AIDS LAW PROJECT (ALP)
TREATMENT ACTION CAMPAIGN (TAC)

'LET THEM EAT CAKE' - A SHORT ASSESSMENT OF PROVISION OF TREATMENT AND CARE 18 MONTHS AFTER THE ADOPTION OF THE OPERATIONAL PLAN

JUNE 2005

UPDATED SECOND JOINT REPORT ON THE IMPLEMENTATION OF THE *OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA*

The first joint AIDS Law Project (ALP)/Treatment Action Campaign (TAC) monitoring report on the implementation of the Operational Plan was presented to the People's Health Summit (PHS) held in East London in July 2004. Since then, the Joint Civil Society Monitoring Forum (JCSMF) – consisting of more than 12 civil society organisations, including the ALP and TAC – was formed. In addition to its launch meeting in Polokwane, in September 2004, the JCSMF has met on three separate occasions – in Bloemfontein, Durban and Nelspruit. The resolutions of each meeting, which have been publicly released, deal with a range of issues relating to access to treatment for HIV/AIDS, with a particular focus on the implementation of the Operational Plan.

This second joint ALP/TAC monitoring report considers the implementation of the Operational Plan, some 18 months since its adoption. It focuses on early reports of patient outcomes, explains provincial variations in relation to patient numbers, and addresses some of the key barriers in the way of speedier implementation. Importantly, it is limited to the public sector.

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[1] **This report was compiled based on information collected by the following organisation: Absolute Return for Kids (ARK), NDLOVU HAART programme, One2One Kids, Médecins Sans Frontières (MSF), the TAC, Law & Treatment Access Unit of the ALP, Health Systems Trust, Bio Watch and the 1st – 4th Joint Civil Society Monitoring Forum (JCSMF) Resolutions. The following provincial health departments responded to requests for information: Gauteng, the Eastern Cape, the Western Cape, the Free State, Mpumalanga, the Northern Cape and the North West.**

INTRODUCTION

On 8 August 2003, South Africa's Cabinet made a commitment to provide antiretroviral (ARV) treatment in the public health sector. On 19 November 2003, little more than three months later, government published the Operational Plan on Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (the Operational Plan). In addition to an executive summary, the Operational Plan consists of 16 chapters, divided into six sections. Each section is devoted to a broad area of the Operational Plan and its implementation, with each chapter focusing on a particular aspect.

Each of the 16 chapters contains express commitments made by government in respect of the Operational Plan's implementation. From broad commitments to providing access to antiretroviral (ARV) treatment to over a million people with AIDS by the end of the 2007/8 financial year (Chapter V), the Operational Plan also envisages the hiring of additional health workers (Chapter V), the provision of nutritional assistance to people living with HIV/AIDS (Chapter II), and the provision of a continuum of care at different levels of the public health system (Chapter I), amongst other interventions.

This report provides a preliminary review of whether some of the key commitments made in the Operational Plan have been met, some 18 months after its adoption. Future reports will provide updates about the extent to which ARV treatment is available in the private sector. This report, which is limited to the public health sector provision of treatment, focuses on certain key issues:

- The first section is devoted to good outcomes that have been documented and reported by several ARV treatment sites in the country. Simply put, it shows that carefully and properly managed ARV treatment programmes are saving lives of adults and children living with HIV/AIDS.

- The second section, which provides an update on the latest national and provincial patient numbers, offers some critical comments about the failure of provinces such as the Eastern Cape, Limpopo and Mpumalanga to scale up the pace of implementation.

- The third section identifies and examines some of the key barriers in the way of implementation. For example, several reports of long waiting lists around the country demonstrate both the existence of demand for ARV treatment as well as the inability of many treatment sites to increase patient numbers. This report highlights some of the causes of this inability to scale up treatment, such as the crisis in human resources for health.

GOOD OUTCOMES OF TREATMENT IN THE PUBLIC SECTOR

Several reports confirm good outcomes of ARV use in the public health sector. They provide incontrovertible evidence that the use of ARV medicines has saved the lives of thousands of people living with HIV/AIDS. Below is a brief summary of key aspects of some of the reports that were released prior to the 2nd South African AIDS Conference.[2]

- A study conducted in Cape Town found that people with a CD4 count of 200 or less who do not take ARV medicines have a 35% chance of surviving three years, compared to an 80% chance of survival for those taking ARV medicines.

