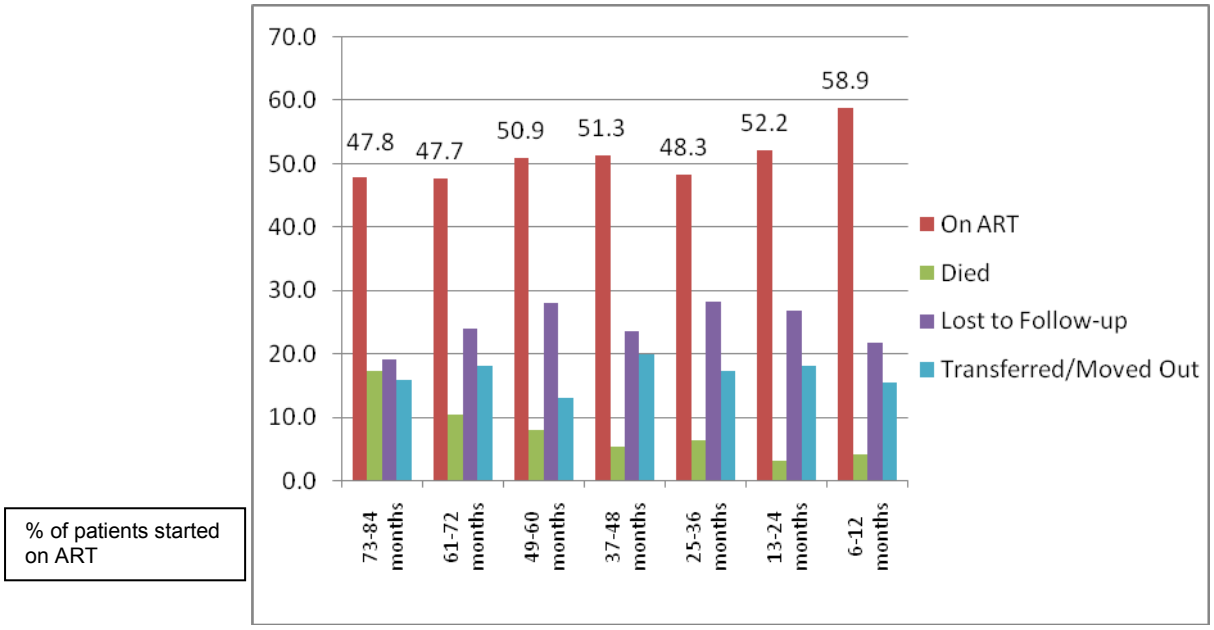

Figure 1 Time on treatment as a variable against outcomes of patients enrolled into ART

Table 6: Time on treatment as a variable against outcome.

Outcome	2004	2005	2006	2007	2008	2009	2010	Total
On ART	100 47,8 %	135 48.2%	230 51%	240 51.2%	140 48.2%	191 52%	236 58%	1272
Died	36 17.2%	29 10.2%	36 8%	25 5.3%	18 6.2%	11 3%	16 3.9%	171
Lost to Follow-up	40 19.1%	68 24%	127 28%	110 23.5%	82 28%	98 26.7%	87 21.6%	612
Transferred/Moved out	33 15.7%	51 18%	59 13%	93 19.8%	50 17.2%	66 18%	62 15.4%	414
Retention in care (On ART + Transferred/moved out)	63.5%	66.2%	64%	71%	65,4%	70%	73.4%	

Analysing time on treatment as a variable against outcomes (refer to Figure 3 and Table 6), it was found that 17,2 % of the patients enrolled into treatment in 2004 had died, while only 3% of the patients started in 2009 died. Only 19.1% of the patients started in 2004 were lost to follow-up, while 28% of patients started in 2008 were lost to follow-up. There was no significant difference between the numbers of patients transferred out per year. The data show no clear change in outcome trends with variation of time on treatment.

