Make antiretroviral therapy available

TREATMENT PROJECT

Funding proposal

16 September 2003

TAC Treatment Project
(Association incorporated under section 21 of the Companies Act)
Registration number 2003/009927/08
Applications for non-profit and tax exempt status pending

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Section 1: Introduction

John Vollenhoven is a resident of Atlantis one of the poorest townships of the Western Cape. He is a father of two children. After starting antiretroviral therapy he has a better chance of surviving AIDS and has already improved his quality of life. “Uncle John” is one of twenty-five TAC members selected across the country to be treated on the TAC Treatment Project.

The Treatment Action Campaign has campaigned for medicine price reductions, for the development of a national treatment plan and for communities to become treatment literate. TAC has supported the MSF programme in Khayelitsha that treats more than 400 people with antiretrovirals and provides medical services to more than 4000 people living with HIV/AIDS. TAC has also helped ARV programmes in Johannesburg, Soweto and Durban. On a daily basis, TAC members across the country engage in HIV prevention and treatment education.

In the last six months, TAC has lost more than 100 members whose lives could have been saved with antiretroviral therapy. Therefore, we formed the TAC Treatment Project. However, TAC believes that everyone has a right to life. So, for every TAC member treated, the TAC Treatment Project commits to treating a person in the community who is unrelated to TAC. We also want to make a direct contribution to saving lives.

Medical and administrative costs of the TAC Treatment Project (including a wellness programme for 5000 TAC members, TAC’s fluconazole programme and antiretroviral treatment for 500 community and 500 TAC members) would need approximately R10.2 million in the 2004/05 financial year. A detailed budget is attached to this document. Medical expenditure for the TAC members at R7609 per patient per year[1] or R634 per month is slightly higher than the R6000 per patient per year budgeted for community slots, owing to the lower costs associated with using exclusively public sector facilities. For detailed calculations please see the attached budget. Estimates of administrative and support spending – higher than in a single-site treatment project and necessitated by patients being unable to pay even for their transport etc. – are based on the experience of the TAC Treatment Project in its first months of operation. The figure of R10.2 million assumes that 1000 patients are treated for an entire year and includes all capital, administrative, medical and other costs.

Budget Summary 2004/2005: 1000 people on ARVs & 5000 on wellness programmes

Item	Amount	Percentage
Capital expenditure	R53 000	0.52%
Operational costs excluding salaries	R1 186 080	11.63%
Salaries	R315 200	3.09%
Medical expenditure: 500 TAC members & Wellness programme for 5000 TAC members	R5 339 944	52.38%
Medical expenditure: 500 community patients	R3 000 000	29.43%
Fluconazole programme	R100 000	0.98%
Accounting & auditing	R100 000	0.98%
Fundraising expenses	R100 000	0.98%
Total	**R10 194 224**	**100%**

The TAC Treatment Project was formed in June 2003 with the following aims:

[1] All medical expenditure excluding the wellness programme, provision for emergency medical treatment and a sundry provision.

- To allow ordinary people to make a contribution to saving lives;
- To treat activists and to save their lives;
- To treat an equal number of individuals who are not TAC members; and
- To assist government in piloting anti-retroviral therapy.

The TAC Treatment Project would rely on the financial contributions of ordinary people in South Africa in its work.

On the 8th of August 2003 the South African government instructed the Ministry of Health to develop an operational plan for the provision of antiretroviral treatment in the public sector. This plan is due at the end of September 2003. Government estimates that 500 000 people need antiretroviral medicines now. Initial government programmes will not reach more than 30% of people who need treatment. Many communities will have to wait years before the phased rollout reaches them. We have a duty to treat as many people that government cannot reach as possible.

In order to ensure that the public sector programme is a success, and that the HIV/AIDS pandemic does not destroy more of our families and communities, other sectors of society like organised business, organised labour, civil society and private healthcare providers have to assist the public healthcare system.

The TAC Treatment Project is a Section 21 (non-profit) company established by the Treatment Action Campaign to make affordable Highly Active Antiretroviral Therapy (HAART) available to people living with HIV/AIDS in South Africa. This will be done on a fully, partially or unsubsidised basis. While the TAC TP has a close relationship with the TAC, it is organisationally and financially independent. Any funds raised by the TAC TP will be used solely for treatment and related support services.

The TAC Treatment project aims to have 50 people on antiretrovirals by December 2003 and 1000 people on antiretrovirals by December 2004. These will be fully subsidised places. Fully subsidised treatment (including medicines, laboratory monitoring and doctors' consultations) will be made available to an equal number of treatment activists and community members not members of the TAC. In other words, for every TAC (or other treatment access) activist treated there will be a corresponding community member treated.

