RHRU

Reproductive Health & HIV Research Unit
of the University of the Witwatersrand, South Africa.

Patient File Review Report

Tshepong Wellness Clinic
Klerksdorp, North West Province
Republic of South Africa

RHRU expresses special thanks to the following for their time and effort in making this project a success.

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ABBREVIATIONS

ART	Antiretroviral treatment
ARV	Antiretrovirals
Aurum	Aurum Institute for Health Research
CCMT	Comprehensive Care, Management & Treatment
DoH	Department of Health
NDoH	National Department of Health
PDoH	Provincial Department of Health
RHRU	Reproductive Health & HIV Research Unit, University of the Witwatersrand
Regimen 1A	Efavirenz (Stocrin), stavudine (d4T) and lamivudine (3TC).
Regimen 1B	Nevirapine, stavudine (d4T) and lamivudine (3TC).
Regimen 2	Zidovudine (ZDV), didanosine (ddI) and lopinavir/ ritonavir-boosted (LPV/r)
TB	Tuberculosis
TWC	Tshepong Wellness Clinic

EXECUTIVE SUMMARY

Introduction

The Tshepong Wellness Clinic (TWC) located at the Klerksdorp/Tshepong Hospital Complex in the North West Province of South Africa initiated the antiretroviral (ARV) component of the Comprehensive Care Management and Treatment (CCMT) plan in 2004. The clinic currently caters to over five thousand adults in need of HIV related care and treatment. It is one of the first sites in the country to utilise a down/up-referral service model. This model has enabled the clinic to continue to initiate large numbers of patients on antiretroviral treatment (ART) while using other sectors of the health care system to manage patients stable on ART. With the increasing number of clients, management of data and of patients lost to follow up have become areas of concern for the clinic. The current record system has not been able to appropriately track the status of patients, making it difficult for the clinic management to ascertain the actual number of patients actively accessing care at the clinic.

The Reproductive Health & HIV Research Unit (RHRU) of the University of the Witwatersrand has been working with this site since 2004, providing technical assistance with HIV related clinical services and capacity building via training and mentorship. In June 2006, the clinic and hospital leadership consulted RHRU regarding their concerns about the difficulty in accessing information on the current status of their patients. It was decided that a file review of all patient files was necessary to get an accurate understanding of the situation. RHRU developed a one page data collection tool and conducted a pilot review of 100 patient files in late June 2006, to establish what information was available in the files, and to test the content appropriateness and feasibility of the data collection tool. This was followed by a review of all files in July 2006. Over 70 individuals participated in the full file review which was a joint effort between the clinic, RHRU, and Aurum Institute for Health Research staff.

Results

A total of 5750 files were reviewed during this process. Data analysis indicated that two-thirds of all patients ever accessing care at this clinic were females and the mean age of the clinic population was 38 years. During the file review, the patient files were classified into one of the following five categories:

- **Active:** Patients currently accessing the clinic services.
- **Pre-ART defaulters:** Patients who had visited the wellness clinic at a certain time but had not returned in over six weeks since their last visit and had not been initiated on ART.
- **Down-referred:** Patients who had been referred to other clinics (these included a large proportion of the patients initiated on ART and some patients who had not been initiated on ART).
- **Post-ART defaulters:** Patients who had initiated on ART but had not returned to the clinic for a follow up or to the pharmacy for a re-fill for their medication in over six weeks since their last visit.
- **Deceased:** These were patients who had died at Tshepong Hospital and who had a TWC file.

The patient file breakdowns were: 41% active, 23% pre-ART defaulters, 19% down-referred, 14% post-ART defaulters and 2% deceased.

Sixty eight percent (n=3942) of the total clinic population was initiated on ART and just over half (51%), of these patients were accessing care at the clinic at the time of the file review. Thirty one percent (n=1765) of the total clinic population did not initiate on ART and only one-fourth (24%), of these patients were accessing care at the clinic at the time of the review.

ART drug regimen 1A (d4T, 3TC and Efavirenz) was the most prescribed regimen. Only 9% of the patients ever had a change in regimen, which was chiefly due to pregnancy, peripheral neuropathy and lactic acidosis. Tuberculosis (TB) was the most prevalent co-morbidity among the patients. Thirty-two percent of all the clinic patients had either completed or were currently on treatment for TB. Ninety percent of the down-referred patients were referred to 12 sites in North West Province, and all were clinically stable at the time of referral.

The median baseline CD4 count of the clinic patients (initiated and not initiated on ART) was 95 cells/mm^3. Analysis of the CD4 counts did not indicate a significant difference in the median baseline CD4 counts of the patients who were initiated on treatment versus patients not initiated on treatment leading to the question about why the patients in the latter group were not initiated on ART even though they clinically qualified. When taking into account the difference between the baseline CD4 count before ART initiation and the last available CD4 count after ART initiation, the median CD4 count increase among patients initiated on ART over the 2 and a half years of clinic operations was 149 cells/mm^3.

Viral load analysis indicated that complete viral suppression was achieved in almost all patients who initiated on ART. Over 70% of patients who initiated on ART but later defaulted treatment did so within the first six months of treatment initiation. For the analysis of deceased patients, only information on patients who had died at the Tshepong Hospital and who had a TWC file was analysed. The mean age of all the deceased patients (including initiated and not initiated on ART), at time of death was 38 years, the same as the overall clinic population. The median baseline CD4 count for all deceased patients was 59cells/mm^3, which was significantly lower than the baseline CD4 count (95 cells/mm^3) of patients who had initiated on ART. Sixty-five percent of patients who died after being initiated on ART died within the first three months of treatment initiation, and TB was the most common cause of death.

Challenges

There were several challenges that affected the data analysis and outcomes of the file review process. The primary problem was missing or incorrect data. Other challenges included: requirement for a large workforce to perform the review; process management especially since many staff used for the audit were not clinicians; and appropriate quality assurance which contributed heavily to the duration of the audit.

Conclusion/ Recommendations

The file review process identified inherent issues that the clinic was facing. Key areas in need of improvement included:

a) Development and implementation of appropriate data recording and storing mechanisms;
b) Processes to monitor and follow up patients initiated on treatment;
c) Systems to immediately identify defaulters and motivate them to return to the clinic;
d) Appropriate follow up processes for patients who are not eligible to start on ARVs – either because their CD4 count is greater than 200 cell/mm^3 or they have to first complete treatment of opportunistic infections; inquiry into reasons for patients defaulting on treatment; and
e) Standardising down referral systems and protocols.

Since the file review, the clinic has successfully implemented a defaulter tracing mechanism to promptly identify and follow up on defaulters, improved their longitudinal data systems, filing system, and quality of care especially for patients not yet initiated on ART. Since the file review, RHRU has revised the data collection tool and the data process. The process, which is being used at other ART clinics in South Africa, now has specific quality assurance mechanisms in place to identify and remedy errors immediately.

A portion of the files that were reviewed during the audit process

BACKGROUND

The Reproductive Health & HIV Research Unit (RHRU) provides technical assistance with HIV related clinical services and capacity building via training and mentorship to various Department of Health (DoH) sites in Gauteng, Kwa Zulu Natal and North West Provinces in South Africa. The Tshepong Wellness Clinic (TWC) located at the Klerksdorp/Tshepong Hospital Complex in North West Province is one of the sites that RHRU is assisting with. This clinic started its antiretroviral (ARV) roll out programme in April 2004 and is one of RHRU's larger ARV treatment partner sites, catering to over five thousand adults in need of HIV related care and treatment. Patients get referred in by a network of primary health care clinics who establish the eligibility of patients in terms of their HIV status, CD4 count and WHO stage before referral. TWC is also one of the first sites in South Africa to utilize a down/up-referral service model. In the down-referral model, patients are initiated on antiretroviral treatment (ART) at the TWC and are regularly followed up there until they are stable enough (measured by an improved CD4 count and undetectable viral load) to continue treatment at primary or secondary health care sites. This model is enabling the clinic to continue to initiate large numbers of patients on treatment while using other parts of the health care system to manage patients stable on ART

With an increasing number of clients, management of data and patients lost to follow up have become areas of concern for the clinic. The current paper-based records system is not adequate for the growing number of patients. Aside from the physical space that is required for a paper-based records system, data duplication and loss or lack of integration of relevant and complementary data, as well as clarity of information, are issues that have been identified by the clinic administration. To date, the clinic has put in place three electronic database systems to capture data; however, none of these are appropriately able to capture all information, leading to an absence of clear and accessible baseline data. Additionally, manual tracing of data, through review of logbooks and registry books, is still being used by staff to retrieve data for reporting. This situation is by no means unique as this problem with data management has been identified by various large ART sites across South Africa.

In response to the above issue, the clinic management, in consultation with RHRU decided that a retrospective review of all patient files was necessary to assess and improve clinic operation and the quality of care provided to the patients. Subsequently, RHRU conducted a pilot review of 100 patient files in June 2006, to establish the scale of the problem and to test the feasibility of the data collection tool developed for this exercise. This was followed by a review of all patient files in July 2006. The file review was a joint effort between staff at the clinic, RHRU, and Aurum Institute for Health Research[1]. This document presents the outcomes from the file review.

[1] Aurum Institute for Health Research is a health systems and research organisation, currently working on the database systems at the clinic.

METHODOLOGY

RHRU developed a one page data collection tool to capture relevant data from the patient files. The tool was piloted with 100 patient files to check for content appropriateness, reliability and feasibility. The results of the pilot were circulated to the relevant stakeholders for their comments and the data collection tool was revised based on the outcomes of the pilot and input from the stakeholders.

The pilot assisted the RHRU staff in identifying the most common locations of the different information in the patient files and planning the logistics of the full review. Over the years, the clinic had separated files of down-referred patients from the active ones and stored them in a separate location in the clinic. A small group of RHRU staff made a separate visit to the clinic to record information from the down-referred patient files. Most of the deceased patients' files were kept in the office of the head of hospital services. These files were reviewed by senior TWC staff and the completed data collection tools were sent to RHRU where the information was transferred to an electronic database and the data was analyzed with the rest of the information collected.

Over 70 RHRU, Aurum, TWC and hospital staff participated in the full review, which was conducted over a weekend. These included doctors, nurses, pharmacists, counsellors and others. The hospital management provided full support for this process by encouraging their staff to participate in the file review activity. At the beginning of the file review, the project manager, along with the head of the hospital services, briefed the participants on clinic operations and the data retrieval and collection process. Participants were allocated to separate rooms, each supervised by a team leader whose tasks ranged from obtaining the files from the records room, disbursing them amongst the reviewers, clarifying tool content and uprising issues, to collecting the completed data forms, conducting limited quality checks on the completed forms and returning the completed files to the records room. Participants who were not familiar with the data collection tool or did not feel comfortable conducting the review independently were paired with individuals who were familiar with the process. Additionally, clinicians were asked to assist non-clinicians with any medical related questions or clarification requests.