- The results of a study of 262 children accessing ARV treatment at Harriet Shezi Clinic at Chris Hani Baragwanath Hospital in Soweto have recently been published. The vast majority of the children are demonstrating excellent outcomes. Only two children (0.76%) reportedly showed signs of toxicity: the treatment regimen was altered for one and discontinued in the other. Although 18 children (7%) died during the study, not a single death was ARV-related. Instead, the deaths were reported to be associated with disease progression – the children simply accessed ARV treatment too late.

- Three clinics at the primary health care level in Khayelitsha provide ARV treatment to nearly 2 000 adults and children. When patients first started treatment, the average CD4 count was below 100 (i.e. advanced AIDS). After three years of ARV treatment, four out of every five patients are still alive.[3] Without ARVs, half would have died within a year. Almost all deaths were due to the advanced stage of the disease, with only four deaths being ARV-related. In three years, only one in every ten patients has had to change treatment regimens as a result of side effects.

- The Ndlovu HAART programme in Mpumalanga has reported a 100% success rate with its prevention of mother-to-child transmission of HIV (PMTCT) programme.[4]

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[2] See (A) *Children receiving ARVs at Harriet Shezi Clinic*. Assoc Prof Pierre Barker, Institute for Healthcare Improvement. Dr Harry Moultrie and Dr Tammy Meyers, Harriet Shezi Clinic & Wits Paediatric HIV Unit. (B) Medecins Sans Frontieres, May 2005. Information provided to the *TAC Equal Treatment Newsletter*. (C) *Initiating highly active antiretroviral therapy in sub-Saharan Africa: an assessment of the revised World Health Organization scaling-up guidelines*. Motasim Badri et al. *AIDS* 2004, 18:1–10 (D) Health Systems Trust, *Treatment Monitor*, Rob Stewart. (E) Ndlovu HAART programme, May 2005. Presentation to the 4th JCSMF. Hugo Templeman.

[3] At the MSF site in Khayelitsha there is an 82.6% survival rate after 30 months and a 92.4% self-reported adherence rate.

[4] The PMTCT programme makes use of triple combination therapy.

- In the Free State, 509 patients started ARV treatment in 2004. At the end of that year, 473 (92.7%) were still on treatment, with 22 having died and four being lost to follow up. The remaining patients are achieving 95% adherence.

- At the Red Cross Children's Hospital in Cape Town, initial treatment outcomes shows that after six months of treatment, 67 (84%) of the children had done relatively well and an 85% adherence rate being recorded. Only seven (8.8%) children had died, with four (5%) being lost to follow up. One child developed a B-cell lymphoma and a second child had withdrawn from the programme.

- The Western Cape department of health's analysis of the outcomes of the first patient cohort indicate that after 12 months of ARV treatment, viral load was undetectable in 83% of cases.

- At Klerksdorp Hospital in the North West, the second largest treatment site after Helen Joseph Hospital in Gauteng, adherence is at about 95%, side effects have been low and the drop out rate is minimal.

NATIONAL PATIENT NUMBERS AND PROVINCIAL VARIATIONS

As at the end of March 2005, official government figures indicated that at least 42 000 patients were accessing ARV treatment in the public health sector. Of these, less than 4000 were children. The 3rd JCSMF meeting heard that most patients on ARV treatment in the public sector are receiving care at academic hospitals and the so-called "main sites", with very few patients accessing ARV treatment at rural and remote sites. The report of the 3rd JSCMF shows that for a number of reasons, some of which are discussed below, many treatment sites are not treating substantial numbers of children.

Given the need, patient numbers in the public sector are significantly lower than what the demand actually requires. The resolutions of the 4th JCSMF have recommended that a more aggressive approach to scaling up is needed to avoid falling further behind as the AIDS epidemic matures. In comparison, the number of patients on ARV treatment in the private sector (as of the end of March 2005) was between 50 000 and 60 000.[5]

Table 1 tracks patient numbers over five time intervals: from the first joint ALP/TAC report (July 2004) though each of the four JCSMF reports (September 2004, November 2004, February 2005 and May 2005) to the 2nd South African AIDS Conference (June 2005). At first glance, the national total of 42 000 may

[5] This figure includes medical scheme beneficiaries, patients on employer-funded workplace treatment programmes, patients in the unfunded sector (out of pocket payments) and patients receiving treatment through the support of not for profit programmes, which are mainly run by faith-based and community organisations.

appear to demonstrate significant progress.[6] But the figures, when viewed together, are misleading. This is because a few provinces – KwaZulu-Natal (KZN), Gauteng, the Western Cape and the North West – are responsible for the bulk of patients on ARV treatment. Disaggregated, the figures highlight massive provincial variations, demonstrating inequities in access as well as the slow pace of implementation in certain provinces.