TAC activists will be treated directly through TAC TP. While TAC TP will fund medicines and support for other community members, their actual treatment will be administered through public health facilities. Only public sites that meet rigorous standards, clinical selection criteria and levels of care maintained by TAC TP will be used.

This funding proposal relates to fully subsidised treatment for activists and communities. Partial subsidisation refers to patients who make a voluntary contribution to the project (which will in no way affect their chances of selection or level of care and support). For unsubsidised treatment the TAC Treatment Project will operate as a non-profit distributor of generic antiretrovirals not otherwise available. Any surplus realised will be used to subsidise treatment.

Objectives

The project has the following objectives:

- to extend and improve the quality of life of people living with HIV/AIDS;
- to provide access to Antiretrovirals (ARVs) for treatment access activists and others in South Africa, through full and partial subsidy by the project. This includes monitoring costs and where necessary medical consultation fees;

- to promote and use safe, effective and quality generic anti-retrovirals in order to save lives;
- to provide social support to ensure that treatment is optimised;
- to co-operate with and affiliate to bodies with similar objectives locally, regionally and internationally;
- to improve capacity in the public healthcare sector by working with the national and local departments of health, hospitals, clinics and healthcare workers; and
- to provide a model for governments and private providers of healthcare in developing countries, by demonstrating how the use of low-cost generic ARVs could broaden access to HAART significantly.

For the first six months of operation the project will focus exclusively on providing subsidised treatment to TAC activists and community members and building organisational and operational capacity. Thereafter the activities of the project will be incrementally expanded in order to make treatment available to larger numbers of people.

Project duration

The TAC TP commits to the provision of antiretroviral therapy to all patients admitted to the project for a minimum of five years. It is hoped that the introduction of a universal HAART programme in the public sector would enable the TAC TP to ensure that its patients are guaranteed access to treatment for life. The project will operate for at least six years, although its lifespan may be extended depending on circumstances.

Starting date: 1 June 2003

Project location

The project will operate throughout South Africa starting in Gauteng, Kwazulu-Natal, Eastern and Western Cape. Public facilities will be promoted and private facilities used where necessary. Community slots will be located in public health facilities where nurses and doctors have the capacity to treat. All patients will use public health facilities for the treatment of Opportunistic Infections (OIs) and hospital care where possible.

Project description

The project will provide antiretroviral treatment to people with HIV/AIDS based on accepted international standards. It will also promote prevention, wellness and openness among HIV/AIDS activists, their families and communities. The TAC Treatment project aims to have 50 people on antiretrovirals by December 2003 and 1000 people on antiretrovirals by December 2004. The responsible medical officer is Dr Kwezi Matoti. His details are attached to the Treatment Protocol. The pharmacist is Mr. Gavin Brown.

The implementing organisation is the TAC Treatment Project and it is independently managed. The project maintains strong links with the TAC and that organisation provides financial and human resources for the initial phases of the TAC Treatment Project. The project will make use of public sector facilities wherever practical, especially for the treatment of OIs (including TB) and hospitalisation where required.

Medical and administrative costs of the TAC Treatment Project (including a wellness programme for 5000 TAC members, TAC's fluconazole programme and antiretroviral treatment for 500 community and 500 TAC members) would need approximately R10.2 million in the 2004/05 financial year. A detailed budget is attached to this document. Medical expenditure for

the TAC members at R7609 per patient per year[2] or R634 per month is slightly higher than the R6000 per patient per year budgeted for community slots, owing to the lower costs associated with using exclusively public sector facilities. For detailed calculations please see the attached budget. Estimates of administrative and support spending – higher than in a single-site treatment project and necessitated by patients being unable to pay even for their transport – are based on the experience of the TAC Treatment Project in its first months of operation. The figure of R10.2 million assumes that 1000 patients are treated for an entire year and includes all capital, administrative, medical and other costs. They key outcomes will include:

- Prolonging life in 1000 people on ARVs with an impact on their families and communities;
- Improving the quality of life and openness for 5000 people, their families and communities accessing the wellness programmes;
- Assisting the state with the development of capacity to scale up ARV access in the public sector.

The ethics committee supervising the project is University of Cape Town Ethics Committee at the Faculty of Health Sciences. The committee can be contacted on +27 21 406 6492.

Participating health workers

All participating doctors and nurses have extensive experience or training in HIV medicine, including antiretrovirals. Doctors and nurses will be trained in the contents of accepted WHO and SA HIV Clinicians Society Guidelines on the use of antiretroviral medicines in people living with HIV/AIDS. The principal medical officer and the board of the TAC TP will support healthcare professionals with additional training.

