treatment access in a variety of settings in South Africa have shown that people with HIV in poor and disadvantaged areas can adhere successfully to treatment regimens and thus can achieve treatment outcomes that are the same as in developed countries.
8. The capacity and infrastructure to use anti-retrovirals safely and effectively and to treat tens of thousands of people with AIDS already exists within the private health sector, parts of the public sector, and within some non-governmental organizations. These provide a foundation to devise and implement a national treatment plan, while simultaneously identifying needs and gaps in under-resourced sectors to promote equity.
9. Administration of anti-retroviral medications to reduce mother-to-child transmission must be introduced country-wide.
10. Post-exposure anti-retroviral prophylaxis for sexual assault is a moral necessity and an essential public health intervention.
11. Tuberculosis (TB) is the most common AIDS-related opportunistic infection and cause of death amongst HIV patients in South Africa. ART substantially reduces the risk of acquiring TB disease. Access to ART will relieve the burden and cost of TB and other common AIDS-related opportunistic infections on the public health system. New and recurring TB cases will be reduced and prevented by ART and TB treatment.
12. Anti-retroviral medicine prices must be further reduced. Price reductions should be across the board, and not limited to the public sector. Generic competition of bio-equivalent medicines is essential in order to arrive at the lowest and most sustainable prices for essential medicines. This is especially important if treatment is to be accessible to and sustainable by all people in South Africa.
13. Price reductions for diagnostic tests and tests monitoring the efficacy of ART are a priority. The price of these tests contributes substantially to ART costs and can result in inadequate clinical management.
14. However, even at current prices, HIV/AIDS medications could pay for themselves through reduced hospitalization, prevention of opportunistic infections, and improved quality of life and productivity of persons with AIDS. This has been demonstrated worldwide, including developing countries such as Brazil.
15. Most clinical research into ART in South Africa is currently driven and funded by pharmaceutical companies. This needs to change to grant-driven research that investigates issues such as:
  - 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.

On the basis on the above points of consensus we state our belief that advocacy for access to anti-retroviral treatment is an ethical duty for health professionals. In addition, expanded capacity to treat HIV is an immediate imperative. Treatment literacy, support systems and de-stigmatizing HIV/AIDS is a duty of community activists and institutions of civil society such as trade unions, faith-based organizations, community organizations and NGOs at every level. Ensuring expanded, equitable and sustainable access to life-saving and prolonging medicines is a moral and legal responsibility for government, business, international agencies and private health-care funders.

## Individuals endorsing this statement

Mr. Zackie Achmat (Chairperson, TAC), Dr. Steve Andrews (GP with special interest in HIV), Mr. Ralph Berold (University of Witwatersrand, HIV/AIDS Co-ordinator), Ms. Edna Bokaba (Registered Nurse, Hospersa), Dr. Brian Brink (Board of Health Care Funders), Justice Edwin Cameron (Supreme Court of Appeal), Mr. Henri Carrara (Epidemiologist), Professor Sharon Cassol (Molecular Virologist, Nelson Mandela School of Medicine, University of Natal, Durban), Dr. David Coetzee (Epidemiologist, Department of Community Health, University of Cape Town), Dr. Karen Cohen (Clinician, University of Cape Town), Dr. Francesca Conradie (Clinician, Wits HIV Clinical Research Unit), Dr. Shaun Conway (Physician, International Association of Physicians in AIDS Care), Professor Hoosen Coovadia (Head: HIV/AIDS Research, Nelson Mandela School of Medicine University Natal Durban), Ms. Sharon Ekambaram (AIDS Consortium), Professor Gerald Friedland (Director AIDS Program, Yale School of Medicine), Dr. Eric Goemaere (Médecins Sans Frontières, Head of Mission, South Africa), Dr. Glenda Gray (Pediatrician, Baragwanath Hospital), Rev. J.P. Heath (Aids Co-ordinator, Anglican Church), Mr. Mark Heywood (Head of the AIDS Law Project), Dr. Prudence Iwe (Physician, HIV Clinical Trial Unit, Wits Health Consortium), Ms. Jenifer Joni (Attorney AIDS Law Project), Professor Quarraisha Abdool Karim (Epidemiologist, Nelson Mandela School of Medicine, University of Natal, Durban and past National Director of HIV/AIDS and STD Programme, Department of Health), Professor Salim S. Abdool Karim (Epidemiologist and Head of Research, University of Natal Durban), Ms. Anita Kleinsmidt (Attorney AIDS Law Project), Ms. Mapule Khanye (Director, AIDS Consortium), Mr. Teboho Kekana (TAC NEC Member), Ms. Nonkosi Khumalo (TAC Executive Secretary), Mr. Stephen Laverack (HIV/AIDS Education Awareness Consultant), Sister Tshidi Mahlonoko (Registered Nurse), Ms. Thembeke Majali (TAC Co-ordinator), Sister Nondala Noziphiwo (Registered Nurse), Ms. Tsakane Mangwane (Southern African Catholic Bishops Conference HIV/AIDS Office), Dr. Nyameka Mankhayi (Psychologist), Dr. Des Martin (Chairperson Southern African HIV Clinicians Society), Mr. Willie Madisha (President COSATU), Professor Gary Maartens (Senior HIV Physician, Groote Schuur Hospital), Sister Zola Mathebula (Registered Nurse), Professor James McIntyre (Chris Hani Baragwanath Hospital), Ms. Tanya van Meelis (CEPPWAWU Researcher), Ms. Anneke Meerkotter (Researcher, Community Law Centre, University of Western Cape), Dr. Tammy Meyers (Chris Hani Baragwanath Hospital), Dr. Clarence Mini (NAPWA Board Member), Ms. Precious Modiba (Senior Researcher, Centre for Health Policy), Mr. Tumi Modise (HIV Co-ordinator, National Council of Trade Unions), Ms. Teboho Motebele (Attorney AIDS Law Project), Mr. Dan Mullins (HIV/AIDS Co-ordinator OXFAM), Archbishop Njongonkulu Ndungane, Dr. Lana Oatway (Ethembeni Clinic), Mr. Lew Oatway (Ethembeni Clinic), Ms. Annie Parsons (SHARPP), Ms. Joyce Pekane (Vice-President of COSATU), Sister Penny Penhall (Registered Nurse), Mr. Pholokgolo Ramothwala (TAC Co-ordinator), Dr. Leon Regensberg (AID for AIDS), Sister Sue Roberts (Registered Nurse, Helen Joseph Hospital), Dr. Ian Sanne (Specialist HIV/AIDS Physician, University of Witwatersrand Health Consortium), Ms. Mercedes Sayagues (Advocacy and Media Officer OXFAM), Ms. Judy Seidman (Graphic Artist), Mr. David Shaproski (OXFAM), Mr. Christopher Shaw (Registered Nurse Saint Mary's Hill Hospital), Dr. John Sim (Virologist), Ms. Theo Steele (Campaigns Co-ordinator of COSATU), Dr. Francois Venter (Johannesburg General Hospital Infectious Diseases Clinic and Wits Health Consortium), Professor Robin Wood (Senior HIV Specialist and Infectious Diseases Specialist, Somerset Hospital), Mr. Zamokuhle Zwane (TAC Organiser)

## Organizations endorsing statement

AIDS Consortium, AIDS Law Project, Board of Healthcare Funders, Church of the Province of Southern Africa, Ethembeni Clinic, HIV Clinicians Society, Hospersa, Médecins Sans Frontières, National Council of Trade Unions (Nactu), Oxfam GB, Southern African Catholic Bishops Conference, University of Witwatersrand Health Consortium