File reviewers were asked to classify each patient file into one of the following five categories after completing the data collection tool. The files could be classified as:

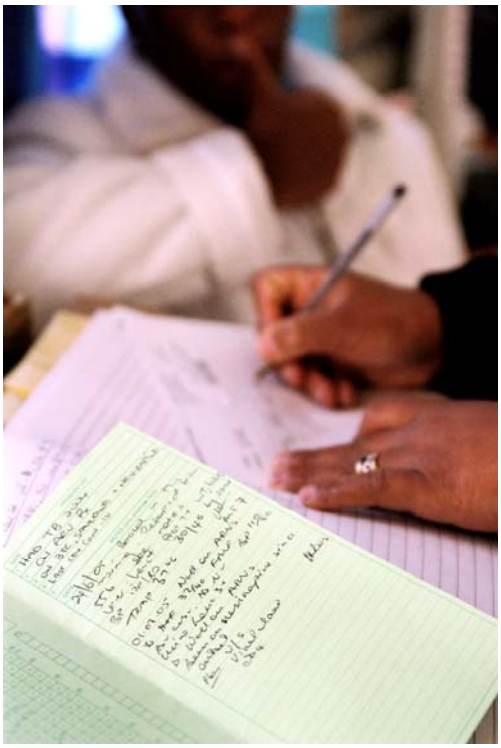
- **Active:** Patients currently accessing the clinic services;
- **Pre-ART defaulters:** Patients who had visited the wellness clinic at a certain time but had not returned in over six weeks[2] since their last visit – these patients had not initiated on ARVs;
- **Down-referred:** Patients who had been referred to other clinics;

[2] The six week cut-off criterion was based on the outcome of a defaulter study conducted at the Johannesburg Hospital ARV clinic which found that patients who had not returned for their appointments for six weeks most often did not return to the clinic at all.
Mqhayi M, Dalal R, J Wing J, Venter W, Causes for Defaulting ART in an Urban Clinic; Poster 550; 13th Conference on Retroviruses and Opportunistic Infections, Denver, February 5-8 2006

- **Post-ART defaulters:** Patients who had initiated on ARVs but had not returned either to the clinic for a follow up or to the pharmacy for a re-fill of their medication, in over six weeks since their last visit.
- **Deceased:** These were patients who had died at Tshepong hospital and who had a TWC file.

Each of the above categories was assigned a colour and the reviewers were asked to put a sticker of the appropriate colour on the front of the patient file. Additionally, the reviewers were asked to make a note of the file classification on the corresponding data collection tool. One of the issues that the clinic had indicated was that the staff were having a difficult time differentiating the files of active and non-active patients. At the end of the file review, only the active patient files (ascertained by the sticker colour) were returned to the shelves. Files of patients who were pre- or post-ART defaulters, had been down-referred or had died were stacked separately to be addressed appropriately by the clinic staff.

At the end of the file review, the completed data collection forms were compiled, and RHRU staff transferred the information into a Microsoft Access database and conducted descriptive analysis.

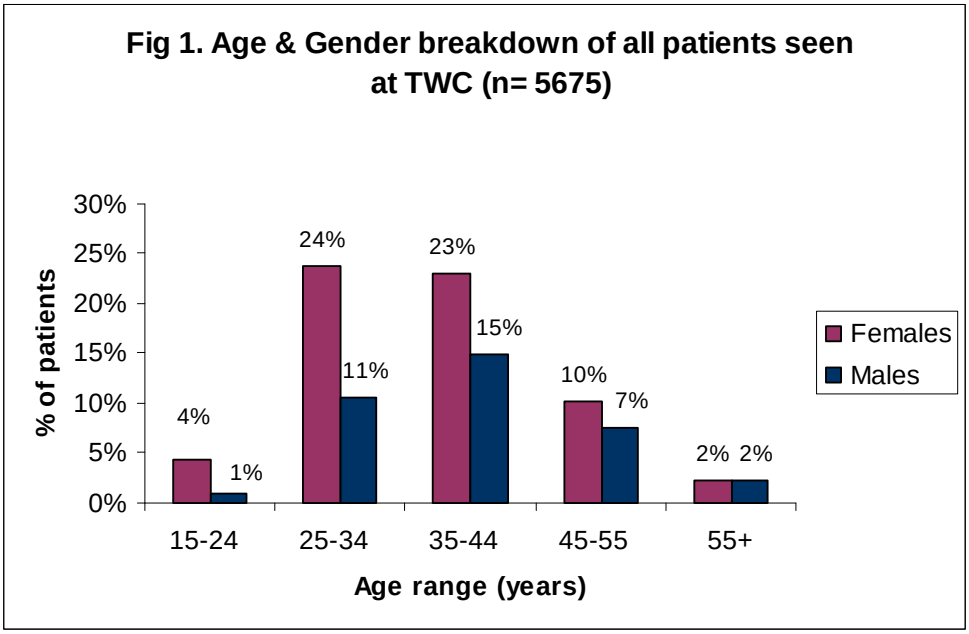


Audit participant reviewing a file

RESULTS

Demographics

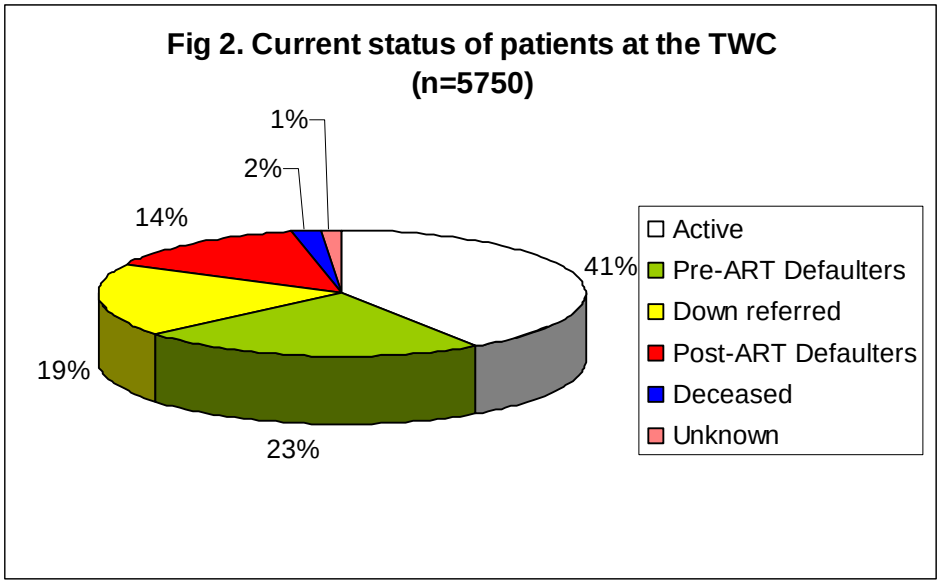
A total of 5750 patient files were reviewed during the file review. Sixty-four percent of patients accessing services at the Wellness clinic were female and 36% were male. The mean age for the cohort was 38 years (Range 15-66 years). Figure 1 represents the age and gender distribution of the adult population of the clinic. This information was missing for 1% (n=75) of patients and has been excluded from calculations in Figure 1.



There are more women accessing care at this clinic versus men, and the largest proportion of patients accessing care are in the 25-44 years age groups.

Patient status

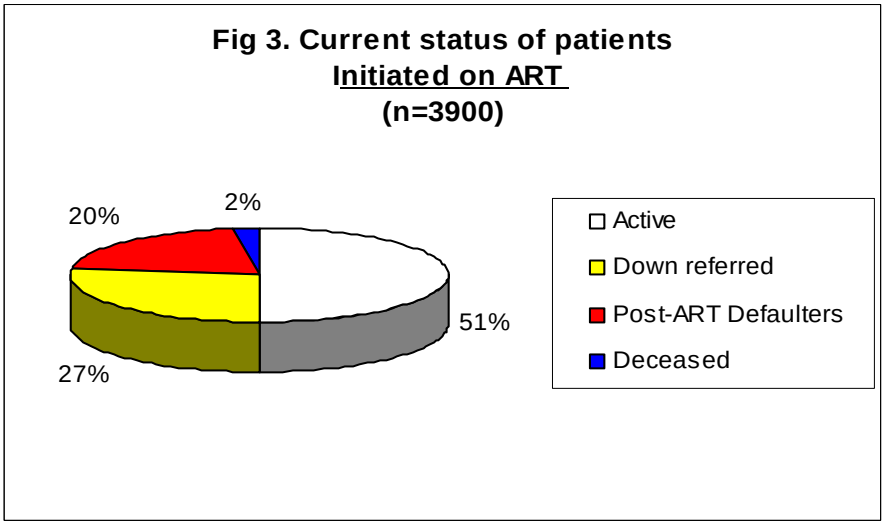
As shown in Figure 2, of the 5750 files reviewed, 41% were classified as active, 23% as pre-ART defaulters, 19% were down-referred and 14% were classified as post-ART defaulters. 2% of files belonged to patients who were known to be deceased. One percent of patient files could not be classified due to missing data. The 2% deceased were possibly underreported because the only way for the clinic to know with certainty that a patient had died was if the patient had died at the Tshepong Hospital. It is probable that a subset of patients classified as pre- and post-ART defaulters have died.



At the time of the file review, 41% of all patients ever visiting the TWC were actively accessing care at the clinic, 23% were pre-ART defaulters, 19% had been down-referred, 14% were post-ART defaulters and the remaining 2% were deceased.

(i) Patients initiated on ART

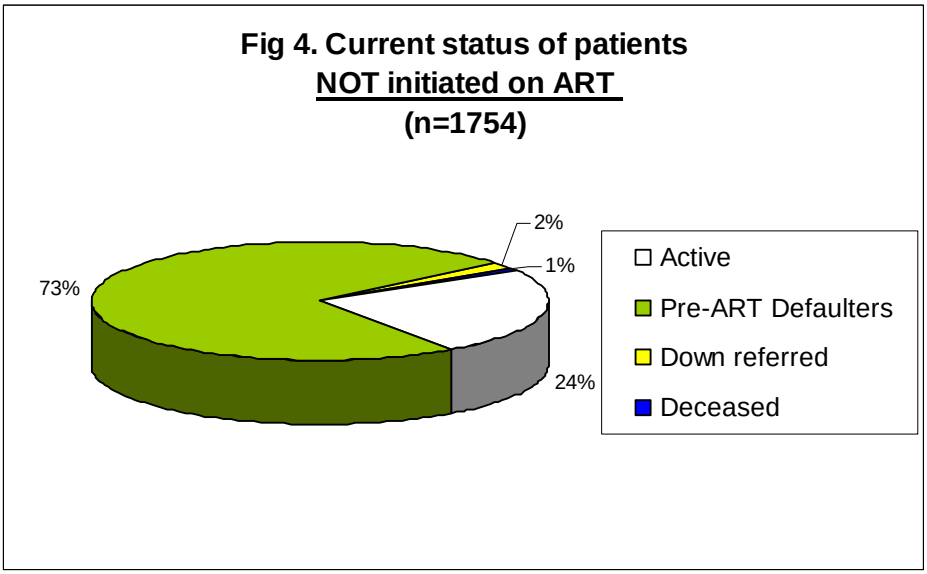
At the time of the file review, 68% (n=3942) of patients out of 5750 had ever been initiated on ART. Figure 3 gives the current status of patients initiated on ART. The status of approximately 1% (n=42) of patients could not be ascertained due to missing data and have been excluded from analysis in Figure 3. About half of the patients initiated on ART were actively accessing care at the clinic. Just over one-fourth had been down-referred and about one-fifth had defaulted treatment. As mentioned earlier, the proportion of deceased patients in this category may be underreported.



