

# **Roundtable discussion on progress in the Western Cape Province in addressing HIV treatment needs:**

## **What does our data tell us?**

**Minutes from meeting held on 15 April 2008**

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## **Summary**

According to existing modelling, the gap between patients newly presenting with AIDS, and the number accessing treatment has been increasing in the Western Cape Province in recent years. Even if the Province were to progressively reach 80% of the estimated number of new AIDS-sick patients by 2010/11, this gap would remain constant, and there would not be a decline in mortality.

The meeting agreed on using projected new patients with AIDS as a denominator for coverage estimates, and newly enrolled patients as a numerator. This estimate (currently at 64%) would be substantially lower if the denominator was based on other criteria such as CD4 counts below 200 cells/ $\mu$ l, or WHO guidelines.

In Khayelitsha, which has maintained coverage at this level for a few years, the number of registered AIDS and TB deaths has remained constant in recent years, suggesting that the estimated gap in this sub-district is validated by mortality data. In the Mitchell's Plain sub-district, work with health services has revealed a large treatment backlog not readily appreciated without systematically assessing the various missed opportunities for enrolling eligible patients into care. Similarly, backlogs have been uncovered each time a new treatment service has been opened, reflected by the level of disease advancement in enrollees in the first months of the new service.

Data on inpatients in the medical wards at GF Jooste Hospital, reveal that in the last few years, HIV has consistently accounted for over half of inpatient deaths and inpatient admissions, suggesting that a substantial treatment backlog has remained throughout this time.

Province-wide data on the number of patients with CD4 count test values below 50 cells/ $\mu$ l reveals that the absolute number of patients known to services with CD4 counts in this range has continued to increase year-on-year in the province, and cannot be accounted for solely by patients initiating ART.

Mortality data at a provincial level has shown an increase between 2000 and 2007 of 5500 deaths from natural causes. This correlates very well with the gap between the estimated number of patients newly presenting with AIDS, and the number initiating treatment, assuming a two year lag between AIDS and death.

Overall, bringing all these data sources together, the estimates of treatment coverage and trends in this parameter appear to be valid. In essence, the province has managed to keep HIV-related mortality constant for the past few years, but is likely to see an increase in natural deaths as a result of HIV unless treatment coverage increases more rapidly than has happened in recent years.

## Introduction

The Western Cape has reached a level of population coverage in ART services not yet seen by other provinces; however scale-up needs to increase substantially in order to meet the NSP targets of 80% coverage by the 2010/11 financial year. Consensus on the current and future treatment gap estimates is required in order to deliver a service which meets the year-on-year HIV care needs of the Western Cape Province. Presentations were made covering comprehension of modelling techniques, population level laboratory and mortality data, sub-district trends and the burden of care at primary and secondary facilities in order to triangulate the Western Cape estimates of coverage.

## Overview of presentations

### Andrew Boule: ART patient projections in the Western Cape Province

According to the Actuarial Society of South Africa (ASSA) 2003 Provincial HIV model, the highest incidence of HIV infection occurred during the years 2002 to 2003 in the Western Cape, and that the annual number of patients requiring ART is estimated to increase each year until 2014.