TABLE 1: TRACKING PATIENT NUMBERS ACROSS SIX TIME INTERVALS

	TAC/ALP July 2004	**1st JCSMF Sep. 2004**	**2nd JCSMF Nov. 2004**	**3rd JCSMF Dec 2004/ Jan 2005**	**4th JCSFM March 2005**	**SA AIDS Conf.**
Gauteng	2300 A 1924 C 416	2800	5588 A 4788 C 800	9691	12 412 A 10 916 C 1496	No new data available
North West	130 A 130 C 0	< 200	1124	2625	2645 A 2541 C 104	4720 (May) A 4600 C 120
Northern Cape	51 A 51 C 0	150	Not available	515	Not available	953 (May)
Eastern Cape	298 A 287 C 11	504	1525 A 1458 C 67	2749	Not available	4635 (May)* AM 1499 AF 2648 C 488
Western Cape	3750 A+/- 2300 C 800	3834	5137 A4083 C1054	6188	7670 A 6386 C 1284	No new data available
KwaZulu Natal	120	535	3004? A2850? C154?	Jan 8467	11 000 A 90% C 10%	No new data available
Limpopo	Not available	20	300? A260? C40?	Jan 935	Not available	1800 (May)*
Mpumalanga	51	130	500?	936	Not available	***Not available***
Free State	50 max	240	602	945	1785 M 509 F 1024 C 156	1806 (May) AM 538 AF 1096 C 172
TOTAL	**< 6000**	**± 8000**	**± 15 000**	**± 29 000**	**± 42 000**	**± 45 000**

A = adults; M = male; F = female; C = children * unconfirmed

[6] It is difficult to measure whether government is meetings its commitments as set out in the Operational Plan. This is because government has, to date, failed to release revised patient targets. It has also refused to release an implementation plan timetable, if such a timetable indeed exists at all. The Operational Plan set its first patient targets at 53 000 for the first year of its implementation. The target was then shifted twice: first by the Minister of Health and then by the President in his 2004 State of Nation address. In his 2005 State of Nation address, the President did not provide any reasons as to why the target was not reached. In her 2005 Budget Speech, the Minister of Health refused to engage in any debate about patient targets and argued that the initial targets were estimates – and nothing more. She stated that patient targets are not important and that instead, the debate should be about quality of care.

? = unconfirmed at the time

As can be seen from Table 1 and has been documented elsewhere,[7] the situation varies from province to province, particularly in relation to the pace of implementation:[8]

- In particular, North West has in the last few months dramatically increased its patient numbers. This has been attributed to exemplary leadership and commitment shown by health care workers.

- But the North West is not just about patient numbers. It has been particularly creative in the use of its available resources, including human resources. For example, patients are prepared, assessed and staged at wellness facilities prior to their first visit at a designated treatment site. This has managed to decongest the treatment sites, also ensuring that first visits are much shorter and streamlined. In turn, this has reduced waiting periods and waiting lists. Importantly, it has improved the morale of health care workers and patients as the latter move more speedily through the system.[9]

- KZN may have (along with Gauteng) the most number of patients on ARV treatment in the country. But the pace of the programme and its reach is nevertheless cause for concern. Given the very high HIV prevalence in KZN and the associated need for treatment, it requires a dramatic injection of new patients into the ARV programme, including children.

- Provinces such as the Northern Cape and Free State are more cautious with implementation. As in most other provinces, very few children are accessing ARV treatment in these two provinces. However, both show that political leadership and the commitment of health care workers are the crucial ingredients to successful implementation. A positive factor is that both programmes are administered with openness and transparency.

In provinces such as the Eastern Cape, Mpumalanga and Limpopo, the situation is very different. Of significant concern is the fact that they show very little improvement over the last year. Several factors have been advanced to explain this:

- The JCSMF has repeatedly noted that the Eastern Cape health department continues to under spend on its health budget. It has placed a moratorium on new appointments, despite the public health care sector being understaffed.

[7] For example, in the 1st to 4th JCSMF reports
[8] Some provinces, such as the Free State, North West, Gauteng and the Western Cape, are cooperating well with civil society organisations, willingly sharing information about their programmes.
[9] Johannesburg General Hospital is also working on similar initiatives to decongest main treatment sites.

- Mpumalanga is struggling to meet the overwhelming demand for treatment because it is under resourced and is in urgent need of technical support from the national department of health.

