



Rapid scale-up of a community-based HIV treatment service Programme performance over 3 consecutive years in Guguletu, South Africa

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Background. Despite rapid expansion of antiretroviral therapy (ART) in sub-Saharan Africa there are few longitudinal data describing programme performance during rapid scale-up.

Methods. We compared mortality, viral suppression and programme retention in 3 consecutive years of a public sector community-based ART clinic in a South African township. Data were collected prospectively from establishment of services in October 2002 to the censoring date in September 2005. Viral load and CD4 counts were monitored at 4-monthly intervals. Community-based counsellors provided adherence and programme support.

Results. During the study period 1 139 ART-naïve patients received ART (161, 280 and 698 in the 1st, 2nd and 3rd years respectively). The median CD4 cell counts were 84 cells/ μ l (interquartile range (IQR) 42 - 139), 89 cells/ μ l (IQR 490 - 149), and 110 cells/ μ l (IQR 55 - 172), and the proportions of patients with World Health Organization (WHO) clinical

stages 3 and 4 were 90%, 79% and 76% in each sequential year respectively. The number of counsellors increased from 6 to 28 and the median number of clients allocated to each counsellor increased from 13 to 33. The overall loss to follow-up was 2.9%. At the date of censoring, the Kaplan-Meier estimates of the proportion of patients still on the programme were 82%, 86% and 91%, and the proportion who were virally suppressed (< 400 copies/ml) were 100%, 92% and 98% for the 2002, 2003 and 2004 cohorts respectively.

Conclusions. While further operational research is required into optimal models of care in different populations across sub-Saharan Africa, these results demonstrate that a single community-based public sector ART clinic can extend care to over 1 000 patients in an urban setting without compromising programme performance.

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In 2003 the World Health Organization (WHO) and the United Nations AIDS Organization (UNAIDS) launched a strategy to extend antiretroviral treatment (ART) to 3 million people living with HIV/AIDS in low- and middle-income countries by the end of 2005.¹ As a result of this strategy there are now over 500 000 people on ART in sub-Saharan Africa, where the burden of disease is greatest. This reflects a 3-fold increase in the number of people receiving treatment in the region during the 12 months up to June 2005.² With this dramatic expansion in services, concerns have been raised that expanding access

to ART in resource-poor settings will lead to 'antiretroviral anarchy' characterised by poor adherence to therapy, widespread viral resistance to medications and ultimately poor clinical outcomes.³

To date, a number of programmes have demonstrated the feasibility of providing ART services on a relatively small scale,⁴⁻¹⁰ and have shown that in these instances clinical and virological outcomes in these programmes parallel outcomes in Europe and North America.^{11,12} A recent article by Severe *et al.*¹³ makes an important contribution to the published literature on the scale-up of access to ART in resource-limited settings. The results of the first 1 000 patients treated in Port-au-Prince, Haiti, with limited infrastructure and staff are remarkable compared with those from First-World settings. After 1 year of therapy, 87% of adults and 98% of children were still alive. An editorial in the same journal¹⁴ called for accelerated enrolment in both urban and rural settings. But despite the rapid expansion of ART services in sub-Saharan Africa, there are few documented experiences of how the expansion of ART services over time may affect their quality. As ART programmes increase the numbers of patients served, there are parallel increases in the burden on staff, affecting each category of health care provider. The increased burden on health providers associated with scale-up may result in reduced time, on average, spent in the care of each patient in

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the service. Similar phenomena, with increases in patient load associated with reductions in programmatic success, have been documented in a number of other primary care services, including the diagnosis and management of tuberculosis and sexually transmitted infections.¹⁵⁻¹⁷ In this light it is possible that the good programmatic outcomes – including high rates of virological suppression and retention in services along with low mortality – that have been achieved by small, focused ART services, may be difficult to maintain as programmes grow in size.

The question of how programmatic outcomes in antiretroviral services are influenced by rapid increases in patient load has significant implications for the scale-up of HIV care and treatment services in sub-Saharan Africa. While there is a wide range of different approaches to delivering ART services, there are few insights into the service delivery models that can best maintain optimal patient care and programmatic outcomes. For example, if programmes with large patient loads have difficulty maintaining the high levels of viral suppression and patient retention and low levels of mortality that can be achieved with smaller services, then multiple small-scale services may be preferable to fewer, larger services for delivering ART to a specific population. Insights into these questions of programme expansion and optimal patient load are urgently required to inform health systems and policies for ART scale-up in resource-limited settings.