Table 7: Gender as a variable against outcomes of patients enrolled at TC Newman

Outcome	Female	% of Females	Male	% of Males	Total	% of total
On-Art	834	53.6%	438	47.8%	1272	51.5%
Died	82	5.2%	89	9.7%	171	6.9%
Lost to Follow-up	388	24.9%	224	24.4%	612	24.7%
Transferred/Moved out	250	16%	164	17.9%	414	16.7%
Total	1554		915		2469	

Analysing gender as a variable against outcomes was found that 9.7% of males had died and 5.2 % of females died. (Table 7)

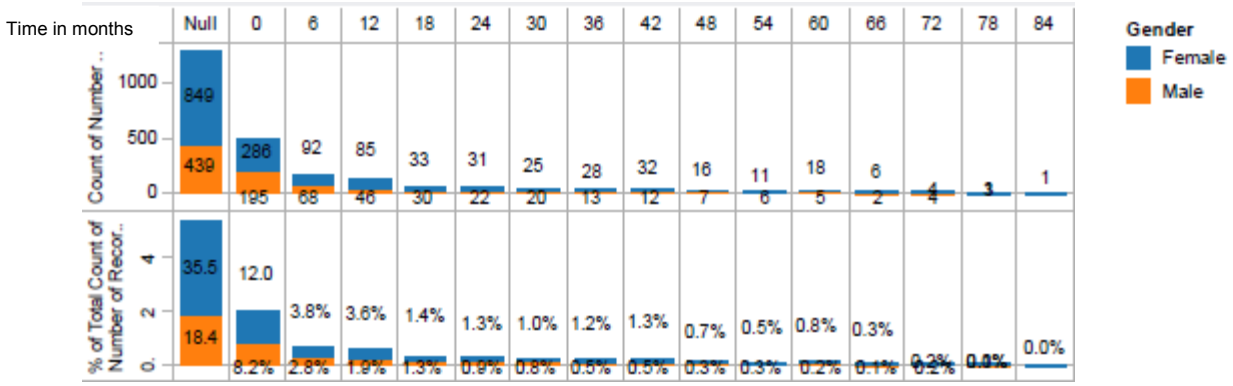

Figure 2 Total number of patients not on treatment at the end of June 2011 as a function of time in months after initiation of ART. (Null = patients still on ART)

Figure 4 illustrates that of all the patients not on treatment anymore, 43% left (either Died, Lost to Follow-up or Transferred/Moved Out) the programme between 0 to 6 months after treatment initiation and 70 % left between 0-18 months after treatment was started.

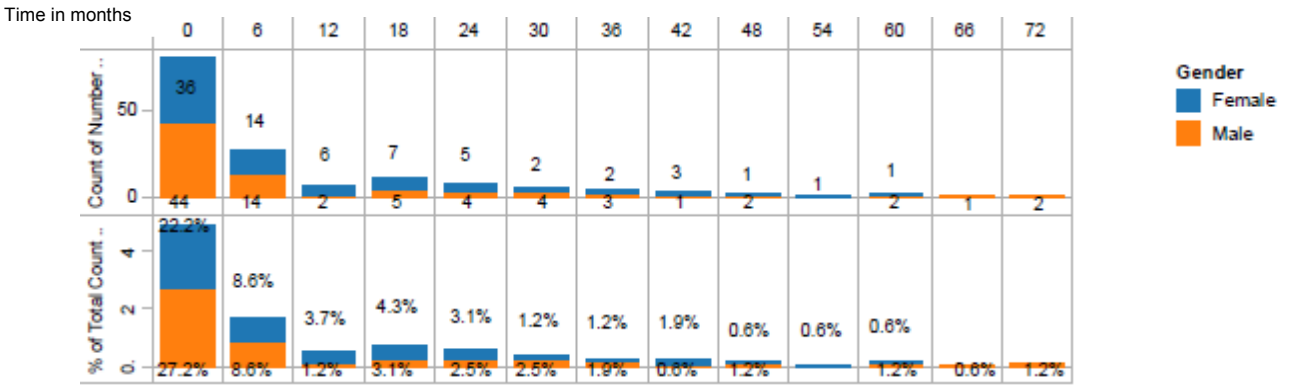

Figure 3 Summary of time since ART initiation of patients who died

Figure 5 shows that 49.4% of all patients who died did so in the first 6 months after treatment initiation and another 17,2% died between 6 and 12 months on treatment.