All participating counsellors have completed training courses as well as advanced TAC treatment literacy training. The person responsible for training counsellors and treatment supporters is Ms Sipho Mthathi, TAC National Treatment Literacy Coordinator. She can be contacted at the TAC National Office, at +27 21 788 3507.

Section 2: Organisational and Operational Structure

Organisational structure

As mentioned previously, the TAC TP is registered as a Section 21 (Non-Profit) Company, (registration number 2003/009927/08). Registration under the NPO Act is still pending.

The highest management body will be a Board of at least seven members but not more than nine, democratically elected by the members at a founding meeting and thereafter at an Annual General Meeting (AGM). Provincial Selection Committees will be responsible for the selection of patients. Please see Section Three, entitled “Patient Selection” for further details.

The Board has employed a number of staff members to conduct the daily operations of the project. These include:

- A national coordinator
- A pharmacist (part-time)
- A financial manager
- An administrator; and

[2] All medical expenditure excluding the wellness programme, provision for emergency medical treatment and a sundry provision.

- Three provincial coordinators, with more to follow soon.

The project will ensure that management is devolved to the local level, except where it is more efficient to manage nationally (for example, procurement) or where it is necessary to maintain standards.

A National Office as well as Provincial Offices will be established (preferably leasing space from existing TAC offices). The national office will be responsible for:

- Procurement;
- Distribution;
- Record and data collection;
- Financial management; and
- Fundraising in association with provinces.

Monitoring, Evaluation and Reporting

The TAC aspires to the highest quality of financial management, control and accountability. The TAC Treatment Project adopts the same values with regard to pecuniary matters.

An independent evaluation mechanism will be established that will allow the Board to assess the performance of the project on an ongoing basis. The Board may decide to employ one person (or utilise volunteers) to obtain regular feedback from patients and counsellors.

All financial transactions will be recorded in accordance with standard accounting practice. Annual audited financial statements will be published. To ensure accountability, both quarterly and annual narrative reports will be produced. The TAC TP's financial manager is Dawn Wilson and we have appointed the well-respected auditing firm of Douglas & Velcich, based in Johannesburg. The TAC TP is negotiating with another respected firm of auditors for verification of quarterly reports.

Financial management and fundraising strategy

The national office will be responsible for accounting and day-to-day financial management. The Board will take overall responsibility for financial management and medium to long term financial planning. Quarterly financial reports will be made to the TAC Treatment Project Board.

TAC Treatment Project aims to build individual donations from the broad public in South Africa and internationally. In South Africa, the project aims to convince more than 10 000 individuals to donate R50.00 per month to treat 1 000 people. Over the first two years, the TAC Treatment Project will require 60% of its budget from institutional or large donors. For the last four years, the TAC Treatment Project aims rely for less than 10% on institutional and large donors.

Financial arrangements

The TAC TP will provide or pay for:

- Antiretroviral drugs;
- Laboratory monitoring (incl. $CD4^+$ cell counts, viral load tests and adverse event monitoring);
- Fluconazole;

- Any prophylaxis or treatment for opportunistic infections included in the public sector prescribed minimum benefits; and
- Emergency ARV-related hospitalisation where public facilities are unavailable.

Where possible, TAC will provide volunteer treatment supporters from its membership base.

Contributions

TAC Treatment Project has pending registration to ensure that contributions are tax deductible in South Africa. Contributions are tax exempt in the USA through the Southern African Development Fund (SADF).

Section 3: Patient Selection

Principles of selection

The number of people with HIV/AIDS in need of treatment countrywide far exceeds the number of patients the TAC TP will be able to provide with antiretrovirals. For this reason a clear and transparent selection mechanism is in place to assess eligible candidates for inclusion in the project. As mentioned previously, for every treatment access activist that is treated there will be a member of a community who has no previous involvement in the TAC, who will be treated. Community members will obviously have to meet the same clinical criteria as treatment access activists. Social criteria will differ slightly.

- Only people who fulfil the clinical criteria as stipulated in the WHO or SA HIV Clinician Society Guidelines will qualify for antiretroviral therapy.
- All patients (TAC members and community people) must show some record of treatment adherence and support.
- Only people who cannot afford to pay for medicines will be considered for subsidised positions.
- In addition, TAC members must have a record of work as activists.

Selection Structures and Procedure: TAC members

Each TAC Provincial Executive Committee will appoint, in consultation with the TAC TP board, a provincial TAC TP coordinator and convene a provincial selection committee consisting of two provincial TAC leaders, one doctor, one nurse and one trained counsellor.

