MEDINFO 2010
C. Safran et al. (Eds.)
IOS Press, 2010

doi:10.3233/978-1-60750-588-4-476

Using a File Audit to Evaluate Retention in Care and Patient Outcomes in a Programme to Decentralise Antiretroviral Treatment to Primary Health Care Facilities in a High Prevalence Setting in KwaZulu-Natal, South Africa

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Abstract

HIV care and antiretroviral treatment (ART) provision is largely hospital-based with an over-reliance on doctors. Existing ART sites are reaching capacity and are increasingly unable to initiate new patients and also see follow up patients. In response, the Reproductive Health and HIV Research Unit (RHRU), has supported the KwaZulu-Natal provincial Department of Health with developing a model to decentralise services to primary health care (PHC) level. The programme has been in operation since 2006, and currently nine ART initiation sites down refer stable patients to 24 PHC clinics. Data on patient numbers, treatment outcomes and patient retention rates were collected through a file audit of 2071 adult patient files and analyzed. Results indicate that a file audit is a feasible mechanism to provide this data and can be used to identify gaps and improve quality of care. PHC sites in resource-constrained settings are able to manage stable patients on ART; however, sites need support with monitoring and evaluation and with tracking patients that have been down referred. In terms of quality of care, PHC sites need to ensure that clients receive CD4 count tests and viral load monitoring at six monthly intervals to ensure that treatment failure does not go undetected. Patients suspected of experiencing adverse events or treatment failure appear to be managed according to standard operating procedures, but there is a need to ensure that adverse events are clearly documented in patient files.

Keywords:

Antiretroviral treatment, Primary health care, Retention.

Introduction

eThekwini district in KwaZulu-Natal has an estimated 1.5 million individuals infected with HIV; 12-15% of whom require antiretroviral treatment (ART). HIV care and ART provision is largely hospital-based with an over-reliance on doctors. Existing ARV sites are reaching capacity and are increasingly unable to initiate new patients and also see follow up patients. In response, the Reproductive Health and HIV Research Unit (RHRU), has supported the KwaZulu-Natal provincial Department of Health with developing a model to decentralise services to primary health care (PHC) level. The rationale for shifting the care of stable patients to PHC level is two fold. Firstly, it will allow for stable patients to access care closer to their homes saving them time and resources and ensure that waiting times for services are minimized. Secondly, it would allow more new patients to be initiated on ART, reduce waiting times for treatment initiation and result in more efficient use of human resources if doctors are freed up to focus on new patients and follow up patients are managed by nurses. This approach has been used in countries such as Malawi [1], Rwanda [2] and Lesotho [3, 4] and is promoted by the World Health Organisation [5]. The HIV and AIDS and STI Strategic Plan for South Africa 2007-2011 mandates decentralised care and nurse-driven services [6] and there is widespread recognition for the need for decentralised care and task shifting/sharing in the South African context [7, 8].

RHRU has developed a comprehensive model for decentralising care. The model starts at PHC level, where clients are prepared for ART (all services prior to ART initiation are conducted at PHC level) and then referred for ART. Once clients are stable on ART (at least 6 months), they are down referred to be managed at PHC level. In order to support implementation, RHRU has developed standard operating procedures for the up and down referral process [9]. This includes documenting the procedures for up referral of adults (including pregnant women) and children; management of patients at initiating sites; down referral of stable patients; dispensing ARVs to PHC; and the management of side effects. Standardized data collection forms and a two-way referral form were developed in consultation with the provincial department of health to track patients up and down referred. RHRU conducts a three day training programme for nurses and provides follow-up mentoring & coaching on-site in order to implement the model. RHRU has implemented the programme since 2006. However, no formal assessment of the programme has been conducted. In order to assess patient retention in care and how well patients, who are down referred are being managed, RHRU conducted a file audit of patients down referred to RHRU supported PHC sites. Currently nine ART initiation sites down refer patients to 24 PHC clinics.

Research Objectives

The objectives of this study were to:

1. Collect information on the numbers of patients currently accessing care at PHC level
2. Collect information on treatment outcomes and inconsistencies in patient management to inform improvements in quality of care
3. Identify areas requiring follow-up interventions, quality improvement projects and to improve the quality of routine data collected.

Methods

RHRU has developed a file audit process for the collection of valid and reliable data in hospitals and clinics using paper-based record keeping systems. The file audit methodology allows for the collection of valid and reliable data in a way that keeps disruption of normal clinic operations to a minimum and makes use of all available clinic staff at various levels of training and expertise. The process has been found to be useful to establish the need for specific follow-up interventions, such as introducing staff for defaulter-tracing and identifying improvements to existing data collection systems. RHRU has used this method in numerous facilities in KwaZulu-Natal, Gauteng and North West Province [10].