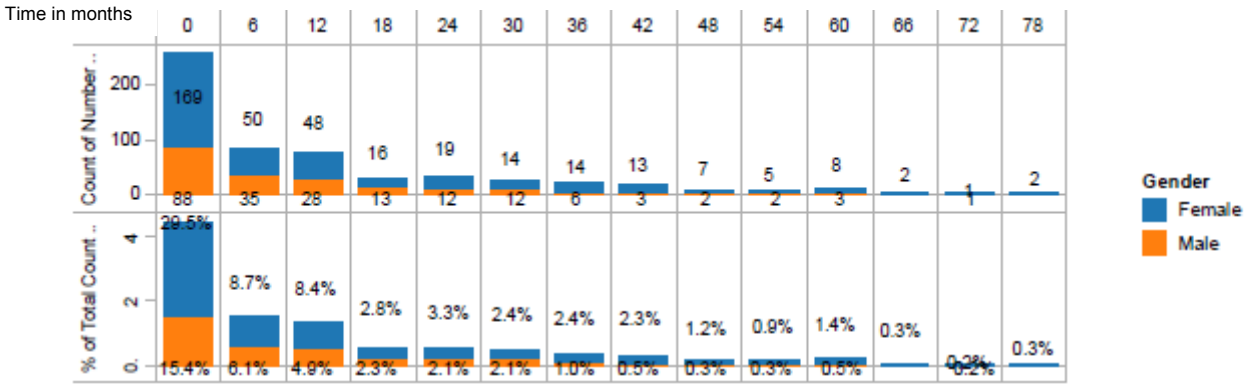

Figure 4 Summary of time since ART initiation of patient who were Lost to Follow-up

The primary reason for patients not staying in the programme was Lost to Follow-up (refer to Figure 6), 44.9% of patients became lost to follow-up within 0-6 months, 14,8% between 6-12 months and another 13.3 % between 12-18 months

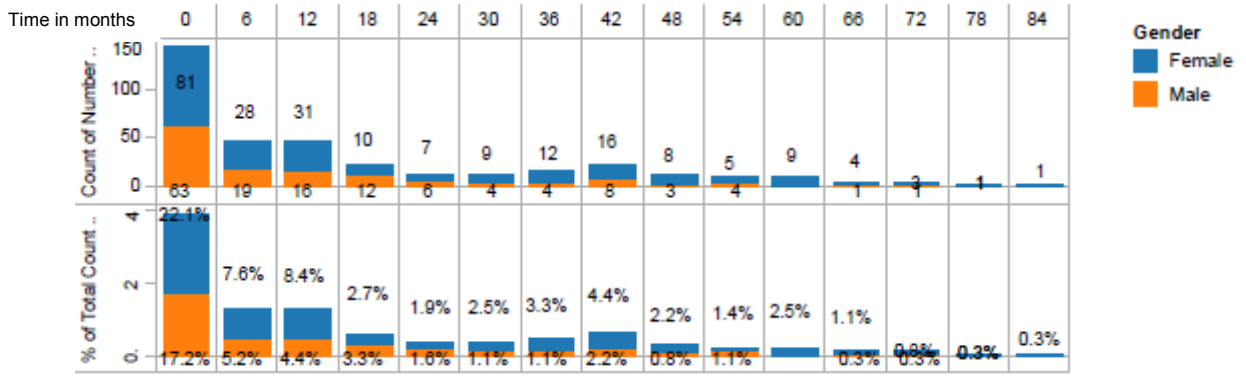

Figure 5 Summary of time since ART initiation of patients who Transferred/Moved Out

.The patient who Transferred/Moved Out showed a similar pattern (Figure 7).

3.3 Objective 3: Regimen 1 durability and "On-treatment virological suppression" (The stayers)

The aim of this section is to describe, understand and evaluate programme performance of the patients that are on ARV treatment at the clinic. Of the 2254 patients that started on ARV's, 1172 (51.9%) patients were still on treatment at the end of June 2011. Regime 1 Durability and "On-treatment virological suppression" are determinates to evaluate the performance of the clinic in providing care to patients on treatment.

