

ITHEMBALABANTU
"PEOPLE'S HOPE" CLINIC
KWAZULU-NATAL, SOUTH AFRICA
FIRST YEAR
PROGRESS REPORT
JULY 2003

ITHEMBALABANTU PEOPLE'S HOPE CLINIC

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BACKGROUND TO ITHEMBALABANTU CLINIC PROJECT

Southern Africa is one of the epicentres of the worldwide AIDS pandemic. With more than 5.2 million people infected with HIV, South Africa has the highest number of people living with HIV/AIDS of any country in the world. It is estimated that over 600 South Africans die every day from an AIDS-related illness. The majority of these deaths are avoidable with the effective use of ART. In South Africa the government so far has not introduced ART in its public health facilities.

KwaZulu-Natal, the province in which the clinic is situated, has one of the highest HIV prevalence rates in South Africa. The 2002 UNAIDS/WHO Epidemiological Fact Sheet on HIV/AIDS and Sexually Transmitted Infections for South Africa, which relies primarily on HIV prevalence data gathered at sentinel antenatal clinics, reports that the HIV prevalence rates in 1999 and 2000 at these clinics were 22.4% and 24.5%, respectively. "HIV prevalence is still exhibiting an upward trend; HIV prevalence rose rapidly from 7.1% in 1990 to 36.5% in 2000."¹ And HIV prevalence among sex workers in KwaZulu-Natal increased from 50% to 61% in just one year from 1997 to 1998.

To date, the enormous resources spent on HIV prevention with minimal emphasis on HIV treatment and care has not proved effective in stemming the increasing tide of HIV infections. Stigma and discrimination as well as the many myths around HIV still abound, such as the belief that the rape of a virgin girl is the only cure for HIV/AIDS, or that ART is highly toxic and does more harm than good. In such a desperate environment the Ithembalabantu Clinic has proved to be a beacon of hope. Challenging the myths and misconceptions, both locally and internationally about the benefits of ART, the clinic, but moreover the clients receiving treatment, are a living testimony that HIV does not have to equal death. That it is possible to manage HIV and live a healthy life without fear of persecution, stigma and discrimination. Many of the clients are now strong community leaders involved in HIV counselling and support, education and training, ensuring that their valuable experience, knowledge and skills benefit the broader communities.

OBJECTIVES

The Ithembalabantu Clinic Project aims to demonstrate that treatment of poor people in developing countries with HAART is successful, feasible and replicable. The project aims to establish a model of ART delivery that is cost effective and efficient, serving as a resource to a province and a country that has limited experience in delivering ART to poor people who are not fortunate enough to have access to private health insurance.

INTRODUCTION

With 42 million people now living with HIV/AIDS globally, expanding access to antiretroviral therapy (ART) to those who urgently need it is one of the most pressing challenges in international public health. Providing treatment is vital to alleviate suffering and to mitigate the devastating impact of the epidemic.

In response to a call for help from a local South African community-based organization called the Network of AIDS Communities in South Africa (NetComSA) to provide ART to the poor of KwaZulu-Natal, the AIDS Healthcare Foundation (AHF), the largest non-profit HIV/AIDS community medical service provider in the United States, established an international initiative called AHF Global Immunity (AHF-GI). AHF-GI's mission is to act as an catalyst to extend the provision of comprehensive HIV/AIDS treatment and care to those who would benefit but are denied access to ART because they are poor and live in the less-developed countries of the world. Apart from South Africa, AHF-GI now has a presence in Uganda, Honduras, and Ukraine and will soon be expanding activities in China and India. AHF-GI works with local NGOs and governments to extend the competent provision of ART to people who would otherwise not have access to life-sustaining treatment and would most certainly die needlessly.

In 2001, the Ithembalabantu "People's Hope" Clinic was established by NetComSA and AHF-GI to show that that provision of comprehensive treatment and care, including ART, in resource-constrained settings is feasible and effective to people with advanced stage of HIV infection.