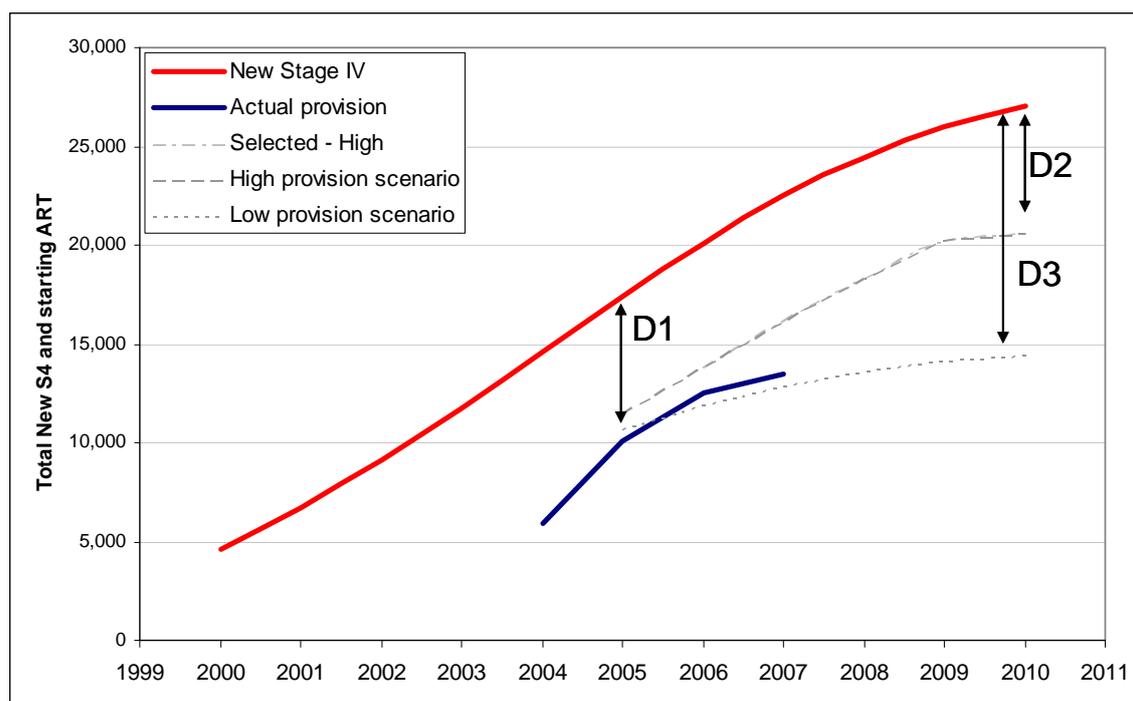


Figure 1: ARV coverage in the Western Cape

Using the ASSA model, Dr. Boule plotted the new WHO Stage IV infections per year against the enrolment per year during the last three years of the ART programme (Figure 1). Trajectories developed in 2006 were plotted from 2005/6 forward marking a future 'high ART provision' scenario and a 'low provision' scenario. The high provision scenario represented a gradual increase in enrolment to reach 80% of new stage IV patients by 2010/11, and the low scenario attaining 60% of this total. During 2006/7 and 2007/8, the gap between enrolment (blue line) and the number of

new stage IV patients (red line) increased. The double arrowed solid lines (D1, D2 and D3) denote the treatment gap of those patients who develop AIDS but never get onto ART. At the beginning of 2005, this estimated number of future deaths in people eligible for ART but never initiating treatment was about 6,000 patients. If the high provision scenario were met an estimated 6,000 to 8,000 patients would still die per year without ever accessing treatment.

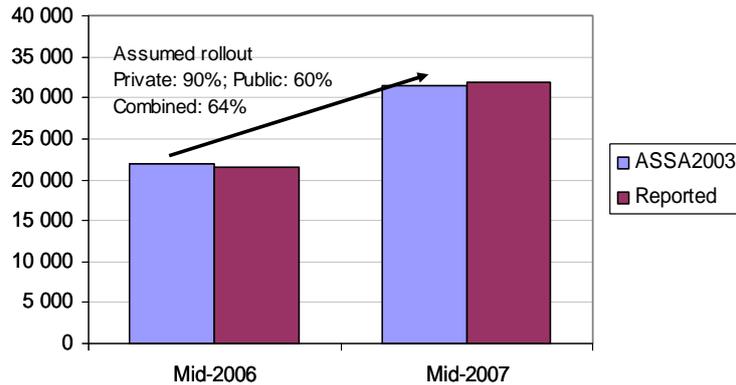
A major impact on increasing enrolment is the accumulated number of patients remaining in care from previous years. These patients require follow up care on a regular (monthly or two-monthly) basis putting pressure on facilities.

It was pointed out that the red line, which currently plots the number of new WHO Stage IV patients, could be moved to the left (or increased) if one were to include all patients eligible for treatment according to the national protocol (CD4 < 200 cells/ $\mu$ l or WHO Stage IV), or proposed changes to guidelines to include all patients with a CD4 count below 350 cells/ $\mu$ l.