- Limpopo is faring the worst:

    - It was the last province to start treatment

    - It has substantially less patients on ARV treatment despite an overwhelming demand for treatment

    - It only has a handful of children on treatment

    - It has not accredited essential treatment sites, resulting in long waiting periods and lack of access to health services

    - It shows inexplicable contempt for civil society organisations

    - It refuses publicly to release information about its programme.

DONORS SUPPORTING THE PUBLIC SECTOR

Several donors partially or fully fund patients accessing ARV treatment in the public sector and contribute towards the costs of staff or medical equipment. For example, many provinces have entered into partnerships with donors such as Médecins Sans Frontières (MSF), Absolute Return for Kids (ARK), One2One Kids, Catholic Relief Services,[10] the South African Medical Association (SAMA) and the US President's Emergency Plan for AIDS Relief (PEPFAR). Without this type of support, the public sector patient figures would be even lower. Nevertheless, the long-term sustainability of these partnerships must be monitored closely. But the Western Cape example of a donor initially kick-starting an ARV treatment programme that is – over time – taken over by the province is a useful model.

Below we examine the nature of support provided by key donors, paying attention to patient numbers and any other support provided.[11]

- **MSF** supports four public sector sites in the country (three in the Western Cape and one in the Eastern Cape). In the Eastern Cape, MSF initially paid for the drug costs of all patients (about 750). As at

[10] **Catholic Relief Services** supports three sites in the Free State. As at the end of May 2005, it was funding 96 patients, including a handful of children.

[11] In the next year we hope to establish a proper information sharing system for the private and not-for-profit sector so that the work of many organisations and entities is duly monitored and evaluated.

May 2005, the province took over the function of paying for drugs for most adults (600) with MSF funding the drug costs of the others (about 100) and the children (50). MSF also contributes towards staff and other HR costs. In the Western Cape, MSF funds the drug costs of about 300 of the 1900 patients and also contributes towards HR costs.

- **ARK** supports 17 – 19 ARV treatment sites in the Western Cape. From December 2003 – April 2005, it paid for all costs including ARV drugs and laboratory tests for primary carers and their partners. From May 2005 until March 2007, ARK will pay for staff costs and community mobilisation programmes. By the end of May 2005, ARK was funding about 3000 patients in the Western Cape. Since April 2005, ARK has been supporting ten sites in KZN (paying for staff costs) and purchased six CD4 machines for the KZN provincial laboratory service, which is not part of the National Health Laboratory Service (NHLS).

- Through *Kidz Positive*, **One2One Kids** supports two sites in the Western Cape. It funded the treatment of children from May 2002 until November 2004, when the province took over drug costs. At present, One2One pays for a pharmacist at the sites, as well as a data capturer, a mothers' support group and a physiotherapist at the children's clinic at one. It also runs an income generation project for mothers at this and six other sites, and contributes medical equipment for clinics in the Cape Metropolitan area and Southern Cape region. It is currently in partnership with MSF at the Site C clinic in Khayelitsha.

- As at December 2004, **PEPFAR** supported 112 primary sites. Of these, about 31 are in the public sector and the rest are in the not-for-profit sector or are public-private partnerships. As at the end of December 2004, EPFAR was funding the costs of 9591 patients in both the not-for-profit and public health sectors.[12] One of the problems with PEPFAR-funded projects is that they are required to use drugs that have been registered both by the Medicines Control Council (MCC) and the US Food and Drug Administration (FDA).[13] This means that there may be delays with using generics, which are ordinarily less expensive.[14] Not being able to access generic ARV medicines also means that PEPFAR sites are reliant on a single drug supplier, which threatens the sustainability of medicine supplies.

[12] Of these 317 were male patients under 14 years, 3181 were male patients over 14 years, 286 were female patients under 14 years and 5642 were females over 14 years.
[13] In the case of the FDA, tentative approval is sufficient, meaning that the medicines would qualify for registration but for the fact that they cannot receive marketing approval solely because the originator drugs are still protected by patent.
[14] To date, only two generic ARV products have received such tentative approval, neither of which has also received MCC approval. This means that PEPFAR-funded programmes in South Africa are not yet using generic ARV medicines.

BARRIERS TO ACCESSING AND SCALING UP TREATMENT

CRISIS IN HUMAN RESOURCES FOR HEALTH

The pace of implementation is being hampered by the lack of trained doctors, nurses, pharmacists and other health care providers. Attracting, retaining and training health care workers remains a formidable challenge for the public health sector. But without addressing the crisis in human resources for health (HRH) – including poor working conditions, low salaries, concerns about career pathing, the lack of incentives and the international poaching of HRH – our health programmes will suffer. Without a reasonable, flexible HRH Plan that addresses short, medium and long term needs, the Operational Plan will continue to be undermined.