In this light, we reviewed changing patterns in virological outcomes, patient survival and programme retention among patients attending a public sector community-based ART programme in a South African township. The programme was established in September 2002 and rapidly expanded its services, enrolling 1 139 patients by October 2005.

Methods

Setting

Guguletu Clinic is situated in the urban Nyanga district of Cape Town, which has an estimated population of 350 000 and is served by 10 primary care HIV clinics¹⁸ that comprised the patient referral base. The district is socially deprived with an estimated 57% unemployment rate and with 81% of households living in informal dwellings,¹⁹ a tuberculosis notification rate of 1 026/100 000,²⁰ and an antenatal HIV-1 seroprevalence rate of 28%, which is among the highest in the province.²¹ The *Usapho Lwethu* (Our Family) ART programme is a dedicated ART clinic based at the Guguletu Community Health Centre, Cape Town.²² A pilot programme was started in 2002 with funding support from an international donor, and the expansion of services in subsequent years has been supported by a grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

ART programme

Enrolment into the programme follows the National Ministry of Health ART guidelines,²³ which are based on the 2002 WHO recommendations for scaling up ART in resource-poor settings.²⁴ The medical criteria for adult ART eligibility include those with a prior AIDS diagnosis or a blood CD4 cell count < 200 cells/ μ l, and for children, paediatric stage III disease or a CD4 cell percentage < 20%.

Following referral from a primary care clinic, the standard schedule of visits was as follows: screening visit (week 0), screening blood tests (week 2), treatment initiation (week 4) and treatment follow-up (weeks 8, 12, and 20, and 16-weekly thereafter). At the screening visit, a treatment-readiness evaluation was completed and a 4-week supply of co-trimoxazole was dispensed to patients with less than 200 CD4 cells/ μ l, with pill counts at 14 and 28 days to assess adherence. Dapsone was used as an alternative for those with co-trimoxazole intolerance. Patients were assessed by a doctor for symptomatic HIV-associated disease. First-line ART comprised stavudine, lamivudine plus a non-nucleoside reverse transcriptase inhibitor (efavirenz or nevirapine). The second-line regimen comprised lopinavir/ritonavir, zidovudine and didanosine. A secure supply of medication was maintained by the local health authority throughout the study period and all treatment was supplied free of charge. In addition to the scheduled clinic appointments, patients had open access to the clinic for medical problems.

Therapeutic counsellors

At the screening visit patients were allocated to a community-based 'therapeutic counsellor' living in the Guguletu area. These community-based counsellors, the majority of whom are living with HIV/AIDS, provide ongoing counselling support, addressing psychosocial issues and reinforcing the need for high levels of treatment adherence. Counsellors were responsible for treatment-readiness group information sessions carried out twice weekly in a local community hall, clinic-based adherence reinforcement sessions and home visiting.

Laboratory monitoring

Plasma HIV load and blood CD4 cell count were performed at week 2 and 4-monthly after commencing ART. Toxicity monitoring comprised a full blood count and liver function tests performed at week 2, and subsequently at 4-monthly intervals. All laboratory tests were performed on site by a single laboratory technician in a self-contained laboratory located in a modified shipping container. Plasma HIV-1 load was measured using the Versant HIV-1 RNA 3.0 assay performed on a 340 bDNA analyser (Bayer Diagnostics, Tarrytown, NY, USA) with a lower limit of detection of 50 RNA copies/ml. Blood CD4 cell counts were measured using



flow cytometry (Becton Dickenson FACSCount, New Jersey, USA). Internal quality assurance (QA) and interlab QA were performed for the viral load and CD4 measurements and full blood counts and CD4 measurements were subject to additional external QA.

Data sources

Structured clinical records were maintained on all patients screened on entry to the ART programme and this information together with laboratory results was regularly transferred to an electronic database. The Research Ethics Committee of the University of Cape Town approved the use of patient information from this service for programme evaluation, and as part of this, all enrolled patients gave written informed consent for anonymous clinical data to be recorded and analysed.

Statistical analysis

Data were analysed using Stata version 9.0 (College Station, Texas, USA). Three annual cohorts were defined as patients initiating ART during the 12 months from 1 September 2002 (the 2002/2003 cohort), 2003 (the 2003/2004 cohort) and 2004 (the 2004/2005 cohort). The demographic profile and baseline immunological and virological characteristics of the cohorts were compared using Wilcoxon's rank-sum and chi-square tests for medians and proportions, respectively; trends across annual cohorts were assessed using Cuzick's non-parametric trend test for medians and Cochran-Armitage tests for proportions. The retention of patients in the programme was compared across annual cohorts using Kaplan-Meier analyses with log-rank tests. All statistical tests are 2-sided at $\alpha = 0.05$.