Dr Boulle motivated for the use of annual enrolment over annual *new* need to estimate coverage, explaining that over time, this should approximate well to coverage of prevalent need where coverage is reasonably stable, and lends itself to ready target setting and interpretation of trends. Using this metric and new stage IV as the denominator, he estimated the coverage to be between 50 and 60% in the Province. He re-emphasised that attaining the high-provision scenario was the pre-requisite for preventing an increase in HIV-related early mortality, and would not necessarily decrease the excess mortality currently observed in the Province.

**Leigh Johnson: HAART access in the Western Cape: ASSA2003 estimates**

The ASSA2003 provincial AIDS model uses demographic data from the 1996 and 2001 national censuses, the 1998 Department of Health Survey and mortality statistics from the population register. Assumptions regarding prevalence of HIV are set per province consistent with the levels observed in the antenatal surveys. The assumed proportion of the population using private health facilities was determined using the 1998 Department of Health Survey. The combined total of patients on ART reported from the private sector disease management programmes and the public provincial Department of Health reports came very close to those projected by the ASSA2003 model (Figure 2).



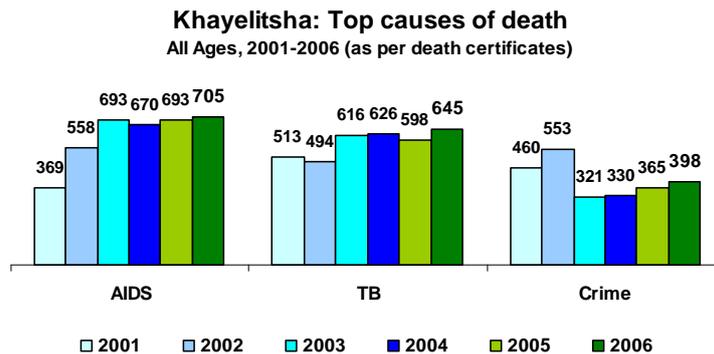
**Figure 2: Numbers on HAART in the Western Cape, 2006-2007**

The ART coverage, using the cross-sectional approach, with the denominator as those with symptomatic AIDS was 66% by mid-2007 (defined as the proportion of people in need who are receiving treatment at a point in time). However, if the DOH or WHO criteria were employed, coverage estimates would drop significantly (30% according to DOH definition which includes the backlog of eligible patients from previous years and 26% using the WHO criteria which include WHO Stage III patients in their denominators). When considering estimates, the level of uncertainty should always be considered. An uncertainty analysis on the ASSA2002 model suggests the ASSA model may be under-estimating or over-estimating the numbers needing antiretroviral treatment by as much as 15%.

**David Coetzee: Khayelitsha experience in scaling up antiretroviral therapy 2001 - 2007: *How far have we got and how far do we still have to go?***

With the doors to the Khayelitsha ART services first opening in 2001, Khayelitsha has seen a lot of changes over time. The clinical profile of adult patients has changed over the years in regards to referral patterns, CD4 counts, and clinical stages. The referral patterns comparing 2003 to 2007 include a 22% increase of patients coming from the primary care clinics (from 33% to 55%) and a 6% increase in referrals from TB services (13 to 19%). Patients initiating ART while on TB treatment doubled from 21% in 2001 to 42% in 2004. The median CD4 count at baseline of ART in adults has risen over time from just over 40 cells/µl in 2001 to almost 130 cells/µl in 2007. The rise in the median CD4 count at ART initiation coupled with fewer complications due to opportunistic infections at baseline has greatly reduced the on-treatment mortality rate during the first three months on ART, even after adjustment for CD4 count and clinical stage.

In spite of these trends demonstrating that a substantial component of the backlog in treatment had been met, the number of deaths known to be AIDS-related or TB-related (where 70% of TB is HIV-associated) remained relatively constant between 2003 and 2006 (Figure 3).