To analyse this group only patients that were started on ARV treatment at TC Newman were included. Patients remaining on treatment were grouped together, based on the ARVs they were receiving. Patients were classified as: on Regime 1 or as a patient on Regime 2. Regime 1 is (NNRTI based) and is used as starting regime. Regime 2 is a "PI based" second line regime and is used for patients who have failed Regime 1.

At the end of June 2011, of the 1172 of the patients started at TC Newman CDC 1023 (87,3%) were still on Regime 1 and (149)12.7% on Regime 2

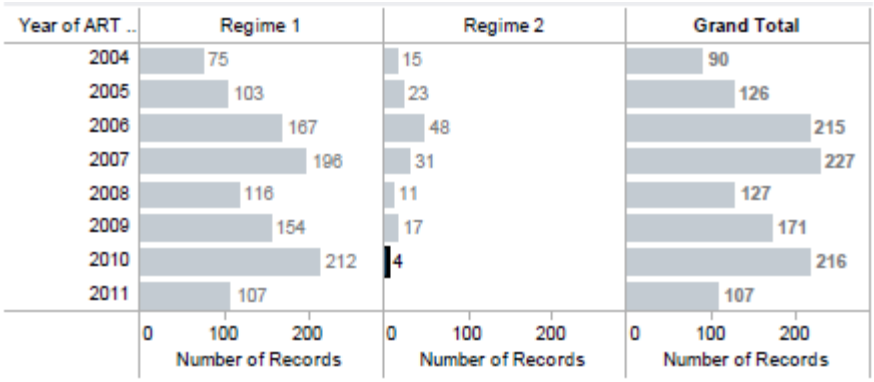

Figure 6 Time on treatment and number of patients on Regime 1 and Regime 2

Table 8: Patients still on Regime 1 as percentage of all patients still on treatment after specified time

Time in months	73-84	61-72	49-61	37-48	25-36	12-24	6-12
% of patients	83, 3%	81,7%	77,6%	86,3%	91,3%	90%	98%

Figure 8 and Table 8 illustrate time on treatment as a variable against number of patients on Regime 1. Even with the increase in time the % of patients on treatment on Regime 1 stayed high compared to the number on Regime 2.

Table 9: Outcomes of viral load testing of the patients on treatment

Number of patients on treatment	Viral load not done	Lower than Detectable level VL	Detectable
1172	215	911	153
	18.3%	85.5%	14.3%

On-treatment virological suppression rates are important determinates of programmatic outcomes. Patients on treatment were grouped together, according to the last recorded viral load measurements. The groups were classified as: No Viral load recorded, Viral loads < 400 copies/ ml = LDL, Viral loads > 400 copies/ml = Detectable

Viral loads were not reported on 18.3% (Table 9) of the patients remaining in treatment. 85.5% of the viral loads done were 'Lower than Detectable Levels'. Of the patients with Detectable Viral loads, 6.6% were on Regime 1 and 6.5 % on Regime 2.