About 50% of all patients ever initiated on treatment were currently accessing care at the clinic. 20% had defaulted from treatment and 27% hade been down-referred. The 2% deceased were probably underreported.

(ii) Patients not initiated on ART

Thirty-one percent (n=1765) of patients had not initiated on ART at the time of the review. Figure 4 gives a breakdown of the file classification of these patients. The status of <1% (n=11) of patients not initiated on ARVs could not be ascertained due to missing data; they have therefore been excluded from analysis in Figure 4. Only 24% of the patients not initiated on ART were found to be actively accessing care at the TWC. These included 1% (n=24) wellness patients[3] who had a baseline CD4 count of >200 cells/mm^3 and who had visited the clinic within the six months prior to the file review. About 73% of the patients not initiated on ART were found to be lost to treatment initiation. These included 5% (n=83) patients who were initially classified as wellness patients[3] but who have not returned to the clinic in over 6 months since their last clinic visit. Information on the date of the first clinic visit was not collected during this file review. Therefore, it is not possible to ascertain how long patients normally stay in the clinic system before initiating on ART.



73% of patients not initiated on ART are classified as pre-ART defaulters, with only 24% actively accessing care at the time of the file review.

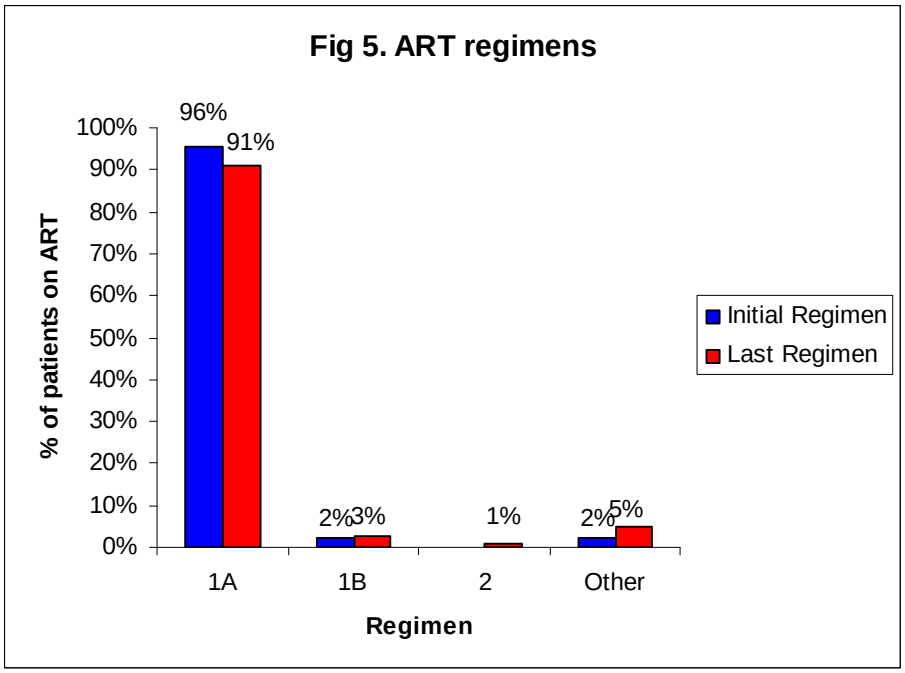
ART Drug Regimens

As shown in Figure 5, the first treatment for 96% (n=3710) of the patients initiated on ARVs since the ARV roll out began at this site was regimen 1A which consists of efavirenz (EFV), stavudine (d4T) and lamivudine (3TC). Two percent (n=84) of patients were initiated on regimen 1B which consists of nevirapine, stavudine (d4T) and lamivudine (3TC). A very small number of patients (n=7) were initiated on regimen 2 which consists of zidovudine (ZDV), didanosine (ddI) and lopinavir/ ritonavir-boosted (LPV/r). Another 2% (n=80) of patients were initiated on "other"

[3] Wellness patients: If the patients have a baseline CD4 count of >200 cells/mm3, and no AIDS-defining diseases, they do not qualify for ART initiation under the current South African ART guidelines and are classified as wellness patients. These patients are asked to return to the clinic in six months time for a follow up CD4 count and re-assessment of their HIV disease progression.

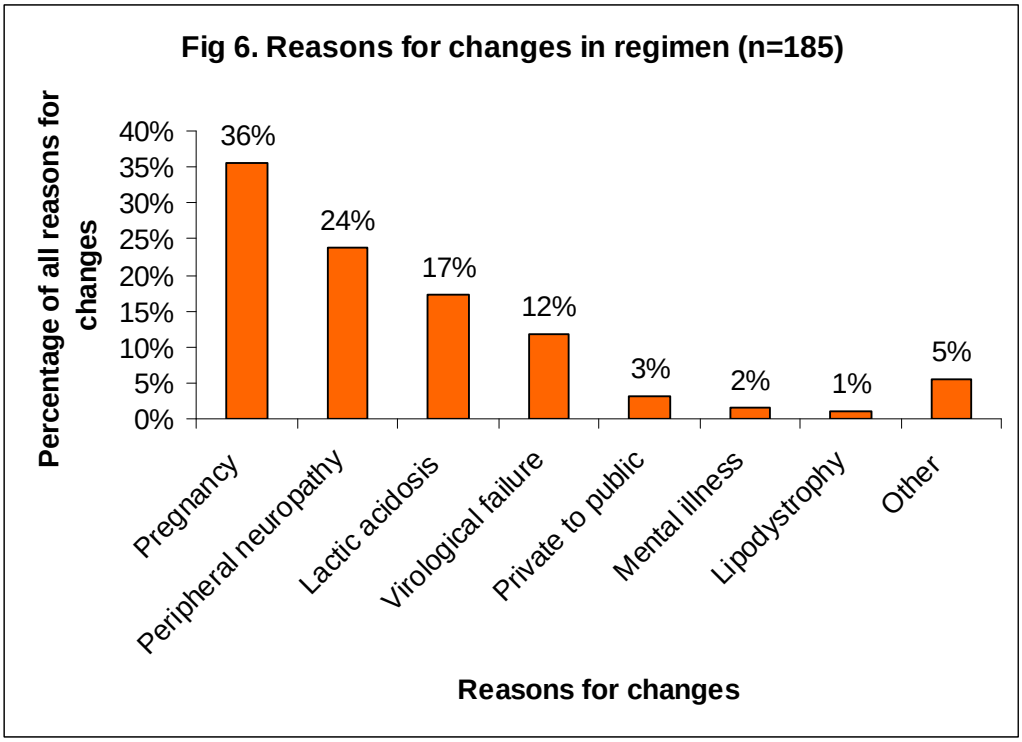
combinations of ARVs. In most of the cases "other" meant that AZT was substituted for d4T in regimen 1A or 1B.

A review of the current or last regimen indicated that 91% (n=3514) of patients initiated on regimen 1A were still continuing on it, 1% (n=25) were switched from regimen 1A to regimen 1B. Another 1% (n=31) of patients were switched from regimen 1A to 2, and 3% (n=117) were switched from 1A to other regimens. There were minimal changes from regimen 1B or 2 to other regimens.



Most of the patients were initiated on ART regimen 1A at this site with minimal amount of changes in their treatment over time.

Approximately 9% (n=344) of the 3942 patients initiated on ART had to change their initial treatment regimen. Information on reasons for change in regimen were only available for 54% (n=185) of the 344 patients, with the most common reasons for changes in these patients being pregnancy, followed by peripheral neuropathy, lactic acidosis, and virological failure (Figure 6). Three percent (n=6) of changes were a result of patients who had initiated on ART in the private sector and had their regimens changed to conform to public sector treatment guidelines (represented in the private to public category in Figure 6). Information on 46% (n=159) of the 344 patients was missing; therefore, these have been excluded from the analysis in Figure 6. This missing information could be attributed to either the information not listed in the patient files or the file reviewers missing the information during data collection.



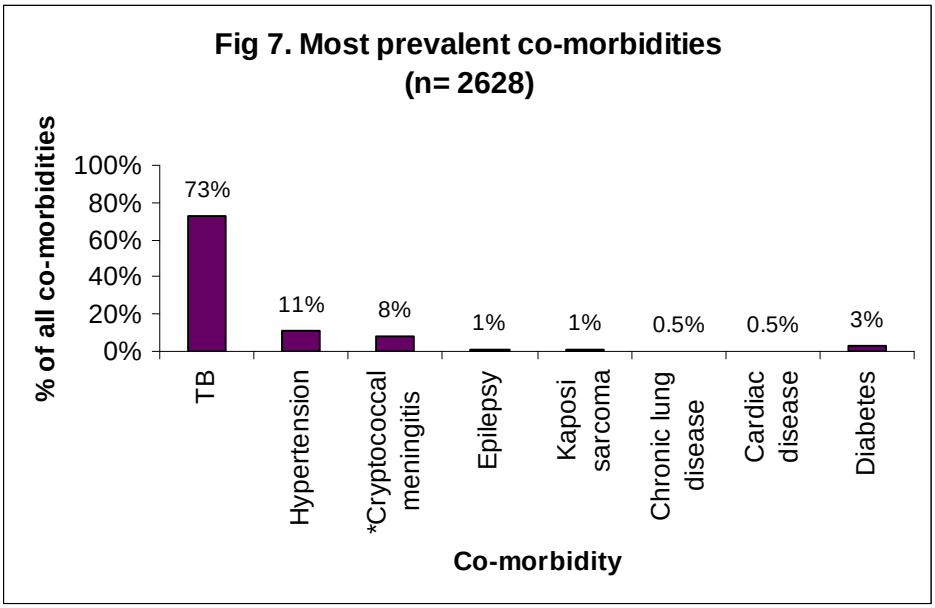
The most common reason for change in treatment regimen was pregnancy, followed by peripheral neuropathy, lactic acidosis and virological failure.

