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RESEARCH

Adherence by a primary healthcare clinic in KwaZulu-Natal to the national HIV guidelines

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Background: The decentralisation of antiretroviral therapy (ART) to primary health care (PHC) was rolled-out in South Africa in March 2010. PHC staff members are expected to initiate ART, monitor patients, and detect and refer patients with adverse events or virological failure to designated referral hospitals. The aim of this study was to assess the monitoring and referral of patients on ART who were being managed at a PHC clinic.
Method: This was a cross-sectional, retrospective study on 488 adult patients attending a PHC ART clinic selected by systematic random sampling between June 2011 and June 2012. Data were extracted from the patient files using a standardised data collection sheet, based on the South African national HIV guidelines for 2010.
Results: Pill count, CD4 count and viral load (VL) were all well assessed by June 2011. Thirty-one per cent of patients being followed-up at the clinic had developed virological failure, of whom 84% were referred. By June 2012, 49% of the patients had developed virological failure, of whom only 52% were referred for further management.
Conclusion: The PHC nurses were excellent at monitoring pill count, CD4 count and VL, but were unable to detect and appropriately refer patients with virological failure. This is of great concern, and needs urgent intervention and further research.

Keywords: ART monitoring, decentralisation of ART, national HIV guidelines, nurse-initiated management of ART, PHC ART initiation

Introduction

According to the Joint United Nations Programme on HIV/AIDS, there were 34 million people living with human immunodeficiency virus (HIV) at the end of 2011. Sub-Saharan Africa remained the most severely affected, accounting for 69% of people living with HIV worldwide.[1] Southern Africa continues to bear a disproportionate share of the global HIV burden, with 35% of HIV infections occurring in this subregion.[2] In 2009, it was estimated that 5.5 million South Africans were HIV-positive, of whom 1.8 million were on antiretroviral therapy (ART).[2] Effective ART coverage still remains a challenge in most countries as only 31% of people estimated to be in need of treatment received it by the end of 2007.[3] Access to health care, particularly in rural areas, has been identified as a significant barrier to those wishing to start ART.[3, 4] In 2007, the Department of Health published its National Strategic Plan (NSP), with detailed annual goals. The NSP estimated that there would be a need to enrol an additional 520 000 patients each year between 2007 and 2011 if the Department of Health was to ensure that 80% of the people who needed ART would be on treatment by 2011.[5, 6]

To increase the capacity of the health service to provide ART, many countries, including South Africa, have begun to decentralise HIV treatment to primary healthcare (PHC) facilities, with the aim of achieving universal access to treatment and care.[7] A number of alternative management strategies and guidelines have been implemented by different countries to achieve the best health outcomes in the most cost-efficient manner. Most of these strategies have targeted the prevention of HIV through the promotion of safe sex practices (abstinence and condom usage), early diagnosis and the initiation of therapy, and the prevention of mother-to-child transmission.[7]

In March 2010, the South African National Department of Health adopted changes to the national guidelines on the management of HIV and acquired immune deficiency syndrome (AIDS) in adults, adolescents and children. The purpose of the revision was to enable PHC clinics to initiate ART, to monitor patients on therapy, and make appropriate referrals of patients with complications, side-effects or treatment failure to designated referral hospitals.[8] According to the revised guidelines, the monitoring of patients on ART included monthly adherence checks (a pill count), an evaluation of psychosocial support and the recognition of any drug-related side-effects. In addition to monitoring adherence, the guidelines expected the nursing staff to clinically stage patients using the World Health Organization (WHO) guidelines at each visit, and to determine CD4 count and viral load (VL) six months after the initiation of ART, and then to annually detect viral and immunological failure. Patients with a VL > 1 000 copies/ml needed to be intensively counselled on adherence, and a VL test repeated after three months. Virological failure was defined as a VL greater than 1 000 copies/ml after three months of therapy despite good adherence, or a VL greater than 1 000 copies/ml after suppression to undetectable levels, despite intensive adherence training. Patients diagnosed with virological failure needed to be referred to a local hospital for assessment and changed to a second-line regimen.[8]

There is limited research on the effectiveness of a decentralised, nurse-based HIV service in South Africa. A comprehensive HIV programme in Khayelitsha, run through a network of PHC clinics, was evaluated in 2002. High levels of condom use, the willingness of community members to undergo an HIV test and a desire by those diagnosed with HIV infection to join an AIDS club were reported in the study, conducted at nine PHC sites in Khayelitsha in the Western Cape.[7] The availability of ART in Khayelitsha led to

an increased uptake of voluntary counselling and testing.[7] The rapid scale-up of patients initiated on ART and well-assessed initiation, monitoring, referrals and outcome over a one-year period were demonstrated in a study on the decentralisation of the ART service to PHC facilities in 2008, in the Hlabisa district. However, it was noted in the study that there was a decreased emphasis on pre-ART management, counselling and adherence (quality care), and that there was no improvement in mortality outcomes, as compared to the pre-decentralisation, hospital-based management of HIV patients.[9]