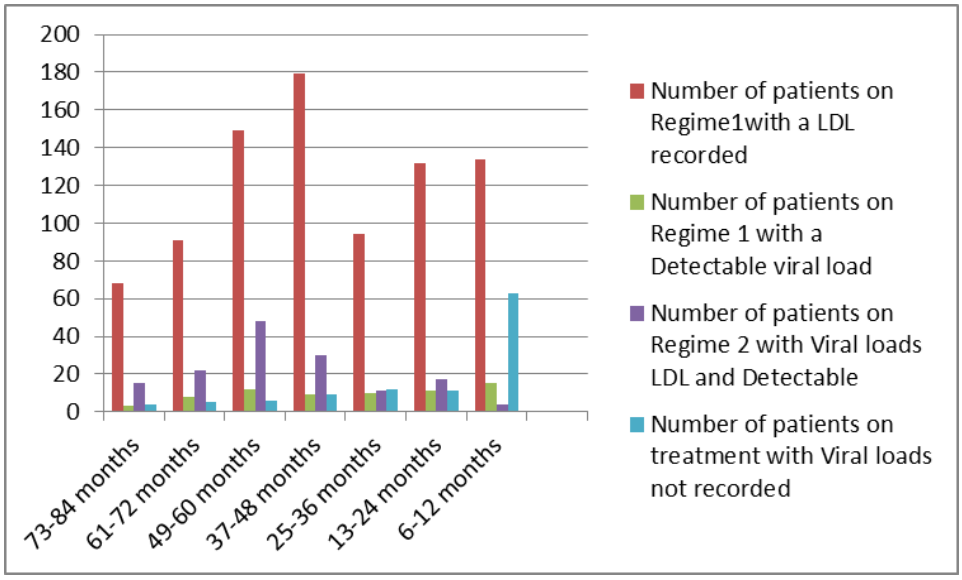

Figure 7 Summary of time on treatment of patients on Regime 1 and Regime 2 and Viral load control

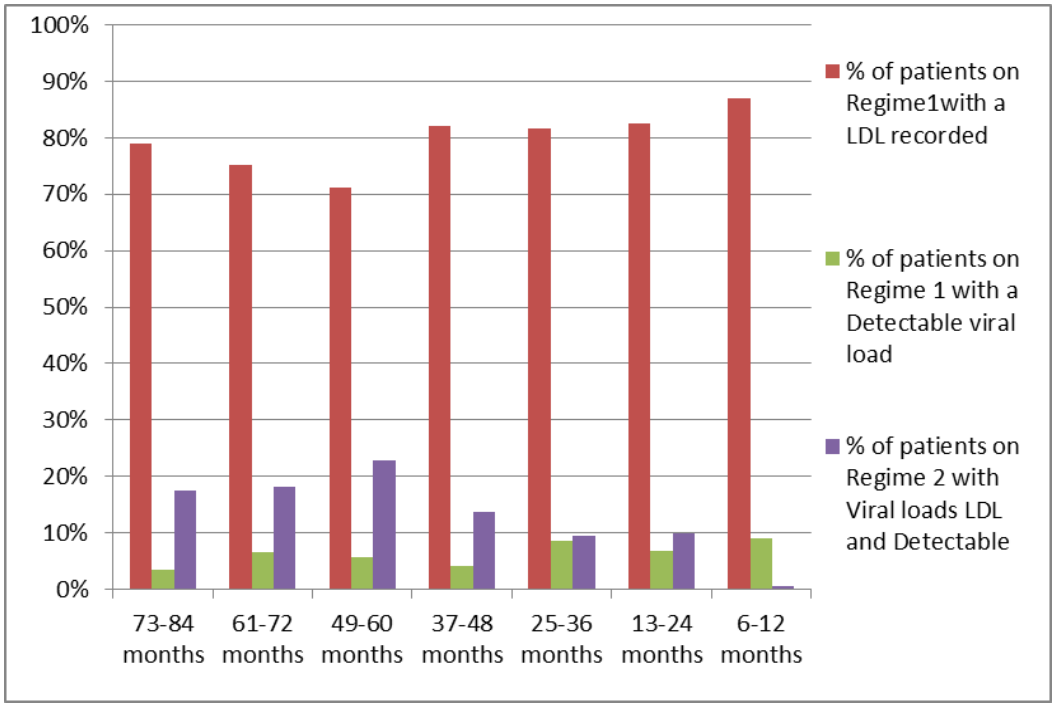

Figure 8 Percentage of patients on Regime 1 and Regime 2 and Viralogical outcomes.

Figure 9 and 10 demonstrate good durability of Regime 1 over time.

4 Discussion:

Over time the quality of data capturing and analysing data became an increasing concern for the staff and management of the clinic. In the absence of curative treatment, lifelong follow-up of patients on ART is required to monitor adherence, treatment response and adverse effects. A growing amount of increasingly complex information needs to be reviewed at each visit, and new data must be added to the record.