TAC provinces will conduct provincial audits of people who are eligible for inclusion in the TAC TP. This will occur in phases of not more than 100 people at a time selected on the basis of need. The audit will compile a waiting list based on all TAC members or their close family members who have had a $CD4^+$ cell count in the last six months and whose count was below 300 /mm^3.

Anyone who believes they might qualify and has not had a $CD4^+$ cell count in the last six months will be allowed to have one (at a laboratory approved by the TAC TP). If the person earns less than R2500.00 per month, the TAC TP will cover the cost of the test. This list of people will be sent to the TAC TP National Office to be placed on a central database. The provincial coordinator and selection committee will also be responsible to keep this database updated by sending through the names of people continuously as they have $CD4^+$ cell counts. Provinces will be allocated places for TAC members on the availability of finance, equity and record of TAC work. In the first round 30 TAC members will be selected – Gauteng (10 places), Eastern Cape (5 places), KwaZulu-Natal (10 places) and Western Cape (5 places).

This will be matched with community places. (A separate document on selection criteria and mechanisms is available on request).

Selection of community places

Public healthcare sites to which community treatment slots are allocated will be responsible for selection of patients. The TAC TP will ensure that such sites employ the same clinical criteria as the TAC Treatment Project, that the selection process is conducted in a fair and transparent manner, and that there is an assessment of an ability and willingness to comply with treatment.

Capacity to treat

There are currently fifteen patients enrolled in the ARV programme and more than 300 on the waiting lists. The TAC TP aims to increase these numbers to fifty (25 tac members, 25 community members) by the end of this year, 2003, and five hundred TAC members by the end of 2004. They will be allocated equally between the six provinces in which TAC is active, namely Gauteng, the Western Cape, Eastern Cape and Kwazulu-Natal, Mpumalanga and Limpopo. Five hundred treatment slots will have been allocated to community treatment sites by the end of 2004.

The TAC TP will also distribute generic ARVs on a not-for-profit, or even subsidised, basis to those who cannot afford them at full cost. This is for the purpose of reaching as many people as possible through the project.

Section 4: Operations and Logistics

Drug procurement and distribution

As far as possible the TAC TP will make use of generic antiretroviral drugs. Such products will be procured through the Generic Anti-retroviral Procurement Project (GARPP). GARPP will distribute generic ARVs registered for use in SA or drugs for which special authorisation was obtained from the Medicines Control Council (MCC) under Section 21 of the Medicines Act. The project will keep good records of all orders, received stock, issued stock and returned or expired stock.

The TAC Treatment Project has a contract with GARPP, which will ensure the quality of the unregistered products by doing ID and assay on each different batch received before releasing them to our project.

The medicines will be received by Mr Gavin Brown, responsible pharmacist, and stored (under Good Pharmacy Practice[3] conditions) in a registered facility with which the TAC Treatment Project has a contractual arrangement. When dispensed to patients who are not in the Cape Town area, the medicines will be couriered to the patient's doctor and handed over to the patient by the doctor him/herself on Mr Brown's behalf. Mr Brown will not authorise the dispensing of the unregistered anti-retroviral medicines to any patient who is not part of the TAC Treatment Project and on the prescription of a clinician participating in the TAC Treatment Project.

Excess or expired medicines will be returned to GARPP.

Please see the TAC Treatment Project Treatment Protocol for details on operational and project management aspects.

[3] Good Pharmacy Practice guidelines for South Africa. South African Pharmacy Council.

Section 5: Clinical Monitoring and Treatment Support

The primary focus in data collection will be on evaluating the advantages and disadvantages as well as problem areas for organisations or associations of individuals to obtain HAART using the model employed in this project. The focus will therefore be on qualitative aspects.

Monitoring of efficacy and safety (i.e. adverse events, immunological markers, viral loads etc.) will be done continuously. Data collected by each participating doctor will be collated in a central database specifically designed for the project. Analyses will be conducted on the impact of antiretroviral therapy on virological and immunological surrogate markers, clinical progression, quality of life, and the cost and cost-effectiveness of care. Adherence will also be monitored.

Assessment of patient and safety monitoring

Assessment of patient and safety monitoring will take place in two ways:

- Continuous administrative monitoring (at every issue of drugs – i.e. monthly intervals – a specific patient will be evaluated in terms of
    - regularly visiting the attending doctor;
    - the doctor having reported all adverse events and other required data;
- Regular audits of patient data will be conducted to ensure that all required data has been collected and captured. Reporting of adverse events to the MCC will also be audited. Comprehensive audits will take place at least 6-monthly and smaller audits as required according to the judgement of the principal medical officer.