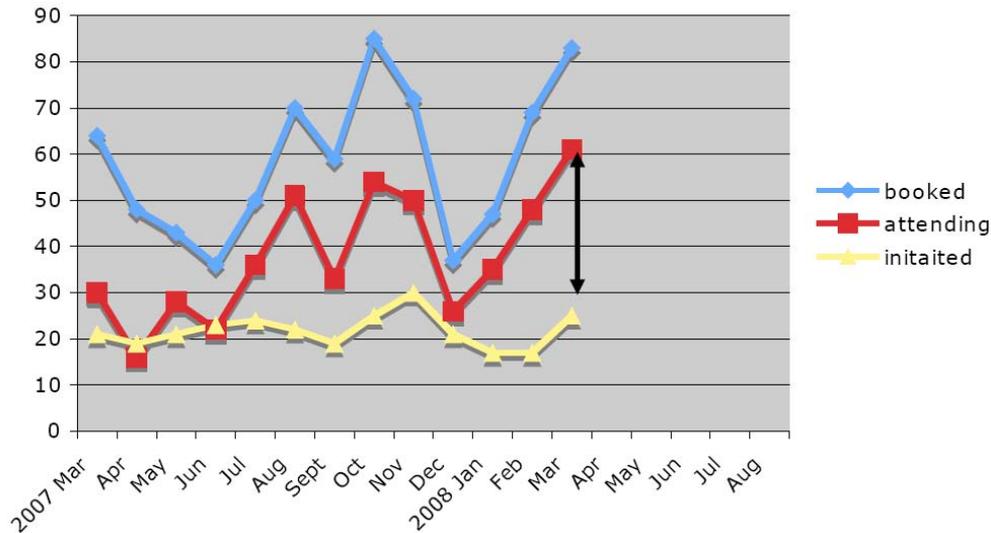


**Figure 3: Deaths in the Khayelitsha sub-district per year**

Although anecdotally clinicians report fewer non-ambulant patients presenting for the first time, there are still many pre-ART patients arriving with very advanced disease requiring immediate referrals to hospital care. Monthly targets set to meet the NSP objectives by 2011 have rarely been met in the sub-district, which also estimates its coverage to be between 50% and 60% of need. Dr Coetzee suggests that a pre-requisite to meeting the target enrolment would be increasing the number of facilities within the sub-district while strengthening the health care system at the same time.

**Michele Youngelson: Enrolment against the NSP target in the Mitchell’s Plain sub-district and the IHI calculator**

There are many patients in need of treatment within the Mitchell’s Plain and Helderberg Basin ART clinics; however health systems issues stop people from initiating ART. There are many points where patients may get lost in the system. For example, too few referrals were coming to Helderberg Hospital and Ikhwezi clinic but by involving the referral clinics with the planning and improvement of health systems, enrolment at the ART sites saw a month to month jump in enrolment. A completely different health systems issue emerged in Eerste Rivier Hospital. In Eerste Rivier Hospital patients silently fell through the cracks at two specific points before initiating treatment, namely between booking and attendance (mainly due to geographic access) and between attendance and initiation. During the 2007/08 financial year, about 70% of the referred patients were not initiated onto ART (Figure 4), while those attending and not getting put onto ART were sometimes as many as 50% of those referred in a given month. Outreach programmes bridging the access issues and new clinics located in highly populated areas along with greater contacts at the PHC referral sites all helped in increasing enrolment and bringing the sub-districts closer to meeting their targets of need based on the IHI calculator.



**Figure 4: Gaps between new patients booked, attending and initiated at Eerste River Hospital**

The IHI calculator uses the ASSA2003 model estimates of incident HIV to derive the ART need at a district level, assuming a six year lag between infection and requiring treatment. The calculator estimates annual and monthly treatment targets based on the population, antenatal HIV prevalence, estimated annual births and the HIV perinatal transmission rate. The use of a monthly enrolment target has been extensively operationalised by IHI in a number of health districts, and has proved a very useful tool for district planning.

**Graeme Meintjes: A view from the hospital referral level: The evolution of the GF Jooste referral and inpatient services**

G. F. Jooste Hospital is a secondary referral hospital for 9 ART clinics and 16 TB clinics, serving a catchment area of 1.3 million people. A specialised ART & TB referral unit at G.F. Jooste Hospital was started in August 2004 to manage complicated referral problems either as out-patients or in the ward. The referral unit has grown rapidly with an estimated 200 patients per month projected to be referred in 2008 and up to 300 per month in 2010 (Kevany, Case Study of the GF Jooste Hospital Antiretroviral Unit, 2005). Problems relating to drug side effects made up the highest percentage of referrals in 2007(22%), with TB diagnostic and other clinical issues being the second largest referral reason (17%). IRIS manifestation constituted another 9% of the referral cases in 2007. Trends in the first quarter of 2008 show that complications relating to TB and IRIS have increased dramatically (24% TB referrals and 13% IRIS referrals), while drug side effect referrals have decreased.