Government has a constitutional duty to develop such a plan. But while the need to address the HRH crisis was identified as far back as 1994, we are still without a plan some 11 years into our democracy.[15] For this reason, TAC and the ALP co-hosted a meeting of various health worker unions, NGOs, research institutions and other interested parties to discuss the urgent need to develop a reasonable HRH plan. Conditions of service, scope of practice, the Operational Plan and growing inequities between the public and private sectors were identified as key issues for the proposed HRH plan.

The 4th JCSMF meeting called on the Minister of Health and her national department to explain its failure – to date – in developing a HRH plan that at the very least addresses the emergency needs of all provinces, and to indicate when the department's draft HRH plan will be publicly available for debate. We support this call. As a result of the crisis in HRH, many sites are unable to take on more patients. Without trained doctors, nurses and pharmacists, patient numbers will not be speedily increased.

DE HOPE CLINIC

De Hope is one of the disadvantaged areas in Limpopo. There are a few tuck shops but no public transport. The clinic covers six villages: Nhanganani, Njhakanjhaka, Doli, Matsele, Nkunzana and De Hope. Patients have to travel very far to get to the clinic and on some parts of the road they have to take their shoes off to cross the river. The clinic does not have a telephone and there is a shortage of staff. They use their mobile phones for emergencies to communicate with the doctors at Elim Hospital. There is only one nurse for voluntary counselling and testing. When she is upset she does not come to work. If there is a patient who is in a critical condition, he or she will have to wait for the ambulance to travel more than 70 kilometres to the clinic. Staff members are often forced to use their own cars to transport patients to Elim Hospital.[16]

[15] A draft HRH plan was to be released publicly at the end of March 2005. Some two months later, the draft plan remains a departmental secret.

[16] This report and those in the following boxes are provided by TAC community reporters.

Largely because of human resource shortages, several sites are placing caps on patient numbers arguing that they cannot take on additional patients.[17] This places an additional burden on other treatment sites. A combination of at least two factors – the shortage of human resources and inefficient systems – has resulted in long waiting lists at several sites.[18]

> **MAJOSI CLINIC**
> Majosi clinic in Limpopo covers eight to nine villages. There are three nurses who are doing the voluntary counselling and testing. The number of people who are testing positive to HIV is increasing daily. Patients are referred to the wellness clinic at Elim Hospital for CD counts, as they are not done at this clinic. Most of the patients usually come back to the clinic because they have problems when it comes to accessing ARV treatment. At the hospital the patients are put on a long waiting list before accessing treatment. One of the problems is that the patients come to the clinic when they are very sick and have very low CD 4 counts. The clinic does not have enough drugs such as fluconazole. They have to order it from the hospital when there is a patient who needs it and it takes a long time to be delivered.

The problem of increasing patient numbers is further compounded by the fact that several sites that are already in a position to commence treatment (and thus reduce the load on other treatment sites) are still awaiting formal accreditation.[19] The unexplained and unjustified delay in formal accreditation is one of the main reasons why several sites across the country cannot commence ARV treatment and help share the burden. Because the Operational Plan requires a site to be accredited before it can commence with its ARV programmes, the formal process of accreditation limits access to health care services unreasonably. In our view, the accreditation process should be decentralised and expedited.

Some sites have shown that often the inefficiency of management and administrative systems has played a part in creating unnecessarily long waiting lists. In this respect, Chris Hani Baragwanath, Johannesburg General and Klerksdorp hospitals have shown that simply addressing and remedying weak management and administrative systems, without any additional allocations of

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[17] Reports indicate that the following sites are using a system of patient caps: Pretoria Academic Hospital (Gauteng); R K Kahn and King Edward (KZN); and Frontier (Eastern Cape)

[18] So far we have received reports that the following sites have substantial waiting lists. In all cases, we have tried to establish the exact period. Our preliminary findings are:

- Letaba (Limpopo) – two months; Tshnidzini (Limpopo) – four months (in May 2005)
- Stanger (KZN) – 500 patients; Prince Mshiyeni (KZN) – the exact period was unknown (in April 2005)
- Far East Rand Hospital (Gauteng) – four months (May 2005)
- Chris Hani Baragwanath Hospital (Gauteng) has now managed to reduce its waiting period from several months to three weeks. Johannesburg General Hospital (Gauteng) has also managed to reduce its waiting period.
- Hermanus (Western Cape) – 902 patients (April 2005)

[19] Reports indicate that the following hospitals/clinics are not treating patients because of this: Khensani, Botlokwa, Sheshego and Tintswalo (Limpopo); Hewu (Eastern Cape); Athlone Park Clinic and Richmond (KZN); Life Care (Gauteng); and Witbank and Standerton (Mpumalanga)

HRH, can reduce waiting lists from several months to a few weeks. This model should be replicated at other sites with long waiting lists.