Informed consent and treatment support

The informed consent and treatment support strategy has the following main objectives:

- ensuring all patients have an adequate understanding of what antiretroviral therapy entails;
- ensuring all patients understand the potential risks and benefits of antiretroviral therapy;
- maximizing adherence; and
- minimizing the impact of adverse events.

Patient support is based on individual counselling and attending support groups. In addition, regular TAC Treatment Literacy workshops assist in the promotion of healthy living, understanding medicines and creating an open and stigma-free environment.

Treatment support at community treatment sites will be the responsibility of the sites themselves. However, the TAC TP will make budgetary allocations for such activities – in addition to medical costs. Local TAC branches and volunteers (includiong counsellors, treatment literacy educators, etc.) will be mobilized to assist community treatment sites.

Specifically, the informed consent and treatment support strategy consists of the following components:

1. *treatment literacy* and treatment readiness workshops for all TAC members, including those being considered for the TAC TP;

2. *assessment of social criteria* relating to an ability to benefir from antiretroviral therapy before the commencement of treatment (and targeted interventions where problems are detected);
3. an individual counselling session in which a counsellor ensures that the patient has a thorough understanding of the contents of the *informed consent* form prior to signing;
4. two *treatment readiness workshops* immediately prior to starting treatment in which patients and their treatment partners (family members) are trained in issues around adherence, adverse events, etc.
5. a *treatment monitor* from a local TAC branch assigned to each patient (to conduct regular home visits); and
6. each patient belonging to a *treatment support group* meeting at least twice per month and facilitated by a trained counsellor.

Section 6: Budget for April 2004 to March 2005

Capital expenditure		**R53 000.00**		
Computer	R40 000.00		5*8000	5 Computers @ R8000
Shredders	R5 000.00		5*1000	5 Shredders @ R1000
Lockup cabinets	R5 000.00		5*1000	5 @ R2000
Cellular telephones	R3 000.00		5*600	5 @ R600
Operational		**R1 501 280.00**		
Staff: pharmacist	R83 200.00		16*100*52	16 hours per week @ R100/h
Staff: coordinators	R90 000.00		5*1500*12	5 coordinators, R1500 per month
Staff: administrator	R42 000.00		3500*12	R3500 per month
Staff: counsellors	R100 000.00		500*2*50	2 init. couns. sessions @ R50/session
Prescription charge	R100 000.00		500*4*50	3-month supply at a time, R50 per dispensing
Postage - drugs	R40 000.00		500*4*20	3-month supply at a time, R20 per batch
Courier costs - general	R30 000.00		50*12*50	50 items per month, R50 per item
Stationery - national	R3 600.00		300*12	R300 per month
Transport: provincial	R150 000.00		2500*12*5	Transport for prov coordinators, counsellors etc.
Cellular airtime:provincial	R6 000.00		5*100*12	
Support group meetings	R420 000.00		24*5*5*(100+40*30)	2x per month; 5/prov; 40 people/supg [travel R30/person; R200 facilitator;]
Wellness workshops	R300 000.00		5000*2*30	2/patient; R30 transport
Sundry provision (10%)	R136 480.00			emergencies,variances in oper costs
Medical: TAC members		**R5 339 944.50**		
Wellness CD4s	R550 000.00		5000*110	5000 CD4 counts @ R110 / test
ARVs	R1 920 000.00		500*320*12	500 monthly doses of ARVs @ R320 per dose
Doctors' consultations	R805 000.00		500*(18*100)+500*5*100	18 visits in first year (see protocol); 5 emergency visits; @ R100 per visiit
Lab: VL+FBC+CD4	R922 500.00		500*(3*615)	3/year
Lab: FBC+Diff	R59 175.00		250*3*78.9	AZT (half): 3 times separate from VL
Lab: ALAT	R79 325.00		500*33.4+375*5*33.4	NVP,EFV (all) once, NVP (75%): 5 times more
Lab: Cholesterol	R18 495.00		75*3*(33.1+49.1)	PI (3 people) 3 times
Emergency hosp+other drugs	R500 000.00		500*1000	R1000/patient/year
Sundry provision (10%)	R485 449.50			
Community slots		**R3 000 000.00**		
ARVs	R1 920 000.00		500*320*12	500 monthly doses of ARVs @ R320 per dose
Support costs	R1 080 000.00		500*180*12	Provision for additional costs associated with treatment support
Fluconazole programme		**R100 000.00**		
Accounting & Auditing		**R100 000.00**		
Fundraising expenses		**R100 000.00**		
Expenses		R10 194 224.50		