A retrospective folder review study by Behroozi looking at all deaths at GF Jooste Hospital during three months in 2006 showed that 52% (138 patients) of all patients who died were known or clinically suspected of having HIV. Among these patients, 82% had never initiated ART (although the number meeting ART eligibility criteria was unknown) and 54% died as a result of TB. Of the patients on ART, 8 of the 19 who died were within one month of initiating ART. None of the patients on ART died from ART-related side effects. A second data review by Tom Crede on mortality from January 2007- March 2008 revealed a monthly admission average of 752

patients, a mean of 115 deaths per month (15.6%), and an average of 58% of admissions having confirmed or suspected HIV infection. According to this data, it appears that the contribution of HIV to inpatient morbidity and mortality has remained relatively constant over time, and cannot be explained by ARV-related clinical complications.

	1 May 2006 - 31 July 2006	January 2007 - March 2008 (monthly mean)
<b>Medical ward deaths in study</b>	264 of the 369	115
<b>HIV infected/clinically suspected patients</b>	52% (138)	58% (67)

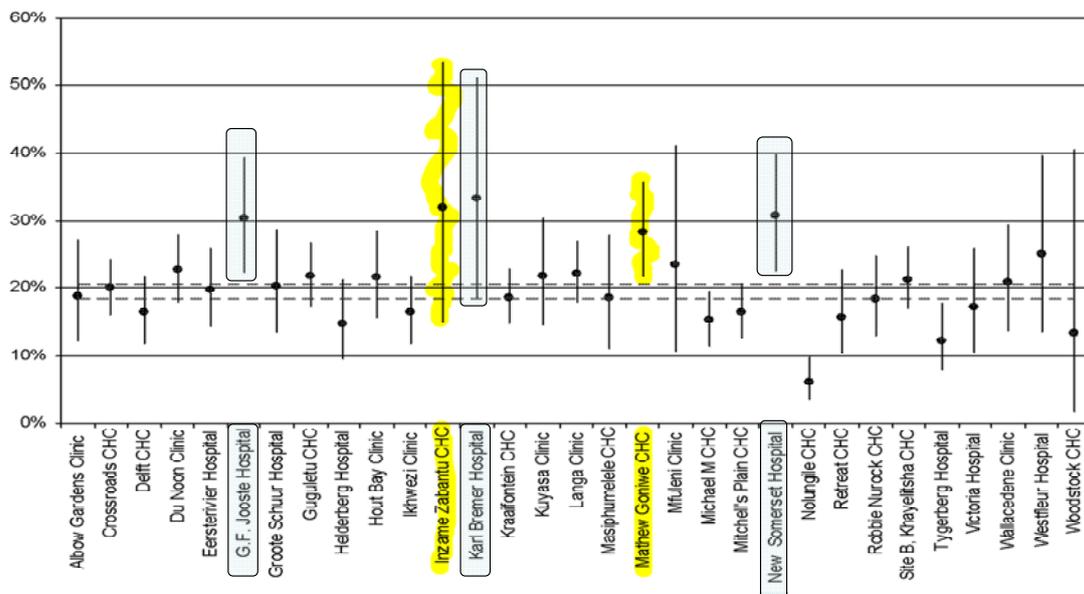
Figure 5: G.F. Jooste HIV associated mortality for inpatients

### **Meg Osler: A view from the laboratory – what if anything can we learn from the CD4 counts sent to the NHLs?**

CD4 count results can reveal patterns of burden as well as trends at both facility and provincial level. Cohort monitoring has described a continuous drop over time in the proportion of patients with CD4 counts below 50 cells/ $\mu$ l when initiating ART across the Western Cape Province, showing the true impact of the ART programme as it matures. Patients, in general, are being referred to ART clinics with less advanced disease as time progresses.