The Ithembalabantu Clinic is an inspiring example of northern and southern NGOs, with a shared passion to see HIV-positive people receive treatment, care and support, collaborate to establish a clinic which now makes an enormous impact on the lives of people living with HIV and enabling them to live healthy and productive lives. The success of the clinic project represents an unprecedented opportunity to promote a more effective response to the global HIV pandemic through involving people living with HIV/AIDS, their families and communities in care, strengthening HIV prevention by increasing awareness, creating a demand for testing and counseling as well as reducing stigma and discrimination. Above all, showing that with support and commitment it is possible to effectively treat HIV/AIDS in resource-poor settings.

To our knowledge the Ithembalabantu Clinic, which currently treats 100 clients is the largest provider of ART in KwaZulu-Natal. The ability of the clinic project to deliver quality service is demonstrated by an adherence rate of >95%, average weight gain which is 8 kg in one year, the resolution of opportunistic infections and increased length and quality of life.

¹ UNAIDS/WHO EPIDEMIOLOGICAL FACT SHEET, SOUTH AFRICA, 2002 UPDATE, p.2

THE MODEL OF COMPREHENSIVE HIV CARE

The Ithembalabantu Clinic provides a comprehensive package of HIV/AIDS services that focus on ART and include counselling, treatment and adherence education and support, prophylaxis and treatment of opportunistic infections, as well as referrals where necessary. The clinic staff includes a medical director, a senior nurse, two counsellors, and a front office manager. After 16 months of operations, from February 2002 to present, 470 clients are registered at the clinic of which 120 are receiving ART.

The operational model of care at Umlazi township is based on AHF's modus operandi and extensive experience in delivering quality HIV care, developed and adapted in concert with our local CBO partners, clinicians, health officials, faith-based organisations, provincial administrators, health officials and local people living with HIV/AIDS

ELIGIBILITY AND INCLUSION CRITERIA

NetcomSA's as well as local clinics and hospitals refer their clients to join the clinic programme. NetComSA provides specialist pre- and post-test counselling service, after which clients are encouraged to participate in a number of the support groups and educational programmes that are run from the clinic staff. Clients are assessed clinically and a baseline CD4+ count is done. Clinical, biological, social and adherence motivation criteria are used to initiate ART, specifically:

- World Health Organization (WHO) Stage II or III (symptomatic HIV disease) or WHO Stage IV (clinical AIDS)
- CD4+ count < 200 cells/mm³
- No access to medical insurance
- Live within a reasonable distance from the clinic
- Disclosure of HIV status to at least one family member, partner, or other person living with client who is willing to be a treatment supporter

Clients who present with TB do not receive ART until they complete their TB treatment. Treatment protocols that were developed for the clinic were subsequently mirrored by WHO's treatment guidelines, including the use of approved medications, first- and second-line ART regimens, proper monitoring of clients response to treatment, treatment of opportunistic infections, adherence support and counseling.

Before the initiation of treatment, clients together with their treatment supporters discuss with the clinic staff their HIV disease status and the risks and benefits of treatment and sign an informed consent form (which is clearly explained to them in their own language).

PREPARATION FOR THE INITIATION OF TREATMENT

Prior to treatment initiation, clients are encouraged to bring their family members, friends, and/or informal caregivers into the clinic to discuss with the medical director and staff nurse about the importance of medication adherence and the near,

medium and long-term support requirements to promote medication adherence. All clients who meet treatment criteria are required to attend four treatment education workshops conducted by NetComSA's treatment educators before the initiation of ART. The workshops involved extensive client counselling and reinforcement of key messages on medication adherence and drug-related side effects. A support group meets weekly for feedback from the clients and also to address any concerns that are raised by the physician. Pillboxes and plastic zip-lock bags are also made available to clients to help facilitate and promote medication adherence.

Laboratory tests are performed to provide at baseline to monitor the response to therapy and adverse events. The tests assess full blood count, liver function test, CD4+ T-cell count and HIV viral load.