The Médecins Sans Frontières programme in Lusikisiki in the Eastern Cape was evaluated in 2008.[10] This rural HIV programme provided HIV services to the local population through decentralised PHC clinics, and emphasis was placed on task shifting (nurse-initiated as opposed to physician-initiated treatment) and community support. This approach allowed for the rapid upscale of treatment with excellent outcomes. The one-year outcomes in PHC around Lusikisiki were comparable between the clinics and hospital. The study highlighted the fact that the conventional hospital-based approach, which provides ART through hospitals, hampered access by the majority of people to ART.[10]

Other African countries have experienced success with the decentralisation of their ART services. The Zambian Ministry of Health scaled up HIV/AIDS treatment and care at PHC clinics in Lusaka using predominantly non-physician clinicians. An open cohort was used to evaluate ARV-naive patients within the programme using 18 PHC facilities between April 2004 and November 2005, based on whether or not patients had received ART as per the Zambian national HIV guidelines. Outcome measurement included survival rates, regimen failure rates and CD4 response. The authors concluded that the programme had led to a massive scale-up of HIV and AIDS services, with improved clinical outcomes, and that quality HIV care is attainable in a PHC environment in sub-Saharan Africa.[11]

These studies, particularly those from Lusikisiki and Zambia, highlight the fact that the decentralisation of ART services can lead to the rapid escalation of ART services, and if adequate resources are established to ensure the quality of service delivery, the outcomes can be comparable or better than those of hospital-based services. However, there is concern in South Africa about the capacity of the PHC facilities to carry out the decentralised HIV treatment programme, particularly as there is a limited number of appropriately trained staff members.[10] The effectiveness of this decentralised initiative, designed to reach more patients, could be compromised by an overburdened PHC system if staff are not adequately empowered to fulfil such roles.[10] This could lead to the poor quality of the services being delivered, and a large number of patients developing drug resistance as a result of poor implementation and monitoring of the programme.

To date, there has been no evaluation on the monitoring and follow-up of HIV-positive patients seen at PHC clinics in uMhlathuze Municipality since the ART services were decentralised to PHCs in 2010. The aim of the study was to assess the adherence of staff at a PHC clinic in the uMhlathuze Municipality to the national HIV guidelines when managing patients on ART. It was expected that the findings of this study would generate information on the capacity, strengths and weaknesses of the PHC clinic in delivering such monitoring services, and that recommendations could be made based on the findings. Permission to conduct this study was obtained from uMhlathuze Municipality, the matron in charge at the clinic and the University of KwaZulu-Natal Research Ethics Committee (BE125/12).

Method

This was a retrospective, cross-sectional study of the clinic records. The study population was adult patients on ART attending the Empangeni PHC clinic from June 2011 to June 2012. In 2011, 1 633 adult patients received ART at the PHC clinic. A study sample of 488 charts, representing 30% of the study population, was chosen in consultation with a biostatistician. Systematic random sampling was used to select every third file in the clinic until a sample size of 488 was reached.

A structured data extraction sheet, generated from the South African National HIV Guidelines for 2010, was used to extract information from the selected folders. The checklist included adherence (using a pill count), clinical staging, CD4 count, VL and identification of patients with virological failure. Data were captured in Excel®, imported and analysed using SPSS® 21, and summarised descriptively.

Results

Of those attending the clinic for ART, 76% (373/486) were women, 39% (189/483) were in the age range of 30–39 years, just under half of the patients (46%, 222/460) were unemployed, and the majority of the patients attending this clinic (64%, 310/467) were from neighbouring suburbs, and not Empangeni (Table 1).

CD4 count and VL monitoring was performed routinely every six months for patients at the PHC clinic, in contrast to annually, as recommended in the guidelines. WHO clinical staging was carried out monthly at every clinic visit, as recommended.