However, a closer look at individual primary health care (PHC) facilities shows that new facilities also experience initial high proportions of patients with CD4 counts below 50 cells/ $\mu$ l, regardless of whether the new facility is an addition to multiple other ARV facilities within a sub-district or an addition to a rural sub-district with few or no other ART services available (Figure 6). The high proportion of patients with CD4 counts below 50 drops over time at these new PHC facilities mimicking the provincial pattern, suggesting that each time a new clinic is opened, there is a treatment backlog identified that had not been adequately serviced by pre-existing facilities.

The pattern is not the same at the specialised secondary ART centres. In 2007, 31% of all ART patients at secondary level hospitals initiated ART with CD4 counts below 50 cells/ $\mu$ l (GF Jooste Hospital, Karl Bremer Hospital and New Somerset Hospital). This proportion is much greater than the average 19% of patients with CD4 counts below 50 cells/ $\mu$ l seen at PHC sites across the province. The decrease in this proportion over time, which has been shown at PHC facilities across the province, was not experienced at these secondary hospitals during 2007. A better understanding of this group of patients including reasons why they had delays in treatment would provide a possible route for intervention.



**Figure 6: CD4 counts <50 at baseline of ART in 2007**

**Note: \* denotes metro institutions**

**\*\* denotes new facility**

A look at all CD4 counts taken province-wide and analysed at the National Health Laboratory Services (NHLS) reveal an increase in volume with each new year. In 2005, about 65,000 of the 82,276 CD4 counts were done in patients not on ART. This number increased to about 95,000 of 144,854 CD4 counts taken outside of the ART programme in 2007. Over 2005 and 2006 the percentage of CD4 counts less than 50 cells/ $\mu$ l and less than 100 cells/ $\mu$ l decreased slowly with time (14% to 11% and 7% to 5% respectively). However in 2007 from April through December, a slight increase over time can be seen in both indicators. In absolute numbers, the number of patients being identified with extremely low CD4 counts, irrespective of ART access, is increasing month on month in the province. The vast majority of these values can be assumed to be in patients not yet on ART, given the rapid response in CD4 count on ART demonstrated in the ART cohort monitoring system.

When looking at the percentage of CD4 counts <50 cells/ $\mu$ l by type of institution, this is highest in the metro institutions (secondary hospitals) irrespective of year during the national rollout.

### **Ria Laubscher: Trends in death registrations in the province and possible associations with ART scale-up**

A rapid surveillance system was established by the Burden of Disease Unit to monitor changes in death rates using data from the population register maintained by the Department of Home Affairs. Deaths stratified by gender were plotted on graphs to show the changes in mortality patterns over the years according to age group.

Nationally, the number of deaths in the 25-55 age range for males and 25-49 age range for females has been increasing rapidly since 1998 and only slowing down in 2004 for males and in 2003 for females. These increases are unlikely to be the result of increased registration or unnatural deaths, as death registration has remained above 95% for adults above 25 years of age since 1999, and unnatural deaths have remained relatively constant over time.

After standardising mortality rates relative to the 1998 population to account for any changes in the population over time, it appears that nationally mortality has declined since 2005 in women aged 25-39, and has stabilised in recent years for men in this age group and for women in the 15-24 year age group. This is consistent with the distribution of advanced HIV and access to ART.

When this same analysis is limited to 25-59 year olds and stratified by provinces (standardised to the national mortality rates in 2000), it shows some very clear patterns. The Western Cape has had the lowest increase in death rates when compared to the other provinces showing a combination of a lower HIV burden and younger epidemic. The ratio has declined in recent years in a few provinces, most strikingly KwaZulu Natal and the Eastern Cape. In the Western Cape there was a slight decrease in the standardised mortality ratio in both 2005 and 2006 for men and women, followed by a slight increase in 2007. As seen in Figure 7 below, when plotting the absolute number of natural deaths by province and age band, the same patterns discussed above can be seen. The Western Cape has had an increase of 5500 natural deaths from 2000 to 2007 in spite of the ART rollout. In discussion Leigh Johnson and David Bourne explained that the Western Cape's epidemic is slightly different from the other provinces as the number of people needing ART is still increasing rapidly year-on-year, while other provinces mortality rates are stabilising as their epidemics are more mature.