Results

Programme entry

During the first 3 years of the service, 1 510 patients were referred to the programme for ART, of whom 1 139 were commenced on treatment. Of the 371 not starting ART, 155 (42%) did not meet entry qualifications or received therapy elsewhere, 146 (39%) were awaiting treatment initiation at the censoring date and 70 (19%) died before starting ART. The pre-ART death rate was 34.6/100 patient-years (confidence interval (CI): 27 - 43) and did not vary significantly between the annual cohorts. Recruitment increased steadily during the study period (October 2002 - September 2005), with greater numbers of children and pregnant women entering the programme in the second and third years (Table I). There was a significant trend for individuals recruited into the programme to have less advanced HIV in the second and third years as demonstrated by higher median CD4 count, lower \log_{10} mean viral load and a lower proportion with an AIDS diagnosis (Table I). The proportion of pregnant women entering the programme who had AIDS was low (5%) compared with non-pregnant adults (30%). The CD4 count of children at programme entry (median 540 cells/ μ l, interquartile range (IQR) 244 - 906) was significantly higher than that of adults (101 cells/ μ l, IQR 48 - 168). As further treatment sites were initiated elsewhere in South Africa, an increasing number of patients were transferred in and out of the programme on ART.

Staffing and physical infrastructure

The programme commenced with a staff of 1 doctor, 1 nurse and 8 counsellors. At the end of the study period staffing

Table I. Baseline characteristics of 1 139 patients starting ART between October 2002 and September 2005

	2002/3	2003/4	2004/5	<i>p</i> -value
Number starting ART	161	280	698	
Median age (yrs)	33	32	32	0.19
Age range (yrs)	7 - 58	1 - 54	1 - 64	
Female (<i>N</i> (%))	114 (74.5)	193 (75.7)	479 (65.4)	0.002
Pregnant at entry (<i>N</i>)	1	39	80	0.06
Children < 14 years (<i>N</i>)	1	3	69	< 0.001
Median CD4 (cells/ μ l (IQR))	84 (42 - 139)	89 (49 - 149)	110 (55 - 172)	< 0.001
Median \log_{10} viral c/ml (IQR)	4.98 (4.58 - 5.33)	4.87 (4.50 - 5.23)	4.72 (4.25 - 5.14)	< 0.001
WHO stage 4 (<i>N</i> (%))	68 (44.4)	64 (25.1)	157 (21.5)	< 0.001
WHO stage 3 (<i>N</i> (%))	69 (45.1)	140 (54.9)	397 (54.2)	
WHO stages 1 and 2 (<i>N</i> (%))	16 (10.5)	51 (20.0)	178 (24.3)	
Transfers in/out (<i>N</i>)	0/1	0/39	32/80	
Died on treatment (<i>N</i>)	21	22	35	
Lost to follow-up (<i>N</i>)	8	17	8	

IQR = interquartile range.



had increased to 4 doctors, 3 nurses, 1 pharmacist and 28 counsellors (Fig. 1). There was a high turnover of the professional staff employed by the local provincial authority, with frequent use of temporary staff to provide services. In contrast, there was very low turnover of counsellors, who constitute approximately 80% of all staff employed by the programme. The number of clients allocated to each counsellor increased over time, with a median of 13, 19, and 33 patients per counsellor during 2002/3, 2003/4 and 2004/5, respectively. In terms of infrastructure, the ART service started in a single clinic room within the local health facility. Increasing patient numbers necessitated a move to an on-site prefabricated cabin in 2004 and to a self-contained building within the clinic grounds in 2005.

Programme retention

One hundred and one patients were lost to the programme, and 78 patients (7%) died after starting ART, with 63% of deaths occurring in the first 90 days of ART.

Thirty-three patients (3%) were lost to follow-up during the study period. The Kaplan-Meier estimate of proportion lost to programme at 1 year did not differ significantly between the 3 annual cohorts (Fig. 2).