Co-morbidities

Information on concomitant diseases or co-morbidities was found in 42% (n= 2418) of all the files reviewed. Patients could have multiple co-morbidities. The prevalence of TB in the whole clinic population was found to be 32%. Figure 6 gives the breakdown of the co-morbidities found in the patient files. TB was the most commonly occurring co-morbidity (constituting 80% (n=1924) of all reported co-morbidities), followed by hypertension, epilepsy, Kaposi sarcoma, chronic lung disease and others. The TB category includes pulmonary TB, miliary TB, TB meningitis, and TB of unspecified localisation. The 'Other' illnesses category in Figure 6 includes asthma, cervical cancer, hepatitis, herpes zoster, peripheral neuropathy, pneumonia and others, all of which constituted less than 5 cases each. Peripheral neuropathy was considered as a co-morbidity if its onset was before ART initiation, as is the case with primary HIV-related peripheral neuropathy. In the data collection tool used for the file review, the question relating to co-morbidities was open-ended (with the exception of TB which was specifically queried). Therefore, much of the prevalence of other important opportunistic infections such as herpes zoster and pneumonia may have been under-reported during this process.

At the end of the first day of the data collection, it was noted that information on cryptococcal meningitis, a highly prevalent opportunistic infection among the TWC patients according to the clinic leadership, was not being collected in the file review. As the clinic leadership was interested in obtaining this information, on the second day of the file review the reviewers were asked to note down if a diagnosis of cryptococcal meningitis was found in the patient files. Time

constraints did not allow the reviewers to re-visit the files from the first day and check for this information, thus the information on this co-morbidity is under-reported. Information collected on the second day indicated 222 cases. An estimate of the overall occurrence of this illness among the patients would be in excess of 400 cases. This would place cryptococcal meningitis as the second most common co-morbidity in this patient population after TB.

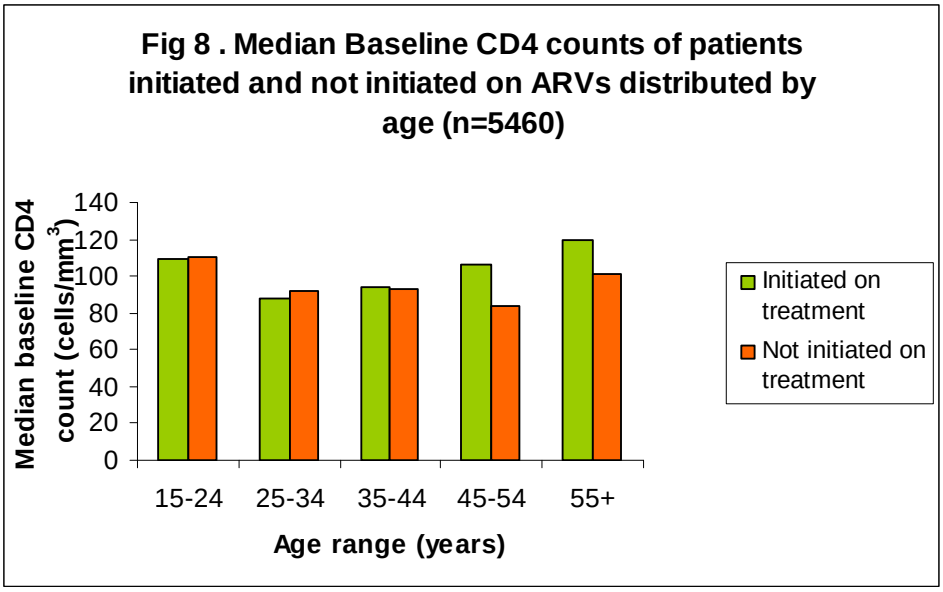


TB was the most common co-morbidity found in files. Hypertension could be secondary to weight gain in patients due to ART or other non-HIV related conditions. *The numbers reported for cryptococcal meningitis are from day 2 of the file review only.

CD4 Count Analysis

CD4 counts and viral loads have been reported as medians as this information was not normally distributed.

Information on the **baseline CD4 count**, defined as the lowest CD4 count before ARV initiation for patients initiated on ARVs, or the lowest CD4 count found in files of patients not initiated on ARVs, was found in 95% (n=5460) of all the files reviewed. The median baseline CD4 count for all adult patients (>15 years) was 95 cells/mm^3. Figure 8 gives the median baseline CD4 counts of patients initiated and not initiated on ART, distributed by age. There is not much of a difference in the median baseline CD4 counts of patients in the two groups, and in both groups, the median baseline CD4 counts are <200 cells/mm^3.

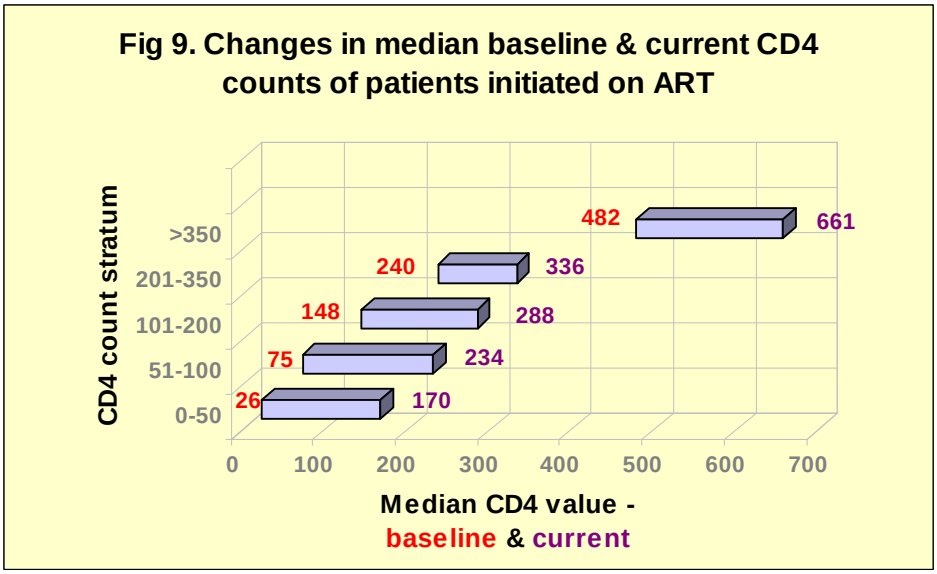


The median baseline CD4 counts of patients in both categories - initiated as well as not initiated on ART - were <200 cells/mm^3. There is a minimal difference in the median baseline CD4 counts in the two groups across the various age groups.

Table 1 and Figure 9 follow the changes in the median CD4 count between baseline and most current CD4 count readings at the time of the file review among patients who were initiated on ART. They show that patients across the different baseline CD4 count strata had an improvement in their CD4 counts after initiating on ART. When taking into account the difference between the baseline CD4 count before ART initiation and the last available CD4 count after ART initiation, the median CD4 count increase among patients initiated on ART over the two and a half years of clinic operations was 149 cells/mm^3. Table 1 also highlights one of the challenges encountered in the file review, that is, attrition of data between baseline and follow up CD4 counts.

Table 1. CD4 count changes between baseline and current/ latest median CD4 counts of patients initiated on ART

CD4 count stratum (cells/mm^3)	Baseline CD4		Current CD4		Change in median CD4 counts (cells/mm^3)
	n (%)	*median* (cells/mm^3)	*n (%)*	*median* (cells/mm^3)	
0-50	1065 (28)	26	607 (27)	170	144
51-100	898 (24)	75	528 (24)	234	159
101-200	1694 (45)	148	1055 (47)	288	140
201-350	84 (2)	240	41 (2)	336	96
>350	21 (1)	482	14 (1)	661	179
All	**3762**	**96**	**2245**	**245**	**149**



An improvement in CD4 counts after initiating on ART is seen in patients in the various baseline CD4 count strata .

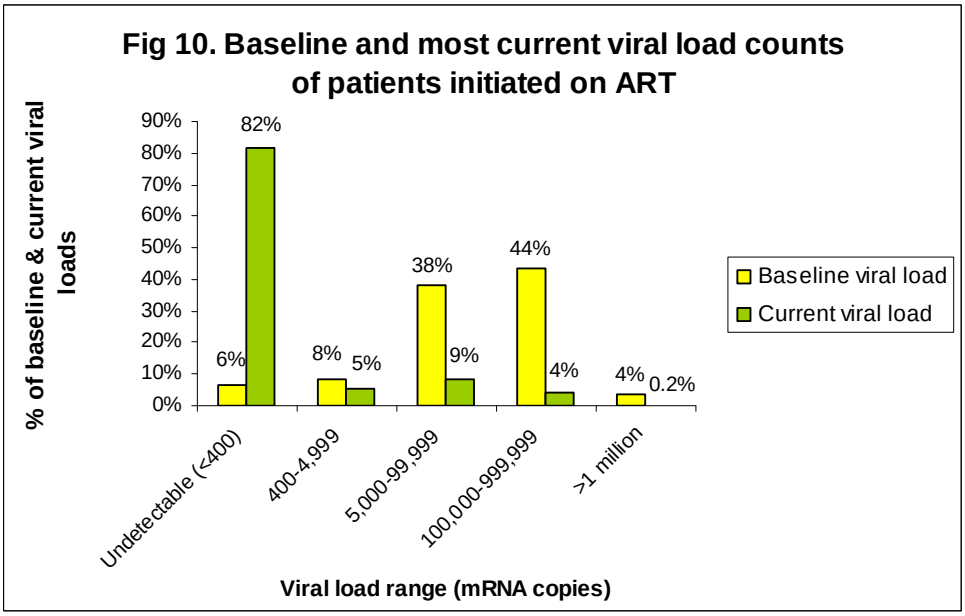
Current status of patients based on their baseline CD4 counts

Analysis of the current status of patients both initiated and not initiated on ART, with baseline CD4 count strata of 0-50 cells/mm^3, 51-100 cells/mm^3 and 101- 200 cells/mm^3 (data not shown), indicated that irrespective of the baseline CD4 count strata of the patients, the breakdown of the current status of the patients were similar. That is, among all the patients initiated on ART approximately 50% were currently active patients followed by about 20% down-referred and another 20% as post-ART defaulters. Similarly, among all the patients in the not-initiated on ART group, only 15% were currently actively accessing care at the clinic and approximately 70% were classified as pre-ART defaulters

The data (not shown) also indicate that a small number of patients (n=175) who had baseline CD4 counts between 200-350 cell/mm^3 and another 67 patients who had baseline CD4 counts >350 cell/mm^3 were initiated on treatment. DoH guidelines make allowance for starting patients with AIDS defining illnesses on ART, irrespective of CD4 count. The information collected did not provide evidence as to whether these patients qualified for ART based on their clinical status; a more detailed review of these patients' files would need to be done to indicate reasons for treatment initiation. However, these patients constitute a small proportion (4%) of the total clinic population.