Cornell studied data collection and data quality at 11 ART programs in South Africa and concluded that although South Africa has implemented the largest treatment programs in the world, the ability to monitor the programs closely has not kept pace with expansion. (18)

Foster suggested that promoting appropriate and sustainable databases and systems to trace patients should be a priority in the context of scaling up ART. (19) Electronic databases can play an important role, particularly as numbers of patients in ART sites increase, but for this to work adequate human resources and staff training are essential.

In line with above recommendations and to facilitate the collection of good-quality data and the transition from a paper based register to an electronic data based register a full time data capture was employed during the period of data collection for the study. The extra staff member helped in reducing the pressures facing the clinic and ensured a complete set of data.

4.1 Objective 1: Enrolment of patients “The Starters”

Access to antiretroviral therapy expanded rapidly in the sub-district and compare well with the 10 fold expansion in 5 years of ART in low- and middle-income countries reported in 2009. (2)

4.1.1 Proportion of transferring in

The ARV service at T. C. Newman CDC was one of the first ARV sites in the more rural areas of the Western Cape. It was expected that a lot of patients on treatment will be transferred to the “new” site. It was also argued that transferred in patients are a “difficult group” to integrate into the “culture” of the clinic, because they were not part of the standard patient education programme. In conclusion the proportion of “transferred in patients” at the TC Newman CDC is small compared to the number started at the clinic. It is unlikely that

the" transferred in patients" have a significant impact on the functioning and outcomes of the clinic.

4.1.2 Gender distribution

Data disaggregated by gender shows that about 60% of adults who were receiving ART in low- and middle income countries were women. (2) At TC Newman 62.9% of the patients started on ARV were women. In the first 5 year 66.6 % of the patients started at the clinic were women, the last two years the percentage has dropped to 58%. This trend justifies further investigation in order to identify and support strategies that enhance men's acceptability of ART services.

Studies had shown that men are less likely to access treatment, present with more advance stages of HIV disease and have a higher risk of defaulting. (20) (21)

4.1.3 Age distribution

It is the young adults in the population that are the worst affected by HIV with 48 % of the patients at the clinic between the ages of 30-40 years. Staff working in the ARV clinics needs to adjust to the needs of the younger adult, like reproductive health needs and the need for flexibility to accommodate the working adult.

4.1.4 Enrolment trends

The fluctuation over time in the number of patients enrolled is closely related to developments and scale-up events at clinic level. Changes in the programme structure and environment tend to have a direct effect on the numbers of patients initiated.

For example:

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- Creating capacity for ART service delivery:

  In the first two years of the programme the enrolment of new patients at the clinic was limited to two days a week, because of the availability of staff and physical space. It is documented that the chronic shortage of health care workers is a major bottleneck to health provision and scaling up treatment. (17) (22) The average number of patients started in 2004 was 19 patients per month and in 2005, 22. In 2006 the number of patients enrolled monthly increased to an average of 35 patients reaching a maximum of 60 patients in one month of the year. The increase in numbers in 2006 follow on the employment of full time doctors at TC Newman CDC ART clinic and the ability of the team to put patients on treatment for 5 days a week.

- Physical space was a critical constraint in the expansion of the programme.
  The sharp increase in total number of patients on treatment since 2006 put a lot of pressure on the need for more physical infrastructure. In 2007 the clinic was relocated and patients were seen at three different rooms in three different corners of the facility. The lack of physical space was one of the main reasons for the drop in the number of patients started on treatment in the second part of 2007. Infrastructure as a key barrier to implementation of ART was identified and it was agreed that new infrastructure were needed, but it would take 3 years for the infrastructure to catch up with the patient needs. Physical space as barrier to implementation of ART access was also identified by Bekker. (9)

- Decentralization of ART services:
  With the help of non-governmental organisation, ART services were decentralised to Primary Health Care clinics in the Drakenstein sub-district. The decentralisation of ARV services started at the end of 2007 and had an impact on the enrolment at TC Newman CDC as seen by the decline in the number of patients enrolled in 2008. In 2008 only 21 patients were on average started on treatment per month, but 4 new ART service points were available in the Drakenstein sub district. Decentralization and task shifting has been shown to work in a number of settings (16) (23) (24)

- Reduction of the frequency of visits for stable patients
  In 2009 a new strategy at the clinic focussed on identifying stable patients and reducing follow-up visits to the clinic to once every 2 or 3 months. Clinic staff had more time to initiate patients and since 2009 (average of 28) there was a steady growth to an average of 31 per month.