FIRST- AND SECOND-LINE REGIMEN

- Choice of First-Line Regimens: d4T/3TC/Nevirapine or d4T/3TC/Efavirenz; In pregnant women, Nevirapine-containing regimen is used as a substitute for efavirenz-containing regimen
- Choice of Second-Line Regimen: AZT/ddI/ Lopinavir/ritonavir

LABORATORY MONITORING

At the initial pre-treatment visit, client's blood samples are drawn for full blood count, liver function test, CD4+ count and HIV viral loads. Clients are then seen on day 7, 14, 28 and monthly thereafter. Nevirapine clients have their liver function tests on days 14, 28 and at 3 months. While those on regimens containing AZT have complete blood counts at one & three months and six monthly, thereafter.

HIV viral load and CD4+ counts are repeated at 3 months and done every 4 to 6 months. We plan to use the WHO guidelines where HIV viral load maybe done once a year for clients who have had a satisfactory treatment response (with CD4+ counts done thrice in a year).

INDICATIONS FOR CHANGE OF THERAPY AND DISCONTINUATION

Treatment may be changed if the following occurs:

- Moderate to severe adverse events incompatible with a satisfactory quality of life
- Secondary failure, as assessed by both clinical and laboratory data
- Primary failure

WHAT TO CHANGE TO

- In case of d4T, change will be to AZT
- Patients who have first-line drug failure will be considered for the second-line drugs.
- Patients who develop severe Nevirapine side effects will be changed to Efavirenz and if there are unacceptable side effects, will be put on second-line drugs.

Change of therapy will take into consideration the client's well being as well as drug adherence.

PROVISION OF PROPHYLAXIS FOR OPPORTUNISTIC INFECTIONS

Medications for prophylaxis of opportunistic infections are prescribed for all clients with CD4+ counts of less than 200 cells/mm³. Namely, fluconazole for recurrent oral-pharyngeal thrush and cotrimaxozole for PCP and toxoplasmosis are given according to the WHO recommendation. TB prophylaxis is not encouraged unless active TB has been actively excluded. In some cases, clients may be referred to TB clinics within their home areas. The Ithembalabantu takes advantage of Pfizer's Diflucan Program.

COMMUNITY OUTREACH AND TREATMENT ADVOCACY

NetComSA, our community based NGO partners continue to lead the effort to mobilize the involvement and support of the local community for the project. NetComSA has organized various community forums in the local community since the implementation of the project. The forums are particularly important in capturing useful feedback to improve relevant components of the treatment and support program, and to seek ways to build on the successes that have been generated at the clinic in shaping public opinion on the delivery of ART and care in resource-poor settings. Many of the clients are involved in helping to increase awareness of HIV treatment, advocating for positive living and in their lives are helping to break down the acute level of stigma and discrimination that surrounds HIV/AIDS in South Africa.

CLINICAL OUTCOMES AFTER 16 MONTHS OF OPERATIONS

A total of 470 clients are registered at the clinic of which 100 have commenced HAART. Ten deaths have occurred, none of which are attributed to ART, and 11 clients have defaulted. The data suggests that 95% adherence has been achieved and maintained by the clients receiving ART.

MEDICAL CO-MORBID CONDITIONS AT TREATMENT INITIATION

ORAL/ORO – PHARYNGEAL CANDIDIASIS 13
 TUBERCULOSIS (FOCAL/DISSEMINATED) WITHIN PREVIOUS 2 YEARS 13
 SYMMETRIC DISTAL PERIPHERAL NEUROPATHY 11
 PULMONARY TUBERCULOSIS DEVELOPED WHILE ON ARVs 5
 CRYPTOCOCCAL MENINGITIS 5
 CHRONIC DIARRHOEA 4
 TB BEFORE AND AFTER STARTING ARVs 3
 NEUROLOGIC CMV 3
 PCP/PNEUMONIA 2
 VALVULAR HEART DISEASE 1
 NEUROPSYCHIATRIC DISEASE 1
 MOLLUSCUM CONTAGIOSUM 1
 PELVIC INFLAMMATORY DISEASE 1
 PARAPLEGIA – FLACCID 1
 DIARRHOEA 1

OVER 75% OF CLIENTS HAVE HAD IMPROVEMENT IN KARNOFSKY PERFORMANCE SCORE FROM BELOW 50 AT BASELINE TO 80–100 AFTER 16 MONTHS OF TREATMENT.