Viral Load Analysis

Baseline viral load, defined as the first viral load count done on patients at this clinic, are only done on patients who are about to start on ART. The guidelines prescribe that viral loads are to be done every 6 months and only on patients who have initiated on ART. Of the 3900 patients initiated on ART at this clinic, baseline viral load counts were available for 46% (n=1792) and most current viral load counts (at the time of the review) were available for 34% (n=1315) of the patients.



The assessment of baseline viral loads showed that 86% of the patients had viral loads in excess of 5000 mRNA copies. Current viral load assessment showed that 82% of the patients were experiencing viral suppression after initiating on ART.

Figure 10 shows the baseline and current viral loads of patients initiated on ART. It does not track the changes in viral load counts among individual patients; rather it captures the proportion of patients' baseline and current viral loads. At baseline, approximately 86% of patients had viral loads of over 5000 mRNA copies. The current viral load assessment indicated that approximately 82% of patients had undetectable viral loads after ART initiation, indicating successful viral suppression in these patients. Further viral load analysis could not be done as substantial amount of data was either not appropriately collected during the file review or missing in the patient files.

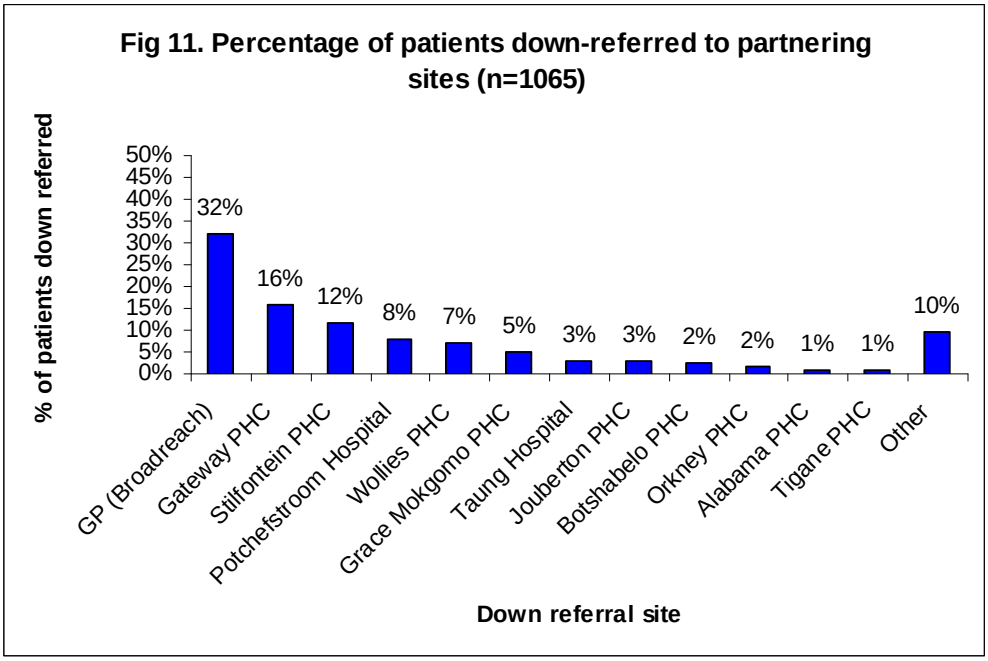
Down Referrals

As mentioned earlier, TWC is one of the first sites in South Africa to utilize a down/up-referral service model. In the down-referral model, patients are initiated on ART at the TWC and are regularly followed up until they are stable enough (measured by an improved CD4 count and undetectable viral load) to continue treatment at primary or secondary health care sites. The patients are then down-referred to appropriate sites based on their location.

At the time of the file review, 19% (n=1097) of patients at this clinic had been down-referred. Of these, 3% (n=32) of patients had not been initiated on ARVs before being down-referred. Figure 11 gives a distribution of patients who were initiated on ARVs (n=1065) and subsequently referred from the TWC to partnering down-referral sites. A third of the patients were down-referred to Broadreach sites[4]. About 40% were referred to primary health care clinics and

[4] Broadreach is a PEPFAR/USAID funded HIV/AIDS treatment program, leveraging private sector providers and disease management, and has a cooperation agreement with North West that allows for referral of stable ART patients to local general practitioners

hospitals in the region, and the remaining 10% were down-referred to other health care facilities, outside the North West Province.



A third of the down-referred patients from the TWC were referred to GPs under the Broadreach[4] programme. Most of the remaining patients were referred to primary health clinics and hospitals in the region. A small number were down-referred to other health care facilities elsewhere in the country.

Mean CD4 counts of down-referred patients

CD4 count before down-referral was available for 83% (n=912) of the down-referred patients. The median CD4 count of the down-referred patients prior to down-referral was 298 cells/mm^3. A baseline CD4 count was available for 97% (n= 1063) of the down-referred patients. The median baseline CD4 count for these patients was 105 cells/mm^3. The overall improvement in CD4 count between baseline and at the time of down-referral indicated that the patients were stabilised before being down-referred.

***Defaulter Analysis** – (in comparison to the overall clinic population)*

(i) Pre-ART Defaulters

These are defined as patients who had visited the wellness clinic at a certain time but had not returned in over six weeks since their last visit and had not been initiated on ART.

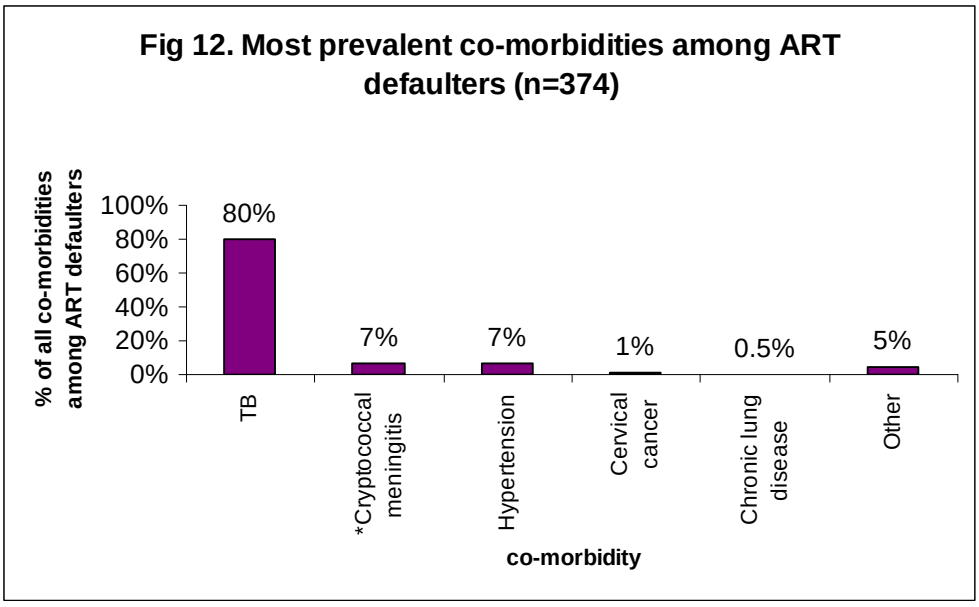
Seventy-three percent (n=1290) of the 1765 patients not initiated on ART were categorised as pre-ART defaulters. Sixty percent (n=782) of the pre-treatment defaulters were females and 40% (n=530) were males. The gender breakdown for this group of patients was similar to the gender breakdown of the overall clinic population ($p<0.05$). The mean age of the patients in this category was 38 years. This is the same as the mean age of the whole clinic population. Baseline CD4 count information was available on 95% (n=1245) of the pre-ART defaulters. The median baseline CD4 count of these patients was 85 cells/mm^3. Of the 1245 pre-

ART defaulters with available baseline CD4 counts, 9% (n=107) had a baseline CD4 count >200 cells/mm^3 which would qualify them as wellness patients. Of these 107 patients, 22% (n=24) had their baseline CD4 count done less six months ago, so these patients should be considered as active patients. The remaining 76% (n=83) of the wellness patients had not returned to the clinic in over 6 months so they should be categorised as lost to initiation, and have been included under the pre-ART defaulters category in Figure 4. The co-morbidities for the pre-ART defaulters were similar to the overall clinic population, with TB being the most prevalent co-morbidity.

(ii) Post-ART Defaulters

In this report, these are defined as patients who had initiated on ART but had not returned to the clinic for a follow up or to the pharmacy for a re-fill of their medication in over six weeks since their last visit.

Twenty percent (n=799) of the 3940 patients who initiated on ART defaulted on treatment and were categorised as post-ART defaulters. An analysis of the gender distribution in these patients indicated that there were slightly more men amongst the post-ART defaulters than amongst the overall clinic population (40% versus 36%) but this difference was not statistically significant (p>0.05). The largest group of ART defaulters were between the ages of 25 and 44 years, however, as shown in Figure 1, patients in this age group also constitute the largest group of patients accessing care at this clinic.

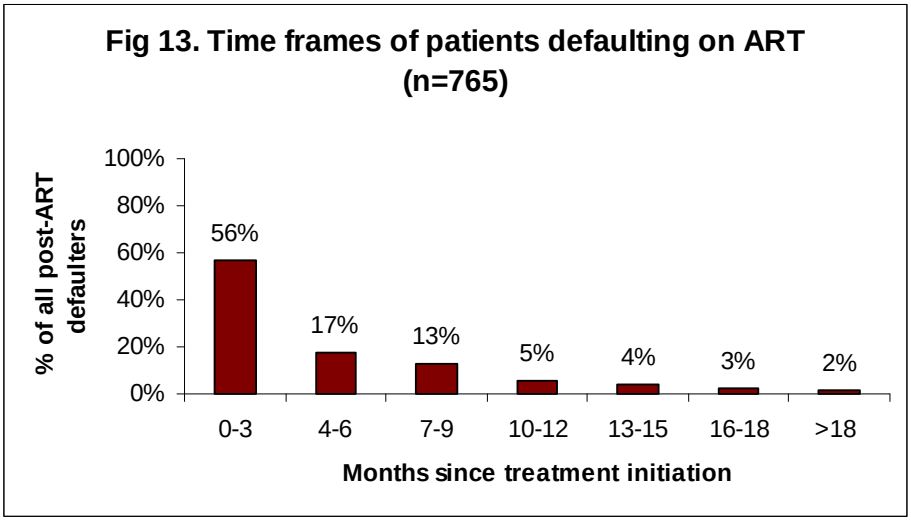


TB was the most common co-morbidity found among the ART defaulters. Hypertension could be secondary to weight gain in patients due to ART or other non-HIV related conditions. *The numbers reported for cryptococcal meningitis are from day 2 of the file review only.