4.2 Objective 2: Evaluating outcomes: The Strugglers

Harries documented that good ART clinic practise must include reliable ascertainment of outcomes of death, loss to follow-up and the formal recording of transfer outs from one ART facility to another. (25)

It was possible to identify treatment outcomes at the clinic through regular scrutiny of the paper-based files and register, but it was labour intensive, done only quarterly and by the time the treatment outcome report became available, it already needed updating. Introducing the electronic registered made it possible to have a daily treatment outcome report after all

the patients visits were entered. The sustainability and timeliness of the electronic register greatly enhanced the ability of the clinic to trace patients who are either late for appointments or who have been recorded at lost to follow-up.

4.2.1 Retention in care

The scale-up of ART has been one of the success stories of sub-Saharan Africa, however tempering the success is a growing concern about patient retention

We defined attrition from ART programs to include patients who died or were lost to follow-up and retention were defined as the opposite of attrition (i.e. 1- attrition) Using the definition 63.5 % of the patients started on ART in 2004 (73-84 month on treatment) are retained in care. The retention in care for the 6 cohort groups averaged 68.8% and with a variation of (63.5%- 73.5%)

This compare well with analysed done by Fox on 33 sources describing 39 cohorts and 226 307 patients on ART in sub-Saharan Africa. It was found that the overall retention by 24 months averaging 70%-77% and overall retention by 36 months averaging 65%-72%.(26)

Measuring retention in care is critical for determining the effectiveness of programmes and can be used as a proxy for the quality of care. (5) Tassie also reported that the countries with highest burden of patients, South Africa, Kenya, Nigeria, India, Zambia did not report on retention as indicator.

By June 2011, 6 and a half years since the start of clinic, 6.9% patients had died after enrolment into the ART programme, 51.5% of patients were still on ART, 16.7% Transferred/Moved Out and 24,7% of patients were reported as Lost to Follow-up. These findings at the TC Newman clinic document that retaining patients in care for lifelong treatment is difficult.

4.2.2 Mortality rate

The overall low mortality rate of 6.9% in the programme was encouraging. Of all the patient who died after enrolment, 49.4% of patients died in the first 6 months after treatment initiation and another 17,2% died between 6 and 12 months on treatment. These findings compare well with other programmes, Bekker reported a 7% mortality rate in Guguletu with 63% of deaths occurring in the first 90 days of ART.(9) and Lawn reported that 8% to 26% of patients entering ART programmes die in the first year in African settings. (27)

The low mortality rate at TC Newman needs to be interpreted with caution, because the high Lost to Follow-up rate can mask a higher mortality rate.

Analysing gender as a variable against outcomes it was founded that 9.7% of males died and 5.2 % of females died. This finding is consistent with other studies documenting men having a higher mortality risk. (28)

The reasons for patients dying on treatment at the clinic need further investigation and to reduce the death rate intervention need to focus on reducing early on treatment mortality.

4.2.3 Lost to follow-up rate.

Of the patients not staying in the program 54% were reported as Lost to follow up, 35% reported as transferred out and 11% died. We do not have a good understanding of reasons for patients not returning to care at the clinic. A systematic review and meta-analysis of studies that traced patients who were Lost to follow up in ART programmes in resource-limited settings showed that the outcome of over a third of patients remained unknown. (29) and among those traced 20% to 60% had died. Common reasons included the transfer to another ART site, financial problems, improvement or deteriorating health and stigma. (29)

Of the patients reported as Lost to follow-up 44.9% become lost to follow-up within 0-6 months. The results confirm the results of previous studies that once a patient have initiated ART and survived the initial few months of treatment the risk of lost to follow up and death is low. (30)