RHRU has subsequently adapted the tool to collect similar data on patients who have been down referred to primary health care facilities. Two audit tools designed by RHRU were utilized in this study, a Client File Audit Form and a Clinic Register Audit Form. The tools allow for data collection on the following variables:

- patient demographics;
- CD4 count & viral load at time of down referral and during the course of treatment;
- ART regimens used;
- Incidence and timing of side effects and adverse events;
- numbers of patients falling pregnant on treatment;
- prevalence of co-morbidities;
- number of patients and timing of defaulting including patients not reaching down referral sites and those defaulting after down referral;
- number of patients up-referred to ART sites;
- number and timing of deaths.

A total of 14 individuals were trained on the tools and participated in the audit including 11 of RHRU's monitoring and evaluation team and three visiting students. The team visited 9 initiation sites and 24 primary health clinics over a one month period in October 2008 and reviewed a total of 2071 files. Data on the above variables were extracted from patient files, registers, two-way referral forms and other sources of data at each site and entered on a file audit form for each patient. Data were captured in EpiData and analyzed with SPSS Version 17.

Results

A total of 2071 adult patients were identified as down referred from files opened at PHC sites. The nine initiating sites referred patients to a number of PHC clinics. Table 1 below illustrates the sites and numbers of patients down referred. The number of patients down referred by initiating sites ranged from one to 275, with the average number of patients being 122. As a result of several sites with small numbers of patients and several with large numbers, the median is likely to be a more accurate reflection, at 45 patients per PHC.

Table 1- Number of patients down referred by site

Site Name	Number (n)	Proportion (%)
Prince Mshiyeni Memorial Hospital		
Umbumbulo	15	
Danganye	5	
U21	58	
Folweni	67	
K Clinic	24	
Magabheni	1	
Kwa Makutha	35	
Total	**205**	**10%**
Charles James		
Umbumbulo	19	
Danganye	45	
U21	21	
Folweni	61	
Umnini	45	
Magabheni	37	
Kwa Makutha	104	
Total	**332**	**16%**
R K Khan Hospital		
Shallcross	26	
Unit 6	31	
Total	**57**	**3%**
Addington Hospital		
Addington Gateway	217	
Beatrice Street	176	
Newlands East	116	
Newlands West	50	
Redhill	75	
Total	**634**	**31%**
Kwa Mashu Community Health Centre		
Lindelani	63	
Goodwins	36	
Ntuzuma	64	
Total	**163**	**8%**

Table 1 (continued)

Wentworth		
Cato Manor	62	
Lamontville	13	
Merebank	7	
Total	**82**	**4%**
Don McKenzie Hospital		
KwaNgcolosi	47	
Clermont	7	
Halley Stott	144	
Molweni	86	
Total	**284**	**14%**
Kwa Dabeka Community Health Centre		
Clermont	274	
Total	**274**	**13%**
Clairwood		
Lamontville	38	
Total	**38**	**2%**
Missing	2	

Table 2 presents demographic and patient information for the down referred patients. 72% of the down referred patients were female. Data on gender were missing for 2% of patients. Most patients were on regimen 1A or 1B (94%), while this information was missing for 1% of patients. Most patients (56%) had been down referred for a period of 0-5 months, the primary reason being that the programme has rapidly expanded in recent months. Only 4% of patients had been down referred for 12 months or more. Poor record keeping and the non- completion of the two-way referral form meant that the date of down referral was not available for 20% of the files. At the time of down referral 99.6% of patients had undetectable viral loads and the median CD4 count was 264. Three patients were down referred with detectable viral loads. This is not in line with the standard operating procedures for down referral, but may reflect a transcription error of the results. 164 patients (8%) had no information on CD4 count at down referral in their files, while 37% of patients had no viral load documented.

As shown in Table 3, of the 2071 patients identified as down referred, PHC sites received 78% of these patients, 3% did not ever arrive at the PHC site and there was no data on any visit available for 18% of the patients. One possible reason for the lack of data in the files is that some sites reported preparing patient files in advance before patients arrive and therefore may reflect patients yet to arrive at the site. As a result of this finding, measures to prevent this will be implemented on site.