As shown in figure 12, TB was the most commonly occurring co-morbidity as it occurred in more than 85% (n=298) of all reported co-morbidities, followed by hypertension, cervical cancer and chronic lung disease and others. The TB category includes pulmonary TB, miliary TB, TB meningitis, multi drug resistant

TB (1 case) and TB of unspecified localisation. The 'Other' illnesses category in Figure 16 includes asthma, hepatitis, oesophageal candidiasis, peripheral neuropathy, pneumonia and others, all of which constituted less than 3 cases each. Information on cryptococcal meningitis is excluded from this figure. As mentioned earlier in this report, information on cryptococcal meningitis was collected only on day two of the file review. The gender proportions for TB cases were 66% female (n=198) and 34% males (n=104)

Figure 13 provides information on the time frame between treatment initiation and patient defaulting. A total of 799 patients defaulted on treatment at this site. Information on 4% of (n=34) patients was missing so it has been excluded from the analysis. Fifty-six percent (n=432) of the post-ART defaulters defaulted in the first three months of starting ART. By six months post-treatment initiation, an additional 17% had defaulted. Thus, more than 70% of patients who defaulted treatment did so in the first 6 months of starting treatment. This is an area of concern: What are the obstacles that patients experience in trying to return to the clinic regularly so early in the treatment phase? What accounts for this early loss? And what systems can the clinic establish in order to support the patients in this crucial early period of their treatment?



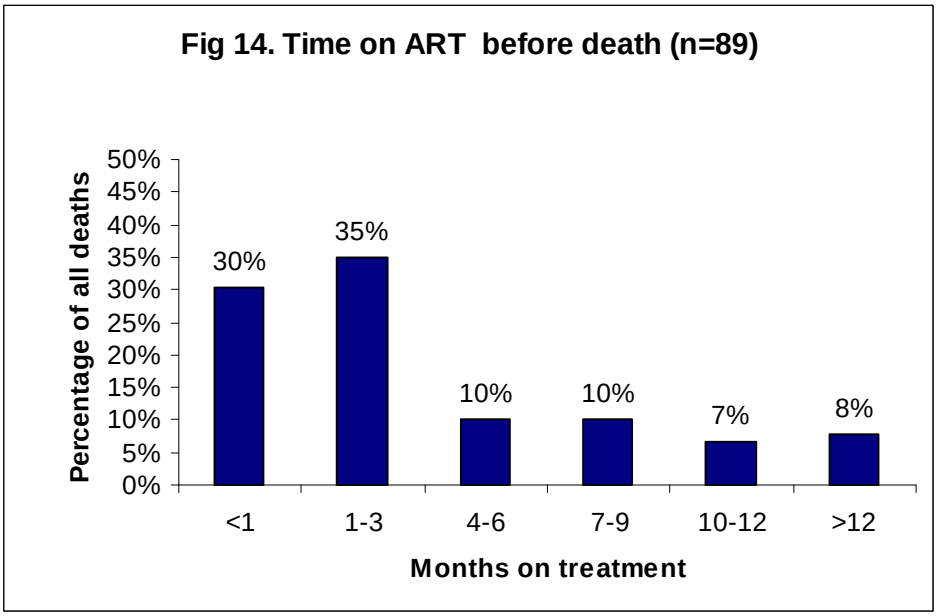
More than half of the clinic patients who ever defaulted on ART did so in the first three months of starting ART. What systems can the clinic put in place to rectify this problem?

Deceased Patients

Of all the 5750 files reviewed, 2% (n=111) of the files belonged to deceased patients. These patients had TWC files and had died while in inpatient care at Tshepong Hospital. These analysed patient files did not belong to any patient who may have died at home or at another hospital, or who may have died at the Tshepong Hospital but did not have a wellness clinic file.

The mean age at death was 38 years (range: 23-62 years). The gender breakdown of the deceased patients was 57% (n=63) females and 43% (n=47) males, indicating that a higher proportion of men have died dying compared to the overall clinic population. However, this was not a significant difference ($p>0.05$).

Baseline CD4 counts were available for all deceased patients and the median baseline CD4 count was 59 cells/mm^3. This is much lower than the median baseline CD4 count of the overall clinic population of 95 cells/mm^3 All deceased patients except for one had a baseline CD4 count of <200 cells/mm^3. Forty-eight percent (n=53) of these patients had a baseline CD4 count <50 cells/mm^3. Of the 111 deceased patients, 82% (n=91) had been initiated on ARVs.



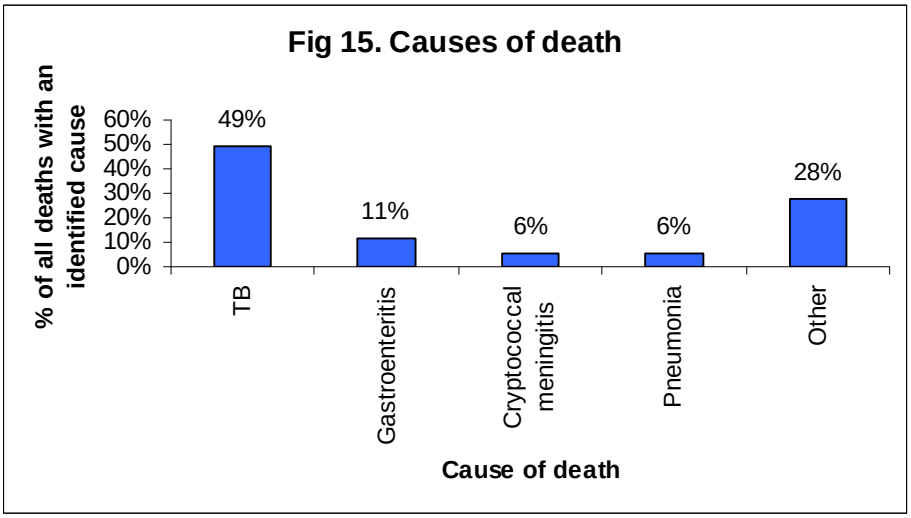
65% of patients died in the first three months of starting ART. The median baseline CD4 count of patients in this group was lower than the patients who died after 3 months of treatment initiation.

Figure 14 gives details on how long patients had been on treatment at the time of death. Information on the date of death was missing for 12 patients, so their last clinic visit date was used to calculate their time on ART. Data was completely missing for 2 patients, therefore these have been excluded from the calculations in Figure 14. Sixty-five percent of patients initiated on treatment died within the first three months of starting ARVs, before treatment could take full effect. Further analyses indicated that the group of patients who died within the first three months of treatment initiation had a lower baseline CD4 count (median CD4 count of 41 cells/mm^3, n=57) compared to the group that died after three months of treatment initiation (median CD4 count of 75 cell/mm^3, n=31).

Calculations for changes in CD4 counts between baseline and last CD4 counts on deceased patients indicated that the overall median CD4 count improved from 59 cells/mm^3 to 134 cells/mm^3. However, the above should be viewed with caution as the baseline CD4 count was available for all 111 of the deceased patients and the last CD4 count was available for only 40 of the 111 deceased patients. The main reason for this attrition is that, according to the national guidelines, follow-up CD4 counts are done only on patients who had been on ART for at least 6 months, and 65% of the deceased patients had died within the first 3 months.

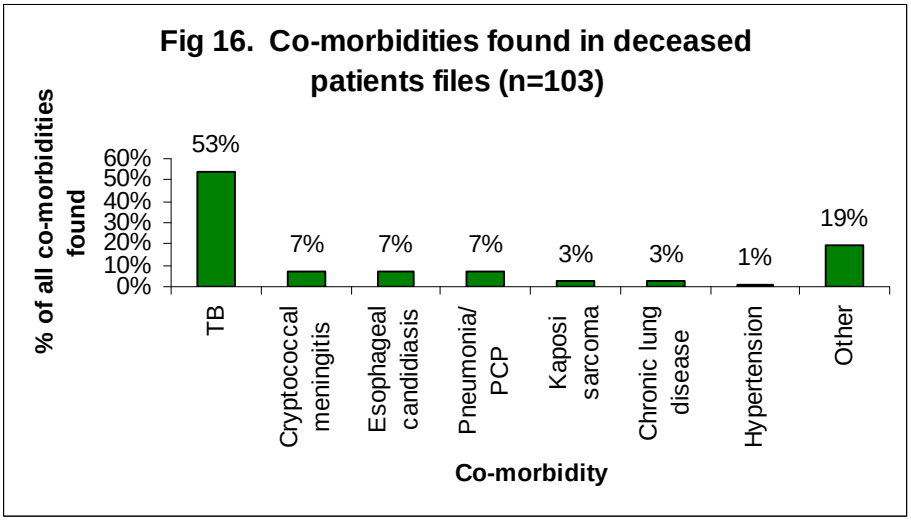
Causes of Death & Co-morbidities

Figure 15 shows the most common causes of death among the deceased patients. Out of 111 deceased patients, the cause of death information was available only in 60% (n=66) of the patient files. The clinicians attending the patient suggested more than one attributable cause of death, and these are reflected. Tuberculosis was the most common cause of death as it was indicated as the reason for death in 49% (n=43) of the patients. The TB category includes 4% (n=4) cases of identified TB IRIS. The second highest reason for death was gastroenteritis. Causes of death under the 'Other' category included lactic acidosis, virological failure and hepatitis. Each of these constituted less than 5 cases.



The most common cause of death was TB.

Figure 16 shows the most common co-morbidities found among the deceased patients. As with the overall population at the clinic, TB was the most prevalent co-morbidity in this group, constituting 53% of all the morbidities noted in these patient files. The 'Other' category included epilepsy, hepatitis B and gastroenteritis. Gastroenteritis was the second commonest cause of death in this group. A patient could have suffered from multiple co-morbidities.



As with the rest of the clinic population, TB was the most prevalent co-morbidity amongst the deceased patients. **PCP stands for pneumocystis carinii/jerovici pneumonia.**

DISCUSSION

A major concern that the clinic administration had mentioned when they approached RHRU for assistance was that over the years, the clinic had possibly lost some patients who had initiated on ART and these patients were being incorrectly reported as actively attending the clinic and being adherent on their treatment. Therefore, one of the main objectives of the file review was to ascertain how many patients who had ever accessed care and started on ART were still attending the clinic. The file review results revealed some interesting information. As of July 2006, less than half of the patients who had visited the clinic since it opened in 2004 were still actively seeking services at this facility. Sixty eight percent of all the patients ever accessing care had initiated on ART. Approximately half of these were actively accessing care at the facility at the time of the file review and 20% had defaulted on treatment. The clinic did not know the reasons why these patients defaulted on treatment. However, it is imperative to identify post-ART defaulters early and get them back on treatment as soon as possible as these patients are at higher risk of developing drug resistance and earlier onset of AIDS. During the file review, the ART defaulter patient files were removed and stacked separately from the rest of the files in an effort to trace the patients. Following the file review, the clinic implemented systems to identify, trace and contact treatment defaulters as soon as they miss their clinic appointments or medicine pick-up date. Preliminary data from this programme has indicated that this intervention has been successful.