Table 1: The demographic profile of the study patients (n = 488)

Variable	*n* (%)
Age (years)	
20–29	38 (7.8)
30–39	189 (38.7)
40–49	169 (34.6)
50–59	68 (13.9)
60–69	15 (3.1)
> 70	4 (0.8)
Total	**483* (99.0)**
Sex	
Male	113 (23.2)
Female	373 (76.4)
Total	**486* (99.6)**
Occupation	
Employed	208 (42.6)
Unemployed	222 (45.5)
Self-employed	29 (5.9)
Student	1 (0.2)
Total	**460* (94.3)**
Location	
Empangeni	153 (31.4)
Rural township	310 (63.5)
Outside district	4 (0.8)
Total	**467* (95.7)**

*: missing data in the patient charts

In June 2011, the majority of the patients (60%, 294/488) were in WHO clinical stage 1, 53% (256/488) had a CD4 count above 350 cells/mm^3 (the mean CD4 count was 420 cells/mm^3), and 61% (297/488) had a VL of less than 1 000 copies/ml. By June 2012, the majority of the patients (56%, 272/488) were still at WHO clinical stage 1, 60% (293/488) of the patients had a CD4 above 350 cells/mm^3 (a mean CD4 count of 481 cells/m^3) and 53% (258/488) had a VL less than 1 000 copies/ml. The mean VL rose from 5 715 to 18 857 copies/ml between June 2011 and June 2012 (Table 2).

In June 2011, virological failure was present in 31% (127/407) of the assessed patients, based on a VL of greater than 1 000 copies/ml after a three-month interval, with intensified adherence counselling, as specified in the guidelines. The clinic detected 112 out of these 127 patients (88%) and referred 108 (85%).

In December 2011, virological failure was present in 45% (209/466) of the patients. It was detected in 83% (174/209) of patients, but only 57% (119/209) were referred.

In June 2012, virological failure had risen to 49% (218/443) of the patients assessed. It was detected in 74% (162/218). However, only 59% (129/218) were referred for further intervention. (Table 3)

Discussion

It was reflected in the demographic profile of patients accessing care at this clinic that the majority were young, unemployed women, which is consistent with the findings of other studies that examined the utilisation of PHC facilities in Gauteng province by Nteta et al.[12] A high percentage of women accessed ART at this clinic. This may have been because the women were aware of their HIV status because of healthcare worker-initiated HIV testing carried out during pregnancies. A tendency by women to utilise the healthcare facilities more frequently than men was also shown in a study carried out at a PHC clinic in Tshwane, Gauteng, which showed a ratio of 13 females to 9 males in clinic utilisation.[12] Some of the reasons given were that services, such as basic antenatal care and Papanicoloau smear programmes, are orientated towards women, and that women tend to bring their children to the clinics for the immunisation services. In contrast, there are few male-oriented services available, such as urology clinics, most of which are specialist oriented and not available in PHC facilities. However, it is possible that the poor utilisation of services could be attributed to poor health-seeking behaviour in the men. Population statistics in South Africa for 2009 shows that 48% of the population of KwaZulu-Natal living with HIV were men.[13] Thus, further investigation is needed into the low number of men utilising the health service. Modification of how the clinic is run (adjustments made to the opening hours) or who sees the patients (ensuring that more male professional nurses are available) may need to be considered if the health service is to adequately cater to the needs of men.

It was concerning that 64% (310/488) of those utilising the clinic were not from the geographical area for which the clinic is responsible. A 2012 study by Wasti et al. in Nepal on factors influencing adherence to ART showed that the majority (68%) of HIV-infected people would rather disclose their status to someone other than a health worker, and would rather travel to distant hospitals to avoid encountering relatives. Thirty-one per cent would rather miss their pill refill in order to avoid stigma and discrimination.[14] This tendency to avoid utilising local healthcare facilities has implications for health planners, and makes the provision of health services more challenging. Clinics are built and staffed according to population norms and the needs of the local community. The study also highlights that there is a need to ensure confidentiality, and to build trust and credibility in the local population. However, it is possible that the large number of out-of-area users in this study may be attributed to the fact that the clinic is situated in town, making it easy for those working in town to access health care.

It was also encouraging to note that the majority of patients (60%) in our study were in WHO clinical stage 1, with a relatively high CD4 count (a mean of 421 cells/mm^3), suggesting that ART was effective in improving the health status in this group of patients. Previous studies have shown that the majority of

Table 2: Trend of World Health Organization staging, CD4 count and viral load from June 2011 to June 2012 (*n* = 488)