Virological outcomes

The median proportions of viral loads < 400 copies/ml and < 50 copies/ml at all monitoring time points were 95% and 82%. At the censoring date, the 2002/3, 2003/4 and 2004/5 cohorts had 100%, 92% and 98% of viral loads < 400 copies/ml and 88%, 67% and 85% < 50 copies/ml respectively (Fig. 3, A and B). During the study period 21 patients had 2 consecutive viral loads > 1 000 copies/ml (6, 11 and 5 in each sequential annual period) and 17 patients were changed from first- to

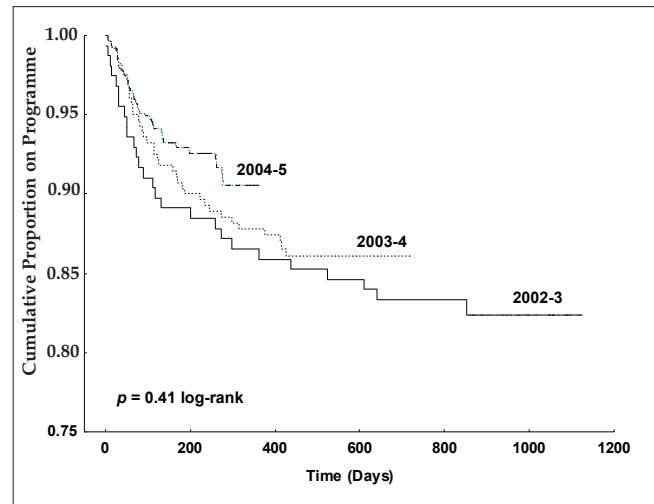


Fig. 2. The cumulative proportion of individuals remaining on ART for each of the 3 annual cohorts (Kaplan-Meier analysis). The survival proportions of the cohorts do not differ significantly (log-rank test).

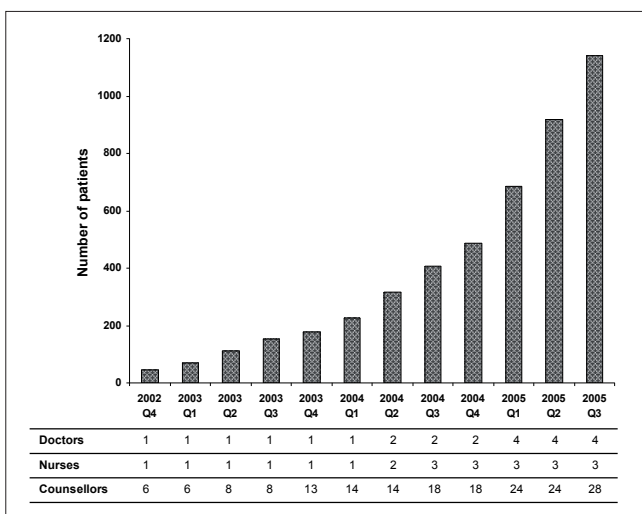


Fig. 1. The cumulative number of patients recruited onto the antiretroviral programme together with number of doctors, nurses and counsellors in each quarter-year period between October 2002 and September 2005.

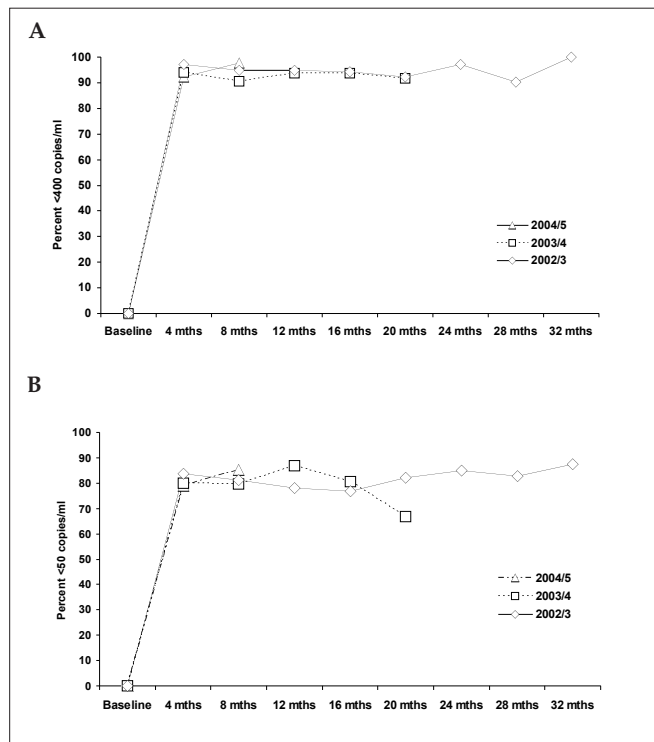


Fig. 3. A: The proportion of individuals in each annual cohort with < 400 HIV copies per ml of plasma at each 4-month monitoring time point. B: The proportion of individuals in each annual cohort with < 50 HIV copies per ml of plasma at each 4-month monitoring time point.

second-line regimen (6, 8 and 3 in each of the sequential annual periods).