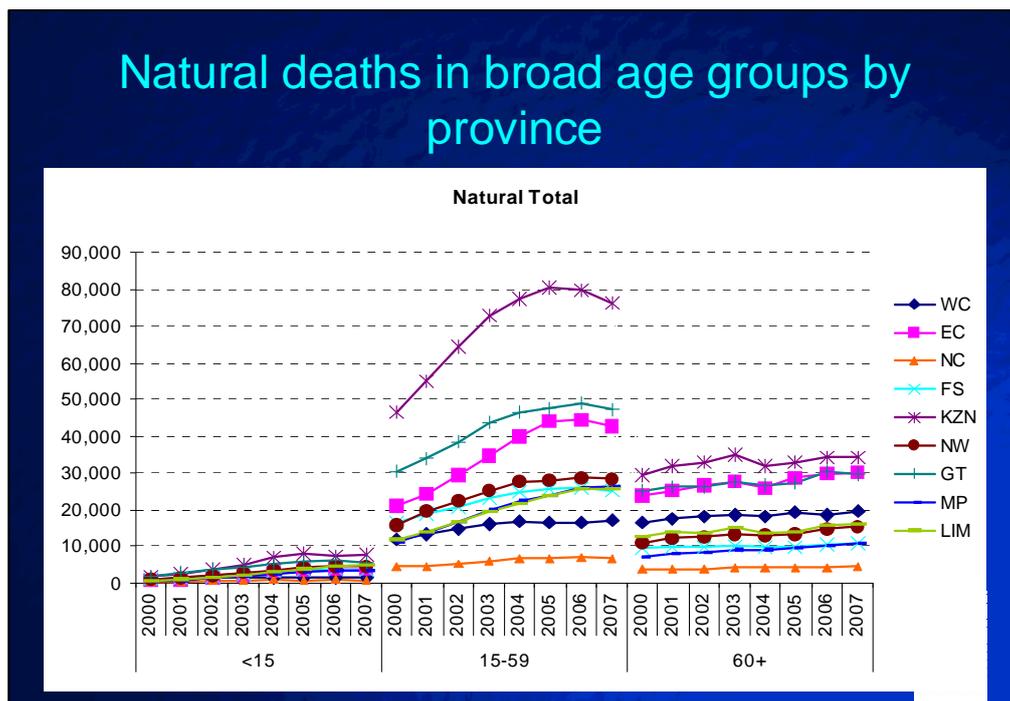


Figure 7: Natural deaths stratified by age bracket and province

## **Discussion**

There were many themes from the presentations that were highlighted and developed further in the discussion.

### *Trends in the need for antiretroviral treatment and coverage in the Western Cape Province*

The Western Cape is currently experiencing an increase in patients needing treatment year-on-year. If the province meets the incremental targets that were drawn up in 2006 it will be able to meet the NSP objectives of initiating 80% of all patients needing ART by the end of the 2010/2011 financial year. This equates to a holding pattern, as the number of deaths per year in patients eligible but not accessing treatment will remain stable.

According to the ASSA 2003 HIV model and the Burden of Disease Unit mortality data many provinces are currently witnessing a decrease in deaths because the number of patients needing treatment is relatively constant with each year as they have already hit or are approaching their peak years for incident AIDS cases. This also means that their pre-existing mortality rates before the start of the national rollout were very high. The epidemic in the Western Cape started much later than other provinces, with the peak incidence of AIDS sick cases yet to come. This tied together with ART treatment which started much earlier in the maturity of the epidemic in comparison to other provinces has resulted in a different pattern of change over time in the Western Cape. This does not equate into the Western Cape doing a poor job with service delivery in comparison to the other provinces, but rather reflects a different epidemiology.

It was highlighted that the Western Cape has a good story to tell; patients are on average less ill when they access treatment compared to previous years so access has improved. Facilities are spread across the Western Cape with more sites located in sub-districts with heavy burdens of HIV so equity is also being met. The increase in mortality seen in other provinces at a similar stage in their epidemics has to some extent being averted in the Province.