The lack of human resources, and in particular paediatricians and health care workers trained to administer paediatric treatment, have been cited as reasons for the poor numbers of children on treatment.[20] According to the Operational Plan, an accredited site must treat both adults and children. This is not happening. Access to treatment for children has not enjoyed the same level of attention as access for adults. Most messaging still targets adults and often ignores children. This must be remedied through stronger community action, awareness and mobilisation.

The 3rd JCSMF reported in February 2005 that unwillingness, fear and/or inability to treat children are also factors that have contributed to too few children being put on ARV treatment. In addition, limited availability of child-appropriate medicines (for example, syrups or smaller tablets or appropriate drug combinations) makes it difficult for health care providers to treat children.

CHILDREN, HIV/AIDS AND TREATMENT

Tonga village is situated at the corner of three countries, South Africa, Mozambique and Swaziland. Most of the children here are being left to survive on their own without food, birth certificates, income or shelter. Their parents, who come from Swaziland and Mozambique, leave them here. Many children are being forced to the street as a result of poverty, abuse, torture and rape, or orphaned by HIV/AIDS. Maranata Home is a non-profit organisation that takes care of 30 orphans. Three are living with HIV, one of whom has access to treatment. 27 have not been tested. The centre survives by means of donations for food and clothing. There are 400 children who still need shelter.

OTHER GAPS WITH IMPLEMENTATION

Aside from the lack of a HRH plan, there are two other serious gaps in the implementation of the Operational Plan. The first is the lack of implementation of the chapter dealing with nutrition-related interventions, with the second being the incomplete implementation of the chapter dealing with drug procurement.

NUTRITION

It is widely accepted that poverty and the lack of food security[21] are major national challenges, and that there is a clear link between employment, access to income and food and nutrition security.[22]

[20] As at the end of March 2005, the JCSMF reported that fewer than 4000 children were on ARV treatment in the public sector in the whole country – with at least 50 000 children in need of treatment.

[21] **Food security** is the attainment of physical, social and economic access to sufficient, safe and nutritious food by all citizens at all times to meet their dietary and food preferences for an active and healthy life (FAO). While South Africa as a country is food secure, there are pockets of food insecurity among vulnerable community segments. Among these segments are specific groups

Recently, the *World Health Organization (WHO) Consultation on Nutrition and HIV/AIDS in Africa* (co-hosted by the national department of health) confirmed that everyone requires good nutrition, including people living with HIV/AIDS. But the *WHO Consultation* also stated that there is no scientific evidence to suggest that good nutrition alone can treat HIV. This is in accordance with official government policy as articulated in the nutrition chapter in the Operational Plan.[23]

Based on the recommendations of the *WHO Consultation*, the 4th JCSMF resolved that while good nutrition is important for everyone, there comes a point where it is medically necessary for people living with HIV/AIDS to commence ARV treatment. The JCSMF recommended that additional studies are needed, including operational studies, to establish how nutrition can best be integrated into existing care programmes. In addition, clinical studies are needed to determine the effect of nutritional interventions in delaying early disease progression, as well as to examine the interaction between nutrition and ARVs – for example, absorption of drug and adverse events.

In assessing the nutrition assistance programme, the 4th JCSMF meeting noted anecdotal evidence indicating fragmentation and unevenness, with the programme being beset by problems. At the Harriet Shezi Clinic at Chris Hani Baragwanath Hospital, the largest paediatric treatment site in the country, only 6% of children who are on ARV treatment have access to nutritional support – fortified maize meal and milk formula – through the resident dietician. Often there are not enough social workers available to advise patients on where and how to access food parcels and supplements. The administrative burden of processing hundreds of applications for food parcels also results in limited access. As at April 2005, none of the adult and paediatric patients at Harriet Shezi were accessing food parcels.

Serious gaps in the nutrition programme at individual facility level have arisen because of a shortage of social workers, dieticians and nutritionists. The lack of proper guidelines, inadequate supervision and poor resources has compounded

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with special dietary and nutritious requirements e.g. people living with HIV/AIDS (Bio Watch, May 2005).