Discussion

This is one of longest-running public-sector community-based ART programmes in sub-Saharan Africa, allowing a unique assessment of trends during a period of increasing recruitment



to more than 1 000 patients at a single clinic. On-treatment virological suppression rates were excellent, were sustained over the 3-year period and compare very favourably with other published treatment programme outcomes in Africa,⁴⁻¹⁰ Europe and North America.²⁵ These results show that key programmatic outcomes can be maintained during a period of rapid expansion of services.

While the experience of this programme in rapidly expanding services is encouraging, these results should be interpreted with the following caveats. Recruitment to the programme was restricted to individuals living within a demarcated urban catchment area. While this geographical proximity may be similar to that of other peri-urban townships where large populations access health care, this model may not be generalisable to rural and other settings where populations are more dispersed. Furthermore the median pre-ART period of follow-up was similar for each of the yearly cohorts and therefore pre-ART mortality rates could be compared. However, the median on-ART follow-up varied and was shorter for the later cohorts. Therefore, while the short-term results were comparable, the long-term results seen in the 2003/4 cohort may not necessarily be achieved by those accessing therapy later.

The low proportion of males together with the advanced clinical stage of non-pregnant adults accessing this programme is of concern, as this may be an indication that ART coverage is still inadequate at a population level. Patients generally accessed the programme when their disease was advanced, which is reflected by high mortality in the pre-ART and early treatment phase. The high mortality and morbidity of those who present with very advanced illness disproportionately utilises medical resources around the time of ART initiation.²⁶ Clinic recruitment could be increased if the programme were accessed earlier. There was a trend towards an increase in median CD4 cell count over the study periods, which was more marked in the third year. It would be encouraging if earlier presentation represented a decrease in the backlog of advanced HIV infection in the population; however the increase in median CD4 cell count was not paralleled by a decrease in pre-ART mortality, which remained unacceptably high. The higher median CD4 cell count was largely explained by an increase in non-traditional recruitment of pregnant women and children. Pregnant women were referred after accessing voluntary counselling together with CD4 cell count testing at the local maternal-obstetric service and had markedly less symptomatic HIV disease. The increasing number of children reflected an increase in collaboration with paediatric HIV services resulting in increased referrals from hospital-based specialist units to community care, and children had significantly higher baseline CD4 cell counts than adults.

To date, physical infrastructure has not been identified as a key barrier to implementation of ART access in the context of small-scale services.²⁷ However our experience has been

that physical space is a critical constraint in the expansion of this programme, as the clinic had to be relocated twice in 3 years, including the development of an off-site location for pre-treatment counselling. In addition, the positioning of a dedicated laboratory in a shipping container on site enabled an efficient monitoring service, avoiding the need for sample courier services and expediting access of results to medical staff. The on-site laboratory was economically viable when monitoring > 1 000 patients on ART (data not shown) and could be used for similar large single clinics or geographically clustered clinics in both urban and rural settings serving 1 000 - 10 000 patients. An increasing number of patients were transferred from and to other treatment centres during year 3. As ART programmes mature there will be an increasing need for tracking systems, which can enable efficient transfer of patients between treatment centres.

Although programme acceptability was not specifically measured as part of routine clinical services, the low rate of loss to follow-up observed may reflect levels of client satisfaction. Shortage of human resources, in particular nurses, has been identified as a major operational constraint to treatment access.²⁷ The specific model of care reported in this study was a dedicated ART community clinic, relying on a high ratio of lay counsellors to clients. The community-based counsellors supplied continuity and served as the major conduit for ongoing interaction between the programme and clients. The allocation of a personal 'therapeutic counsellor' to each client on entry into the programme facilitated the high levels of treatment adherence (contributing to virological suppression rates) and retention in the programme. In contrast to the health professionals, they are readily accessible and their utilisation results in employment opportunities for individuals living with HIV/AIDS in a community with high unemployment.

In summary, this analysis of a community-based, public-sector ART service demonstrates that a single urban public clinic can supply and monitor ART to more than 1 000 patients, without compromising programme performance during rapid scale-up. This finding bodes well for the expansion of ART services in resource-limited settings

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