### *General applicability of the coverage denominator used to date*

The meeting felt that the concordance between estimated treatment gaps (based on the ASSA 2003 model) and observed mortality, as well as observed presentation with advanced HIV (reflected by the laboratory data), was good. This suggests that inferences made on trends relative to patients newly presenting with AIDS have to date been valid, and should be a good reflection of treatment need in coming years. Clinicians in the discussion repeatedly pointed out however, that science is moving towards recommending much earlier initiation of ART, and that calibrating on keeping mortality constant or reducing it in the short term, might not reflect the true gap if existing and emerging treatment guidelines are taken into consideration.

*What is an appropriate target and where should the bar be set?*

Further discussion considered various scenarios of what would be the most appropriate denominator and coverage goals for the Province.

- The target could be set to meet the low-provision scenario which would scale-up the ART services in the Western Cape incrementally in order to maintain treating 60% of those newly estimated to be developing AIDS each year until the 2010/2011 financial year (the Western Cape currently is enrolling ART patients just above the 60% targets), or
- Mortality due to AIDS is much lower than other provinces making the NSP targets more easily attainable. In order to meet the NSP targets, the province could seek to match the incrementally adjusted high provision scenario developed in 2006, represented in figure 1, or
- The Province could seek to treat all patients developing AIDS, represented as the red line in figure 1, or
- An alternative denominator could be used, based on national (CD4 < 200 cells/ $\mu$ l or Stage IV) or WHO guidelines (CD4 <350 or Stage III or IV), providing more ambitious targets for districts.

Many attendees felt that the targets should reflect the actual number of patients in need of treatment and the model outputs should reflect these numbers. Using the word 'target' could create a false sense of attainment when reached if the target is too conservative. An alternative to the word target should perhaps be used.

Dr Mahlati agreed that the red line is an appropriate aspiration; if the reasons for treatment gaps are identified it should enable the Western Cape to hit the red line. Dr Cloete and Ms Smuts agreed that at a minimum we need to hit the high provision scenario and perhaps reach this mark sooner than had been planned in 2006, with the red line being the objective by the end of the 2010/2011 financial year. Dr Cloete further outlined the need for operational research in this next coming year to identify health systems obstacles to meeting the treatment gap, so that these could be addressed in time to reach or exceed the NSP objectives by 2010/2011.

### *Health system challenges*

A general concern was that many health systems issues stop the provision of efficient services for the patients and sometimes negatively impact the services. Many issues were brought up in Dr. Youngleson's presentation including patients not getting referred to ARV sites within one sub-district. Yet in another sub-district the ART clinic does get the referrals and attendance from the patients, but they are still not getting initiated onto ART. Dr Azevedo commented that patients in Khayelitsha are getting tested for HIV but soon thereafter become lost to the programme. These experiences highlight sub-district specific needs and interventions. However, as the agenda did not cover operational issues, these discussions were put on hold. It was hoped that if consensus was reached regarding the provincial need and coverage targets, these objectives would spurn future meetings to discuss how to tweak the health systems in order to meet the goals.

### *Sub-district estimates of treatment need*

Time did not allow a full discussion of how best to arrive at district and sub-district estimates, or to interrogate the approach used to date by the province, or the IHI calculator. The organizers were tasked with arranging a follow-up consultation with a smaller group to specifically address this issue. The approach of setting monthly enrolment targets for sub-districts was generally favoured. In addition the method used by the City of Cape Town in other programmes was proposed, whereby annual targets are set in addition to monthly targets to enable catch up when targets are missed.

### *Further actions*

- A task team lead by Andrew Boulle will determine the optimal approach, given the available data, to develop sub-district estimates of need. These annual sub-district and provincial targets will then become standardized targets that are published in the annual report and displayed on the monthly reports.
- Operational research into health system obstacles to meeting enrolment goals in pre-ART care should take place over this financial year. This research should cut across service platforms to potentially improve referral processes and system efficiencies in all programmes. The province will drive this process.
- A meeting date for the next roundtable discussion to consider paediatric treatment needs should be scheduled. Meg Osler will drive this process.

### **Acknowledgements**

Many thanks to Janis Kennedy for taking minutes