[22] More than 14 million people (35%) of the South African population are estimated to be vulnerable to food insecurity. 43% of households suffer from food poverty and 1.5 million children suffer from malnutrition. A third of South African households are female headed and considerably poorer than male-headed ones. On this count, the Eastern Cape is leading, with 70% (or about a million households) surviving on less than R1 000 per month.

[23] According to the Operational Plan, the Nutrition Directorate in the national department is mandated to develop a nutrition supplementation strategy for people living with HIV/AIDS and TB. The nutrition strategy proposes the dispensing of a macronutrient meal as well as micronutrient supplements in pill or syrup form to selected groups in health settings as part of a nutritional care and support package for individuals with TB and HIV/AIDS. Deputy President Zuma's budget speech (25 May 2005) noted that the National Guidelines on Nutrition developed in 2001 (and updated in 2003) are being redrafted or updated to incorporate the nutrition chapter in the Operational Plan.

the problem. In addition, logistical delays in getting food parcels to facilities (administered by the Department of Social Development) have also added to the weaknesses of the programme. Nevertheless, the ultimate responsibility rests with health. The Operational Plan provides that the national department of health is responsible for inter-departmental co-ordination of the country's overall nutritional assistance programme.[24]

DRUG PROCUREMENT

In the first joint TAC/ALP report, we noted that the drug procurement process had yet to be finalised, notwithstanding an initial forecast made to Parliament by the national department in February 2004 that the process would be completed by June 2004. However the award of the drug tender was only announced on 2 March 2005, some 13 months after the drug procurement process commenced and more than 16 months after the Operational Plan was adopted.

The tender is worth over R3.7 billion and expires in 2007. It was awarded to the following seven pharmaceutical companies for the supply of ARV medicines to public health facilities countrywide. Table 3 below provides some of the detail:

TABLE 3: BRIEF TENDER ANALYSIS

Company	Nature of company	Share of tender (in value)
Aspen Pharmacare	Local generic manufacturer	32%
Abbot Laboratories	Multinational importer	31.5%
MSD	Multinational importer	25.5%
Ingelheim Pharmaceuticals	Multinational importer	6%
GlaxoSmithKline	Multinational importer	2%
Bristol-Myers Squibb	Multinational importer	1.66%
CIPLA Medpro	Local generic importer	1.33%

The Operational Plan recognises that a "central component of HIV and AIDS care and treatment is the production, procurement and supply of medicines, in particular antiretrovirals." It further recognises that in order to support its proper implementation, the drug procurement system must achieve certain objectives, including the following:[25]

- "The supply of medicines must be secure and sustainable at a volume large enough to meet the significant demand envisioned."

[24] In for order for the national department to comply with its mandate, better collaboration between it (responsible for providing fortified maize meal, milk formula, nutritional supplements and nutritional information and counselling), the Department of Social Development (responsible for food parcels and social assistance grants) and the Department of Education (responsible for school feeding schemes) is required.
[25] Operational Plan at page 143

- "The sustainable supply should be ensured through local production of antiretrovirals and sustainable financing."

- In negotiations with pharmaceutical companies for the supply of treatment-related technologies and drugs at affordable prices, certain principles should be used, such as ensuring that "[a]ll proposals should be centred around the principle of sustainability and on this basis, seek to make drugs both affordable and accessible."[26]

- A multiplicity of suppliers, including local manufacturers, is necessary to ensure sustainability of supply.[27]

- The "supply of ARVs must be uninterrupted to meet the treatment needs of patients.[28]

According to the national department, suppliers and provincial health procurement officials will meet four times a year to ensure adequate planning to meet the demand for ARV medicines at public health facilities. Yet despite this, we have received a number of reports over the past few months regarding problems with drug availability in various parts of the country,[29] in particular the supply of efavirenz (marketed by MSD as Stocrin®). In our view, this is largely as a result of MSD's inability to meet demand.

Table 4 below looks at the following three details in respect of each ARV medicine procured by the public sector: tender award; registration and availability on the market generally; and award of licences to generic companies. In light of the public health need to ensure sustainability of supply regarding ARV medicines, the table clearly shows that action against various multinational companies is urgently required.

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[26] Operational Plan at page 144, quoting a declaration of Southern African Development Community (SADC) health ministers adopted at a meeting in Pretoria on 17 June 2000

[27] The Operational Plan (at pages 145, 146 and 148 respectively) expressly mentions the following:

- "A number of viable and competing manufacturers will also guarantee security of supply should any supplier fail for any reason."
- "There is always the risk of failure in the supply chain of pharmaceuticals. It is intended that the procurement plan coordinates a sustainable supply through the participation of viable suppliers, and local production of finished products and active pharmaceutical ingredients."
- "To secure the long-term sustainable supply of ARVs, local production should be enabled through transfer of technology and production of active pharmaceutical ingredients (APIs) in South Africa."