Table 2- Demographic Data

Patients down referred	**Number (n)**	**Proportion (%)**
Number of patients down referred	2071	100
Period down referred	**Number (n)**	**Proportion (%)**
0-5 months	1154	56
6-11 months	424	21
12+ months	77	4
Missing	416	20
Gender	**Number (n)**	**Proportion (%)**
Male	547	26
Female	1488	72
Unknown	36	2
Age	**Years**	
Median Age	37	
CD4	**Number (n)**	**Median**
Median CD4	1922	296
Viral Load (VL)	**Number (n)**	**%**
% VL undetectable	1298	99.6
Regimen	**Number (n)**	**Proportion (%)**
1A	1508	73
1B	433	21
2	7	0
Alternate	103	5
Missing	20	1

Table 3- Number of Patients Received at PHC Sites

Number of patients received at down referral clinic	**Number (n=)**	**Proportion (%)**
Received	1624	78
Not received	65	3
No data available	382	18

Patients showed increasing CD4 counts at 6, 12 and 24 months indicating that management at PHC level is effective. However, of concern is that not all patients were receiving regular follow up CD4 counts at PHC or these were not being documented in their files. Most patients continued to have undetectable viral loads at 6 and 12 months after down referral, with 90% and 97% of patients having undetectable viral loads respectively. As for CD4 counts, few patients had these test results documented in their files, which may hamper the effective monitoring of treatment.

Table 4- CD4 & Viral Load Results

Median CD4	**Number of individuals (n)**	**CD4**
@ down referral	1922	264
6 months	223	339
12 months	49	395
% of patients with undetectable VL	**Number of individuals (n)**	**%**
Baseline	1298	99.6
6 months	224	97
12 months	43	93

Files were also reviewed to identify patients lost to follow up after being received at PHC sites. The review found 13% of patients received on site were lost to follow up (13%). Data on 4% of patients were missing or there was no information on last appointment attended in the file. As only stable patients are down referred, the retention rates at PHC level should be higher than at initiating sites [11]. Without a more sophisticated patient information system, it is not possible to identify whether the patients lost to follow up have returned to the initiating site or another site for treatment. Data on patient deaths were not found in any patient files.

Table 5- Loss to follow up

Patients lost to follow up after down referral	**Number (n)**	**Proportion (%)**
Lost to follow up	263	13
Active patients	1737	84
Not documented	38	2
Missing	33	2

The file review also collected data on patient outcomes. In total only 3% of client files indicated adverse events (AE) and 3% opportunistic infections (OI). This data is presented in table 6. Most common OIs were flu, shingles and other minor ailments. In terms of AE, peripheral neuropathy, lipodystrophy and fungal infections were most common.

Table 6- Adverse Events

Numbers of clients who presented with Adverse events	**Number (n)**	**Proportion (%)**
Clients with adverse events	59	3
Clients with opportunistic infections	68	3

Table 7 shows the number of patients and the reason for up referral. Only 1% of patients were up referred back to the initiating site. Reasons for up referral included pregnancy (16%), medication not being available (12%), side effects (12%) and patients wanting to return to the initiating site (8%). Logistics for the delivery of medication may need to be strengthened at some sites. In 40% of the cases, no reason was documented on file. Without accurate and complete documentation, it is difficult to assess the outcomes of programmes. Sites will need to be supported to improve record keeping if that data are to be used for evaluation purposes. Also of concern is the up referral of pregnant women to secondary level care. Pregnant women should be managed at PHC level and not up referred.

Table 7- Patients Up Referred

Clients Up Referred	**Number (n)**	**Proportion (%)**
Number of clients	25	1
Reasons for Up Referral	**Number (n)**	**Proportion (%)**
No reason stated	10	40
Medication out of stock/not available	3	12
Pregnant	4	16
Lactate levels raised	1	4
Side effects	4	16
Non adherence	1	4
Missing prescription card	1	4
Returned to initiating site	2	8

Conclusions & Recommendations

While PHC sites report that down referral programmes are feasible and effective, programmes may lack accurate data on key variables such as patient numbers, treatment outcomes and patient retention rates. A file audit is a feasible mechanism to provide this data and can be used to identify gaps and improve quality of care. The results of the file audit indicate that PHC sites in resource-constrained settings are able to manage stable patients on ART. However, sites need support with monitoring and evaluation and both the initiating and PHC site should track patients down referred and accessing services to prevent loss to follow up. Systems to track patients not attending appointments need to be introduced at PHC sites. This includes the need to ensure accurate and updated contact details are recorded for patients at each visit. On-going mentoring and support for monitoring and evaluation is required at PHC level and RHRU has introduced regular audits and data quality reviews at PHC to address these gaps. Other gaps identified during the audit included two way referral forms not being completed and no standardised tools being used at PHC sites. The planned introduction of a new ART register should go some way to address this concern. In terms of quality of care, PHC sites need to ensure that clients receive their CD4 count tests and viral load monitoring at six monthly intervals to ensure that treatment failure does not go undetected. Patients suspected of experiencing adverse events or treatment failure appear to be managed according to standard operating procedures, but there is a need that this management is clearly documented in patient files.

Acknowledgments

This operations research was made possible by the support of the American people through the United States Agency for International Development (USAID). The contents of this paper are the sole responsibility of the Reproductive Health & HIV Research Unit (RHRU) and do not necessarily reflect the views of USAID or the United States Government.

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