WHO clinical staging	**June 2011, *n* (%)**		**June 2012, *n* (%)**
Stage 1	294 (60.2)		272 (55.7)
Stage 2	45 (9.2)		46 (9.4)
Stage 3	58 (11.9)		48 (9.8)
Stage 4	15 (3.1)		15 (3.1)
Total	**412* (84.4)**		**381* (78.0)**
CD4 count (cells/mm^3)	**June 2011, *n* (%)**	**December 2011, *n* (%)**	**June 2012, *n* (%)**
0–200	87 (17.8)	58 (11.9)	36 (7.4)
201–350	118 (24.2)	134 (27.5)	101 (20.7)
> 350	256 (52.5)	272 (55.7)	293 (60.0)
Total	**461* (94.5)**	**464* (95.1)**	**430* (88.1)**
Mean CD4 count (cell/mm^3)	420	429	481
Viral load (copies/ml)			
< 1 000	297 (60.9)	288 (59.0)	258 (52.9)
1 000–5 000	71 (14.5)	106 (21.7)	132 (27.0)
> 5 000	39 (8.0)	72 (14.8)	54 (11.1)
Total	**407* (83.4)**	**466* (95.5)**	**444* (91.0)**
Mean viral load (copies/ml)	5 715	12 370	18 857

CD4: cluster of differentiation 4, WHO: World Health Organization
*: missing data in the patient charts assessed

Table 3: Results of the monitoring of the study patients from June 2011 to June 2012 (*n* = 488)

Variable	June 2011, *n* (%)	December 2011, *n* (%)	June 2012, *n* (%)
Pill count performed	404/488 (82.8)	449/488 (92.0)	450/488 (92.2)
CD4 count carried out	461/488 (94.5)	464/488 (95.1)	430/488 (88.1)
Viral load determined	407/488 (83.4)	466/488 (95.5)	444/488 (91.0)
Virological failure present	127/407 (31.2)	209/466 (44.8)	218/444 (49.1)
Virological failure detected	112/127 (88.2)	174/209 (83.3)	162/218 (74.3)
Virological failure referred	108/127 (85.0)	119/209 (56.9)	129/218 (59.2)

CD4: cluster of differentiation 4

patients only present for treatment when they have an opportunistic infection and their CD4 count is extremely low, often well below 100 cells/m^3. A study conducted in Illembe at two PHC clinics found the mean CD4 count of patients to be 144 cells/mm^3 and the majority of the patients (69.1%) to be in clinical stage 3.[15]

The high CD4 count and low WHO stage found in this study may also be because this was an urban clinic, with fairly good staffing levels and patient profile, which showed that almost 43% of the patients were employed. Studies have shown that social status and educational status increase the chances of better patient adherence and good clinical outcomes.[14] It may also be possible that only stable patients were referred downwards to the clinic, and other patients who were more ill, with a lower CD4 count and with higher WHO staging, were referred upwards to the regional or tertiary hospital for more specialised care.

In keeping with the studies conducted in Hlabisa[9] and Lusikisiki[10], the nursing staff members performed well with regard to monitoring and following-up the patients. A pill count (a surrogate marker of adherence) was regularly conducted on between 83% and 92% of patients, staging was determined in 84% and 78% of patients (2011 and 2012, respectively) at each visit, and a CD4 count and VL test were conducted for between 83% and 95% of patients at the appropriate time. This shows nurses are excellent at following and implementing the guidelines, and with appropriate training and support, they would be able to run an excellent service. Well patients with a high CD4 count need ongoing monitoring and care. Successful supervision of these patients would relieve the burden on the district hospitals and ensure that patients receive the best care possible at the most appropriate level.

However, the lack of ability of the nurses to establish virological failure from CD4 and VL data, after three months of intensive adherence counselling, and then make appropriate referrals without hesitation, was concerning. Despite a persistently elevated VL in the repeat specimens, only 85% (June 2011) and 59% (June 2012) of these patients were referred for a possible change of regimen. Virological failure is a surrogate marker of drug resistance. It is important that once drug resistance has been identified, that new effective regimens are initiated timeously to ensure that cross-resistance to other drugs does not develop, resistant strains are not transmitted to sexual partners, and that improvements to health status achieved through the use of effective drugs are maintained.

It was concerning to note that despite near-excellent monitoring of the CD4 count, VL and adherence to ART, virological failure in patients continued to rise throughout the period of study from 31% (127 patients) to 49% (218 patients).

Conclusion and recommendations

The study aimed to determine the efficiency of a PHC clinic in monitoring patients on ART, and its ability to detect patients with treatment failure and to refer them promptly, as per the national HIV guidelines. It was shown in the study that the routine monitoring of patients on ART and the detection of treatment failure cases was not effectively and promptly followed-up with referrals to the appropriate centres for follow-up management. The monitoring of patients on ART, in a bid to detect and manage virological failure, is essential to ensure that the effectiveness of decentralisation is not compromised by an increase in drug resistance due to undetected virological failure. The PHC staff needs to be supported in this regard, and adequate staffing levels and appropriate training must be provided to enable it to carry out this role.

Conflict of interest – The authors declare that they have no financial or personal relationships which may haveinappropriately influenced them in the writing this paper.

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