[28] Operational Plan at page 146

[29] In Gauteng, KwaZulu-Natal and Mpumalanga in particular.

TABLE 4: UPDATE ON VARIOUS DRUG PROCUREMENT ISSUES

Drug name	Tender awarded	Drugs registered and on the market	Licensees: produce or import generics
Abacavir (Not on tender list)	Syrup to GSK	GSK only	No licensees
Didanosine	25, 50, 100mg tabs to Aspen	Aspen – tender drugs + 150mg tabs BMS – tender drugs + 150mg tabs + suspension	Non-enforcement of exclusive rights, so no need for licences
Efavirenz	50, 200 and 600mg tabs to MSD	Only MSD	Thembalami only – but company may not be in existence anymore
Indinavir (not on tender list)	Caps to MSD (no detail given)	Only MSD	No licensees
Lamivudine	Solution to Aspen Tabs to GSK and Aspen (Cipla excluded from the tender because did not get its licence from GSK in time)	Aspen – tender drugs Cipla – tender drugs GSK – tender drugs	Aspen; Cipla Thembalami Feza; Biotech
Lopinavir/ritonavir	Solution and caps to Abbott	Only Abbott	No licensees
Nevirapine	Syrup to Ingelheim Tabs to Aspen (Cipla excluded from the tender because did not get its licence in time)	Aspen – only tabs (syrup expected soon) Cipla – tender drugs Ingelheim – tender drugs	Aspen; Cipla Thembalami TAC Treatment Project; Generic ARV Procurement Project
Ritonavir	Solution and soft gel capsules (SGCs) to Abbott	Only Abbott	Solution not patented No licensees for SGCs (but limited non-enforcement of patent for five years (initially) for local production
Stavudine	Solution to BMS 20mg caps to Aspen 30mg, 40mg caps to Cipla and Aspen	Aspen – all caps BMS – tender drugs Cipla – 30 and 40mg caps	Non-enforcement of exclusive rights, so no need for licences
Zidovudine	Syrup to Aspen 100mg caps to GSK 300mg tabs to Aspen (Cipla excluded from the tender because did not get its licence from GSK in time)	GSK – tender drugs + 250mg caps + infusion Aspen – syrup and 300mg tabs Cipla – tender drugs	Aspen; Cipla Thembalami Feza; Biotech

With this in mind, the TAC has already begun taking the necessary legal steps to ensure that companies such as MSD and Abbott Laboratories grant licences for the local production and/or importation of generic versions of their patented medicines. To this end, the TAC has also demanded that the Minister of Health use her powers under the Patents Act to issue the compulsory licences required. She has until 17 June 2005 to respond, failing which the TAC will institute legal action based on her failure to take reasonable measures to ensure access to a sustainable supply of ARV medicines.

CONCLUSION

TAC and the ALP regret that the absence of proper monitoring systems within the health department is leading to misinformation and misunderstanding about the ARV rollout. There is no shortage of demand for ARV treatment as has been claimed by the Minister of Health. In fact, it is the exact opposite. Supply is not meeting demand. We also regret the repeated creation of controversy about the programme by the Minister. This overshadows the tremendous efforts and commitment of many who work within the health department.

TAC is calling for a national mobilisation to treat at least 200,000 people by 2006. This figure is necessary and possible. It originates from the targets endorsed by the Cabinet approved Comprehensive Plan. It requires the scaling up and improvement of all aspects of the response to HIV. Achieving it needs political will, combined with mass treatment literacy education and greater support to our health care workers. Achieving it will turn the tide of this epidemic.

In addition there are several other urgent matters needing attention:

1. The national HIV prevention Plan (Strategic Plan) expires in 2005. As yet there is no plan and no evaluation of how to massively improve HIV prevention in this country. We cannot have “prevention, prevention, prevention” without a prevention Plan.
2. As stated above, nutritional support is not being provided to most people with HIV. We call for rapid steps to implement and monitor nutritional support. We believe that a right to nutrition is part of the right of access to health care services. Lip service without delivery is cold comfort to people with HIV.
3. Health care workers are bearing the brunt of care in this epidemic, but South Africa still does not have a human resource plan for health. We call for the urgent finalisation of the Plan and for a programme to recruit and train new health care workers, draw back health care workers who have resigned, improve conditions, amend scopes of practice, and restore dignity to this profession.

[ENDS]