DRUG ADHERENCE

ADHERENCE IS ALWAYS DIFFICULT TO ASSESS ACCURATELY AS IT RELIES ON CLIENT FEEDBACK, BUT IS CORROBORATED BY LABORATORY MARKERS.

INQUIRY ABOUT MISSED DOSES (WHICH IS WHAT WAS USED IN INITIAL 3–5 MONTHS) RELIES HEAVILY ON THE PATIENT'S MEMORY. PILLBOXES ARE PROVIDED TO HELP ASSESS ADHERENCE.

$$\text{COMPLIANCE (\%)} = \frac{\text{NUMBER OF PILLS TAKEN}}{\text{NUMBER OF PILL SUPPOSED TO BE TAKEN}}$$

THERE IS A NEED FOR A CONSTANT SUPPLY OF PILLBOXES AND PATIENTS NEED TO BE REMINDED TO RETURN PILLBOXES WITH ALL UNUSED MEDICATION.

OTHER PARAMETERS LIKE WEIGHT GAIN, IMPROVED CLINICAL STATE AS WELL AS LAB RESULTS ALSO COMPOUND THE ABOVE.

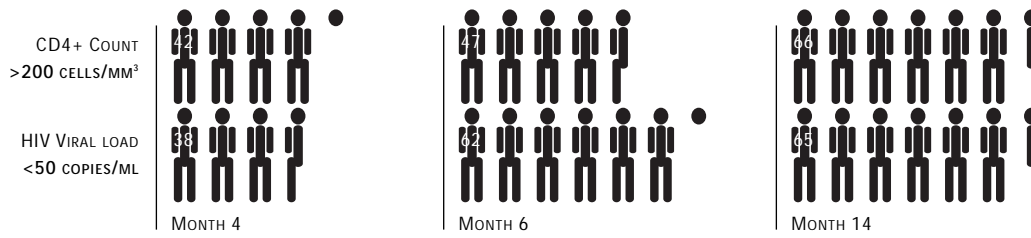
THE ASSESSMENT DURING THE EARLY PERIOD SHOWED AN ADHERENCE RATE OF OVER 98%.

SUSTAINABILITY

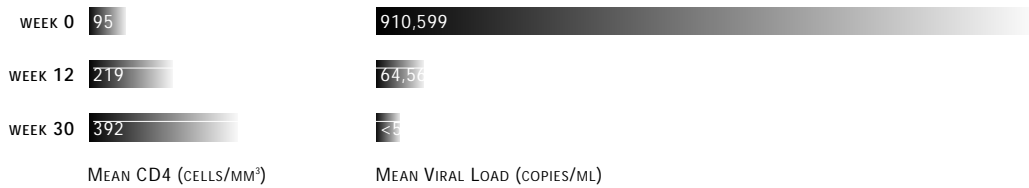
MIRRORING AHF'S HISTORY IN NORTH AMERICA AND EUROPE, AHF-GI HAS FORGED AHEAD AND DEVELOPED WORKING RELATIONS WITH LOCAL NGOs AND HEALTHCARE FACILITIES TO PROVIDE TREATMENT AND CARE FOR PEOPLE LIVING WITH HIV/AIDS IN SOUTH AFRICA. THE PICTURE OF HIV/AIDS THAT WE SEE NOW IN SOUTH AFRICA REMINDS US OF AHF'S EXPERIENCES OVER 15 YEARS AGO, EXCEPT FOR THE SCALE OF HUMAN SUFFERING. THE CHALLENGE IS NOW GREATER, AS IT IS SO EASY TO IGNORE AND DISMISS THE NEEDLESS HOPELESSNESS, SUFFERING AND DEATH THAT A COUNTRY LIKE SOUTH AFRICA IS FACING THROUGH LACK ACCESS HIV MEDICINE AND CARE.