The file review identified another group of patients requiring follow up. These patients, referred to as pre-ART defaulters in this report, constitute 73% of all patients accessing care at this clinic but not initiated on ART. Most of these patients were eligible to start ART based on their baseline CD4 count. They made one or two initial visits to the clinic but did not return for subsequent appointments to initiate ART. There are multiple time points when these patients could have been lost to the system. The clinic may have lost them between the initial test and CD4 count results, during the adherence counselling phase or during/after treatments of opportunistic infections such as TB. From the information collected during this exercise, it was not possible to identify where, when and why these patients became lost to initiation. It is recommended that the clinic establish systems to ascertain the reasons why this number is so high and where the clinic is loosing these patients, and to immediately identify patients who do not show up for their appointments. Additionally, following up on these patients may reveal important information on ART care and treatment.

ART drug regimen 1A was the most prescribed regimen in this clinic. A relatively small number of patients either started on or had to be switched to regimen 1B or 2, with an even smaller number requiring “other” regimens. Changes in regimen, were primarily due to pregnancy, peripheral neuropathy, lactic acidosis and virological failure. The regimen changes at TWC are lower than the number of regimen changes noted at other RHRU partnering ART sites. This is a matter of concern as it might indicate that side effects are either not being appropriately identified or there is some hesitation in changing regimens at this site. The clinic management should look into this to make sure that possible side effects are not being missed by the clinicians.

Half of all the patient files reviewed indicated co-morbidities, with TB being the most prevalent co-morbidity in this group. The file review did not specify TB disease by localisation. Other most prevalent co-morbidities included hypertension, cryptococcal meningitis, and epilepsy. During the data analysis, it was noted that some file reviewers had missed data on TB and other opportunistic infections in the patient files, thus leading to an underreporting of the prevalence of these diseases. The review provided additional evidence on the co-relation between TB and HIV. It further stressed that clinicians at both HIV and TB clinics must take steps to identify or rule out the presence of the other diseases in their patients.

CD4 count analysis of all patients showed that the median baseline CD4 counts for both patients initiated and not initiated on ART were <200cells/mm^3. Yet some patients were initiated on ART and others were not. The file review highlighted that most of the patients in the latter group did not initiate on treatment when they should have and many of these consequently ended up as lost to initiation. The CD4 count analyses highlighted one of the challenges encountered in this file review which was attrition of information of laboratory results between baseline and follow up. Missing data was an issue that was encountered throughout the analyses. It can be attributed to data not found in the files, or available data not captured by the file reviewers, or errors by data capturers when imputing the information into the database. Efforts were made to clean up the data before analyses; however, in certain instances analyses were impossible as a significant amount of data was not available. It should be noted that only information on baseline and last CD4 count were collected during the file review, so the date of the last CD4 count data collected could range from 1 to 24 months post treatment initiation. It was not possible to ascertain changes in CD4 counts at regular intervals post treatment initiation for the whole clinic cohort, however, this information can be obtained for a small cohort of patients, but it may not be representative of the full clinic population.

Analysis of down-referred patients indicated that the clinic has down-referred 19% of all patients accessing care to partnering sites. Ninety percent of these primary and secondary health care facilities were located in the North West Province. A third of the patients were down referred to general practitioners who are represented under Broadreach. Broadreach has been quite successful at managing down-referred patients with low lost to follow up rates at its facilities. As mentioned earlier, the Tshepong Wellness Clinic was one of the first medical facilities in South Africa to systematically down-refer its stable patients, often to ART clinics that have received accreditation after TWC started operations. If the down referral system is found to be effective, it will considerably ease the pressure on the tertiary health care facilities and improve quality of services throughout the referral network. CD4 count analyses of down-referred patients indicated that most of the patients were clinically stable before they were down-referred. Some down-referred patients still return to the clinic every 6 months for laboratory and clinical follow ups, but their month-to-month care lies in the hands of their respective down-referral sites. The scope of the file review did not allow us to determine if the down-referred patients were successfully received at the appropriate sites, and how well they were being looked after. This is an important

area and these questions will be explored at a future date by conducting file reviews at the down referral sites.

Analysis of the ART defaulter data indicated that 70% of all patients who ever defaulted did so in the first six months of starting treatment. This indicates a need for close monitoring of patients who are being initiated on treatment. It is important for the clinic to inquire why patients default and to implement specific interventions to control this loss. These would include modifying and strengthening adherence counselling, placing patient follow up persons on staff whose main task will be to immediately identify and contact patients missing their appointment, and establishing a close referral network with NGOs undertaking home-based care in the clinic's catchment area.

Analyses of the data from the files of deceased patients indicated that, as with the rest of the clinic population, TB was the most prevalent co-morbidity and the highest cause of death in this group. The median baseline CD4 count for the deceased patients was lower compared to the rest of the clinic population, highlighting that these patients were more sick before treatment initiation versus the rest of the clinic population. Most of these patients were initiated on ARVs, however a large proportion of these patients died within 3 months of initiating on ART. This finding is similar to the outcomes of a review of ART cohorts in low-income countries by the ART-LINC collaboration (Antiretroviral Therapy in Low Income Countries)[5]. This study re-iterates the finding that patients in low income countries have increased mortality rates in the first few months on ART when compared to patients in high income countries, and that "timely diagnosis and assessment of treatment eligibility combined with free provision of ART might reduce this excess mortality." Since ART is available free of charge at public health sites in South Africa, timely diagnosis and assessment of treatment eligibility are two key areas that the DoH and ART programme implementers need to focus on. These may require boosting case finding methods, counselling services, and integrating HIV care in primary health care settings. Additionally, studies to ascertain the reasons individuals do not get tested or access HIV related care or the delay in getting tested should be conducted.

[5] The antiretroviral therapy in low income countries (ART-LINC) collaboration and ART cohort collaboration (ART-CC) group. Mortality of HIV-1 infected patients in the first year of antiretroviral therapy: comparison between low-income and high income countries. *Lancet*. 2006;367:817-24

RECOMMENDATIONS/ CONCLUSION

This exercise indicated that systematic file reviews can be used as an effective tool to evaluate the current clinical status of patients obtaining HIV care and treatment at ART clinics 3 years into the public-sector ART roll out. However, a file review is a time and resource intensive process. The support and buy-in from the clinic management and the DoH was critical for the implementation and successful completion of this project.

The file review process and the information collected in the process have been useful in identifying inherent issues that the clinic is facing. The outcomes indicated key areas in need of improvement. These include the following:

a) Development and implementation of appropriate data recording and storing mechanisms and processes to monitor and follow up patients initiating on treatment.

An attempt should be made by the clinic to generate a database of all patients accessing the clinic that is updated at every clinic visit and contains demographic information as well as information on the treatment history (date of ART initiation, past and current ART regimens), side effects developed, time of and reasons for changes to regimens, and relevant other illnesses. It should also include the latest telephone number and precise address, or description of the place of residence in order to facilitate tracing if the patient defaults. Optimally, this database would be updated at every visit and be in an electronic format to enable quick retrieval of timely information on patient status and treatment outcomes. In terms of the storage system for the paper-based records, the clinic would benefit from changing the current system which stores all files under the year of birth of the patient and leads to lengthy searches at every clinic visit to a system that is based on more than one criterion (e.g., the full date of birth in numerical order plus the surname in alphabetical order). Having a system that allows every file to be at one place, and one place only, greatly improves the ease of and time for file retrieval.

b) Systems to immediately identify defaulters and have them return to the clinic.

Here, a system that identifies patients that haven't returned to the clinic on their appointed dates (e.g., by keeping their files apart from the general filing system after a missed visit), is crucial. The information on patients who have not returned to the clinic for a specified length of time (e.g. two weeks) after their appointed visit should be collected and provided to defaulter tracer staff, together with the latest contact information and information on whether the patient has defaulted in the past. Files should be kept apart even after the patient has been traced, and fed back into the general file system only when the patient returns to the clinic.

c) Inquiries into reasons why patients default on treatment.

This should be done by the defaulter tracing staff. Information on every patients' reasons to default should be collected, stored in an easily accessible (optimally electronic) format, and should be analysed for the whole defaulter population and shared with clinic staff and management on a regular basis, with a view to improving patient retention and quality of care, and ultimately preventing defaulting in the first place by identifying patients at risk of future defaulting.

Optimally, the telephonic enquiry would go hand in hand with supplying advice on remedying the situation of the defaulting patient, e.g. by directing patients who claim to lack finances for transport to the possibility of applying for a disability grant, etc.

d) Appropriate follow up processes for patients who are not eligible to start on ARVs – either because their CD4 is greater than 200 or they have to complete treatment for opportunistic infections.

This would include a working Wellness care programme either within the primary health care clinic or, if space and staff are unavailable, then at clinics in the vicinity. A tight referral network capturing especially HIV-positive patients on TB treatment would be paramount, including but not limited to capturing patients who are out-referred for completion of TB treatment for 2 months before the planned initiation of ART in a database at TWC, together with their demographic and contact information and the clinic they are out-referred to (or are most likely to attend, given their place of residence). This database could then be used to phone either the patient or their respective clinic, or both, at the time when the patient is expected back at TWC.

e) Inquiry into the quality of the down referral system and protocols.

This recommendation warrants a similar file review at each of the down-referral clinics, or, in the absence of this, telephonic follow-up at each site to find out how many of the down-referred patients have arrived at the designated clinic and are still in their care. TWC operates a very commendable system of asking patients to return to TWC after 6 months at the down-referral site. This could be complemented by a tracing mechanism whereby patients who have not returned at the planned time are traced either individually or through the clinic. Information on the outcome of these inquiries should be kept, and ultimately fed back into the main database.

f) Inquiry into the low percentage of regimen changes at this site.

Data from other sites suggest that side effects might be underreported and treatment regimens might not be changed often enough. It is recommended that the clinic doctors be trained on actively asking for symptoms of the most common side effects at every visit, and that side effect recognition be included into the group training sessions that TWC offers for its patients. Additionally, simple algorithms should be developed to guide doctors from the symptom through to its treatment and a possible change in regimen. These algorithms should set out the amount and timing of additional laboratory tests, and the exact recommended time of observation before a single antiretroviral is changed.

The incidence of detected side effects should be monitored by the clinic management (through the database mentioned in a) above), and re-training offered, if needed, to individual doctors. Additionally, the frequency of counselling sessions could be increased if staffing levels allow, and the counsellors could be trained to enquire specifically about side effect symptoms, referring patients to a doctor during the same visit if a side effect is noted.

g) Inquiry into the high proportion of patients defaulting before treatment initiation.

Again, optimally an additional study should be conducted to shed light on patients' reasons for defaulting before treatment initiation, and to devise measurements for prevention. In its absence, the clinic could consider reviewing its policy of patients not being seen by a doctor before the third (initiation) visit to the clinic. A second obstacle might be posed by the practice of having patients collect their cotrimoxazole prophylaxis and vitamins at the main hospital pharmacy during the first visits which adds significant waiting time and may demoralise patients.