To understanding the Lost to Follow up group it is recommended that, reasons for lost, and outcomes after Lost to Follow-up, get documented at TC Newman CDC. For this patient tracing procedures need to be in place. (31)
Harries, Zachariah, Lawn and Rosen presented and discuss key interventions they believe might help with improving patient retention.(25) Some of the strategies (the need for simple and standardized monitoring systems to track what is happening, reliable ascertainment of true outcomes of patients lost to follow-up, implementation of measures to reduce early mortality in patients both before and during ART, the use of simple, non-toxic ART regimes and the decentralization of ART care to health centres and the community) were implemented at the TC Newman CDC. Operational research at facility level is needed to evaluate the outcome of these quality improvement strategies.

4.2.4 Transferred/Moved out

Because of the expansion and decentralization of ART services an increasing number of patients were transferred between treatment centres. Good communication and sharing of patient information between treatment centres are needed. Implementing the electronic register at more clinics will help to identify patients that have moved between clinics.

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4.3 Objective 3: Evaluating patients on treatment: The Stayers

4.3.1 Regimen durability

Six years after the programme was started at TC Newman CDC, 87.3% of the patients on treatment were still on Regime 1 and 12.7% on Regime 2.Even with the increase in time the % of patients on treatment on Regime 1 stayed high compared to the number on Regime 2. Change from Regime 1 to Regime 2 was due to treatment failure. Boulle reported on similar settings to TC Newman that at 2 years, 3.7% of adults were on Regime 2, rising to 17.9% at 4 years. (32)

4.3.2 Virological outcome

Routine viral loads were done to monitor efficacy of ART. Of the patients remaining in care, 85.5% of the last viral load reported was ‘Lower than Detectable Levels. The proportion of patients with “Lower than detectable Levels” compares favourably with those reported in other studies. (6) (33) (34)

The stable patients on treatment form the bulk of the patients visiting the clinic daily. They are an ever growing group and because of the nature of ARV treatment will never been discharge out of the ARV services. There are a need to develop sustainable processes and platforms at clinic and community level that will deliver high volume ART safely to stable patients in the context of limited resources.

The good virological and regime durability documented in this study is a motivation for the decentralization and mainstreaming of ART services to stable patients. This is in line with recommendations from the Development of Antiretroviral Therapy in Africa (DART) trail that shows that treatment outcomes are as good with simple clinical monitoring compared with clinical and laboratory monitoring. (35)

5 Conclusion

Good quality data on enrolment (starters), retention in care (strugglers) and virological outcomes is available at TC Newman CDC and can be used to benefit patients directly and indirectly.Access to ART expanded rapidly at the clinic and the number of patients enrolled (starters) is closely related to developments and scale-up events at the clinic.

Retention in care rate over the 6 years (63,5%-73.5%) equal those in other published treatment cohorts. The high 'loss to follow-up" rate is of concern and needs further investigation. (strugglers)

Good virological outcomes over time were documented for the patients in care (stayers).

6 Recommendations:

6.1 Data capturing and analysing

The implementation of the electronic data register at TC Newman CDC opened opportunities for better data quality and the use of the electronic data register is recommended. In the face of the rapid increase of patient numbers, a balance between the needs for services provision and collection of good quality data is needed. A study looking at the impact of implementing the e-register on service provision and to validate data quality in the e-register is needed.

6.2 Starters

Despite progress made with the enrolment on to ART, a lot of people are still in need of ART. Clear enrolment targets are need and strategies enhancing the enrolment need to be implemented and studied. Sub-groups, like men, are more difficult to enrol and justify investigation.

6.3 Strugglers

It is recommended that retention in care be used as an indication of the quality of care. A better understanding of reasons for not returning to care at the clinic is needed and need further investigation. The reasons for patients dying on treatment and for early mortality need investigation.

6.4 Stayers

The stable patients on treatment are an ever growing group of patients and form the bulk of the patients visiting the clinic. It is recommended that facilities define the minimum package of services needed to ensure safe ART to this group of patients.

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