EFFORTS NEED TO BE INTENSIFIED TO PROVIDE MORE PEOPLE WITH TREATMENT, SHARE OUR KNOWLEDGE AND EXPERTISE SO THAT POSITIVE IMPACT CAN BE MADE ON THE HIV PANDEMIC FACING SOUTH AFRICA AND OTHER COUNTRIES AROUND THE GLOBE.

NUMBER OF CLIENTS WHO HAVE ACHIEVED IMPROVEMENTS
IN CD4+ COUNTS (>200 CELLS/MM³)
AND UNDETECTABLE HIV VIRAL LOAD (<50 COPIES/ML) (n=89)



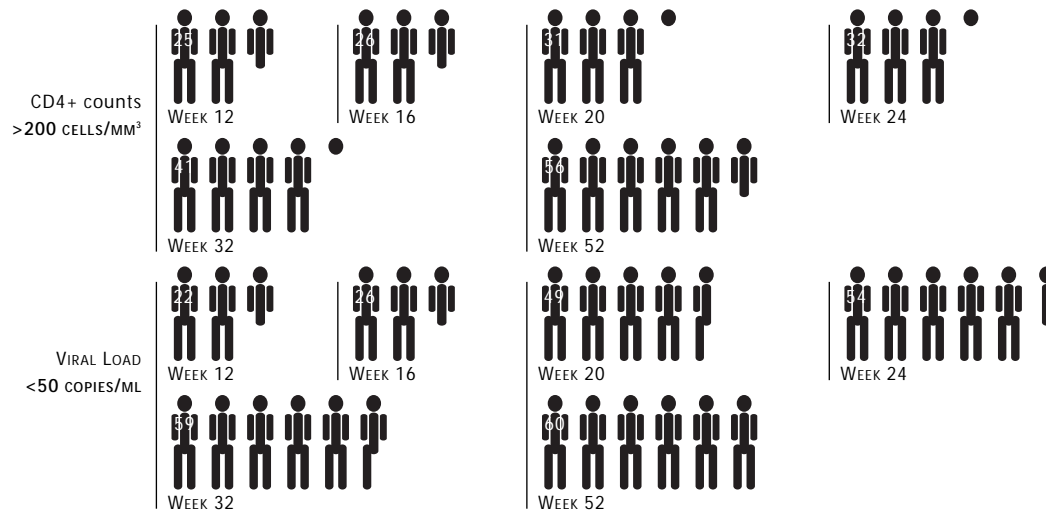
MEAN CD4+ COUNTS AND HIV VIRAL LOAD DATA OVER 30 WEEKS (n=58)



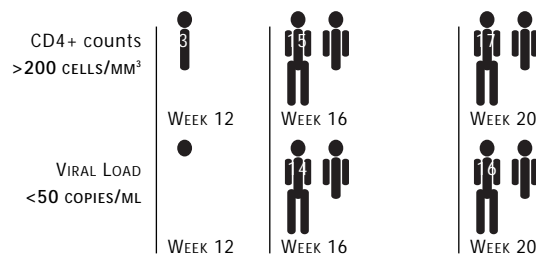
ONLY ONE CLIENT HAD A VL OF 287 AT 23 WEEKS, WHO SUBSEQUENTLY ACHIEVED A VL OF <50 FOLLOWING ADDITION OF KALETRA TO HER REGIMEN

NUMBER OF CLIENTS WITH CD4+ COUNTS (>200 CELLS/MM³)
AND UNDETECTABLE HIV VIRAL LOAD (<50 COPIES/ML)
FOLLOWING 20 TO 52 WEEKS OF ARV TREATMENT

GROUP 1 (n=58)



GROUP II (n=34)



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PRIMAGEN
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