Since the file review, the clinic has implemented a defaulter tracing mechanism to promptly identify and follow up on defaulters.

File Reviewers at work

FILE REVIEW PROCESS: LESSONS LEARNED

There were some challenges that affected the data analysis and outcomes of the file review process. One of these challenges was missing or incorrect data. The other challenge was lack of quality checks during the file reviews. There were no measures established during the file review that would make sure that the data collected during the process was complete and correct. During data analysis it was found that certain mistakes or data omissions were not identified and rectified during data collection resulting in loss of crucial data.

Some of the lessons learned from this process include: importance of having the file reviews conducted by clinical staff versus lay individuals and the importance of incorporating quality assurance mechanisms in the file review process. Appendix A gives a detailed list of recommendations from key participants and stakeholders, for future file review processes.

Since the file review at TWC, RHRU has revised the data collection tool and refined the data collection process with specific quality assurance mechanisms in place to identify and remedy errors immediately. Since June 2006, further file reviews have been conducted at 6 RHRU supported DoH sites. Individual reports for each of these sites will be available soon, and a comparison of the results from the different sites is being undertaken and will be available in 2008.

Appendix A

Post-Audit De-briefing and Assessment

Feedback on the file audit (review) activity was obtained and collated from various participants at the Tshepong Wellness Centre (TWC). This document highlights the strengths and weaknesses of the file review process at TWC and provides recommendations for similar activities in the future.

Strengths:

- Endorsement, buy-in and complete support from the DoH/ TWC leadership and staff.
- A large number of individuals with varying backgrounds participated in the file review. These included 22 RHRU, 50+TWC & 12 Aurum staff members.
- Focus on NOT disrupting the day-to-day running of the clinic. The active files were back on the shelves ready for normal clinic operation on Monday.
- Good logistical planning and management during audit, especially handling of suggestions during audit - still able to incorporate changes to the audit form without major disruption to the whole process.

Challenges:

- Not all participants had the skills to appropriately conduct the file review.
- A large number of files had to be re-audited on the second day because certain errors were not identified immediately.
- There was no time for post-audit de-briefing activities included in the plan to capture lessons learned right after activity. (e.g. an assessment done at the end of the first day could have captured mistakes to avoid doing re-audits)
- Quality assurance was a weak point through the file review.

Recommendations:

1. Audit Tool:

- Review design and flow of tool. (e.g. continuity of treatment could be included with the ARV initiation information)
- Include a section for defaulters who are re-initiated.
- Clarify the co-morbidity section and expand the choices to include serious HIV-related illness, e.g. Kaposi sarcoma, tuberculosis, cryptococcal meningitis and others.
- During the pilot of the newly developed tool, the staff of the health facility should be very involved especially in identifying the location of the most reliable information to capture..
- Terms, like defaulters, list of drugs/regimen, etc should be more clearly defined at the orientation or training of the auditors to avoid confusion during file reviews.

2. Data auditors/file reviewers

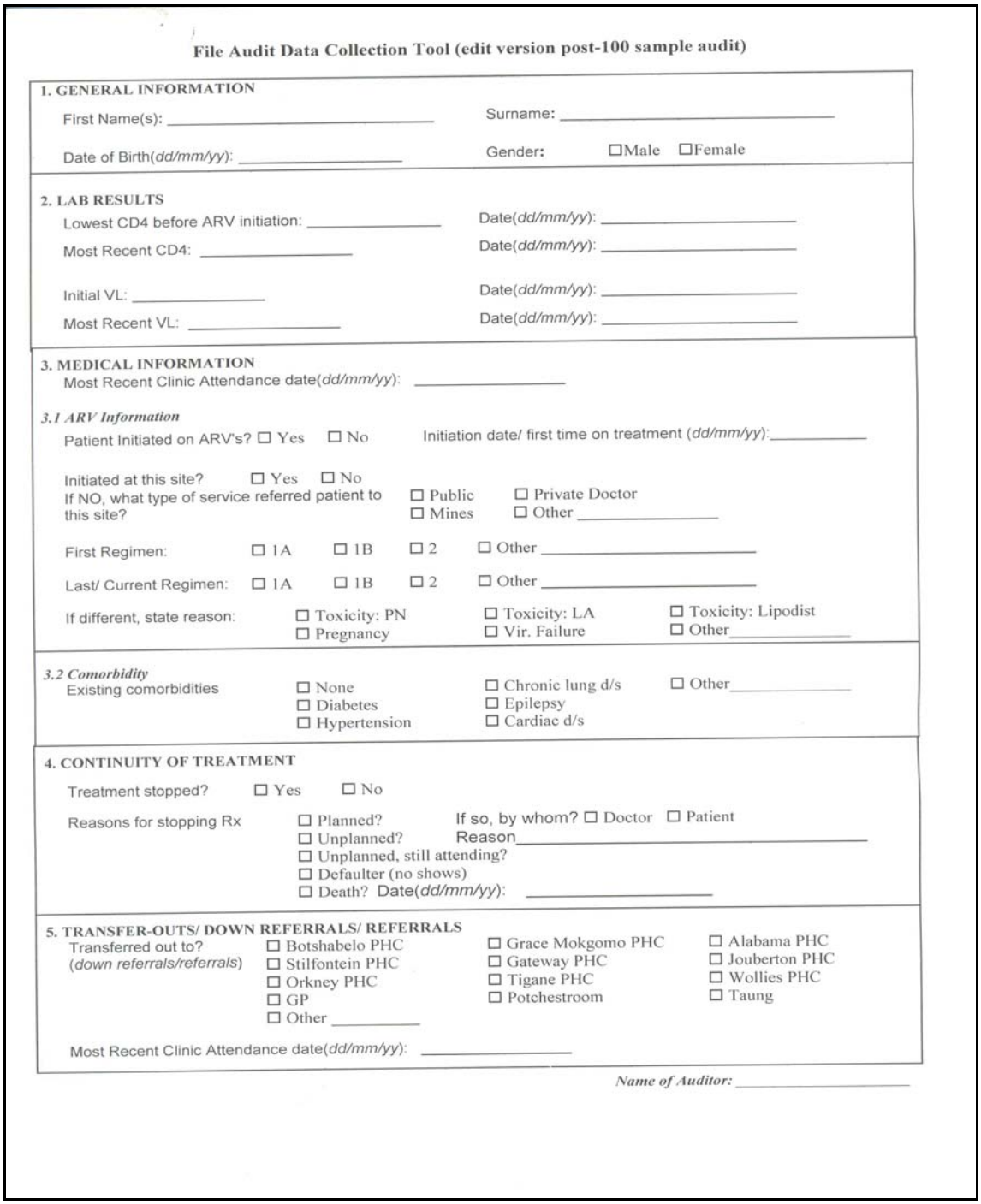
- Quality versus quantity of reviewers. An issue was raised if the audit should be done only by clinicians. However, a consensus was reached that preferably clinicians (physicians and nurses) should conduct these reviews. However, some non-clinicians who have research, biomedical, or data-handling background and who understand the reasons for collecting the various information in the file review can also participate.
- At the beginning of the file review, clinician and non-clinician individuals should be paired together. The clinician would review the files and the non-clinician would scribe the information that the clinician is reading out. After a few files, if the non-clinician feels comfortable, then they can review the files and complete the forms independently. The clinician should be accessible to assist with medical questions. Additionally, efforts should be made to have one person per room or group who has participated in a file review previously.
- Only people with medical or research background should partake in the file review. People that are obviously untrained and not knowledgeable about basic HIV care and treatment should not partake in this process. For example, a general assistant who has no medical insight to understand medical conditions or pharmacy prescriptions.

3. **Data quality assurance:**
   - There should be one or two personnel responsible for overseeing and maintaining quality and validity of the whole file review process.
   - There is a need for a quality assurance team which would check the quality of data being captured. This team will review all completed data collection tools and files. They would immediately intervene if a person has made a mistake to avoid same mistakes from recurring.
   - Proper orientation of all participants to the data collection tool and the review process. Local staff, who are more familiar with data handling of the files, should be included in the team giving the orientation.
   - Have a team leader responsible for each small group of auditors.
   - The quality assurance team needs to review day 1 outcomes and plan for the next day of the audit.

Appendix B

Data Collection Tool

The data collection tool has undergone numerous revisions since the initial file review activity was carried out at Tshepong Wellness Clinic. Below is a sample of the tool used for the Tshepong file review.



File Audit Data Collection Tool (edit version post-100 sample audit)

1. GENERAL INFORMATION

First Name(s): _____ Surname: _____

Date of Birth(*dd/mm/yy*): _____ Gender: ☐Male ☐Female

2. LAB RESULTS

Lowest CD4 before ARV initiation: _____ Date(*dd/mm/yy*): _____

Most Recent CD4: _____ Date(*dd/mm/yy*): _____

Initial VL: _____ Date(*dd/mm/yy*): _____

Most Recent VL: _____ Date(*dd/mm/yy*): _____

3. MEDICAL INFORMATION

Most Recent Clinic Attendance date(*dd/mm/yy*): _____

3.1 ARV Information

Patient Initiated on ARV's? ☐ Yes ☐ No Initiation date/ first time on treatment (*dd/mm/yy*):_____

Initiated at this site? ☐ Yes ☐ No

If NO, what type of service referred patient to this site? ☐ Public ☐ Private Doctor ☐ Mines ☐ Other _____

First Regimen: ☐ 1A ☐ 1B ☐ 2 ☐ Other _____

Last/ Current Regimen: ☐ 1A ☐ 1B ☐ 2 ☐ Other _____

If different, state reason: ☐ Toxicity: PN ☐ Toxicity: LA ☐ Toxicity: Lipodist ☐ Pregnancy ☐ Vir. Failure ☐ Other_____

3.2 Comorbidity

Existing comorbidities ☐ None ☐ Chronic lung d/s ☐ Other_____ ☐ Diabetes ☐ Epilepsy ☐ Hypertension ☐ Cardiac d/s

4. CONTINUITY OF TREATMENT

Treatment stopped? ☐ Yes ☐ No

Reasons for stopping Rx ☐ Planned? If so, by whom? ☐ Doctor ☐ Patient ☐ Unplanned? Reason_____ ☐ Unplanned, still attending? ☐ Defaulter (no shows) ☐ Death? Date(*dd/mm/yy*): _____

5. TRANSFER-OUTS/ DOWN REFERRALS/ REFERRALS

Transferred out to? (*down referrals/referrals*) ☐ Botshabelo PHC ☐ Grace Mokgomo PHC ☐ Alabama PHC ☐ Stilfontein PHC ☐ Gateway PHC ☐ Jouberton PHC ☐ Orkney PHC ☐ Tigane PHC ☐ Wollies PHC ☐ GP ☐ Potchestroom ☐ Taung ☐ Other _____

Most Recent Clinic Attendance date(*dd/mm/yy*): _____

Name of Auditor: _____