The Effect of Home Follow Up Visit in Enhancing Antiretroviral Therapy Adherence Among HIV and AIDS Patient in a Rural Setting, Malawi; An Operational Evaluation Quantitative Descriptive Study

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Abstract

Background: Since the early days of antiretroviral therapy, adherence has emerged a landmark to success. Although there is rapid scale up in initiating antiretroviral therapy, Malawi still needs to deal with issues of adherence which remains largely unaddressed and pose a major challenge. The objective of this study was to compare the level of adherence to ART between patients who received ambulatory treatment at a health facility with home visit program and those receiving treatment at a health facility without home visit program.

Methodology: The study employed an operational evaluative quantitative design at two rural hospitals in Malawi. Five hundred eighty nine (589) ART master cards and passport books of patients accessing antiretroviral therapy for 12 months and over from both hospitals and adherence registers of treatment helpers from St Gabriel’s hospital were analyzed using chi square analysis.

Results: The Chi square test results showed that there was a significant difference in the ART adherence between HIV patients who received ambulatory treatment at health facility with no follow up visit (Kapiri) and that of a follow up visit (St Gabriel’s). \( \chi^2 (1) = 21.02, p=0.001, \alpha=0.05 \) with effective size = 0.189.

Conclusion: Follow up of clients by treatment helpers within the community can help to improve ART adherence and retention of clients on ART.

Keywords: Adherence, Antiretroviral therapy, Follow up visit, HIV/AIDS, Malawi

Introduction

Demands for the introduction of antiretroviral therapy into Africa have been growing over the past few years. The treatment can produce dramatic clinical improvements in people with symptomatic Human Immunodeficiency Virus (HIV) disease and, when used optimally, can delay the progression of the disease [1]. Adherence is the extent to which a patient’s behavior coincides with the prescribed health care regimen determined through a shared decision making process between the patient and health care provider [2]. In clinical practice in western world, roughly one-third of patients comply adequately, one-third comply somewhat adequately, and one-third do not comply at all. Clinical trials and observational studies have repeatedly shown that patients taking their prescribed medications as recommended are likely to be virologically suppressed [1-3]. Despite the benefits of ART and the known need to adhere, non-adherence to ART persists. Recent findings indicate that patients who were non-adherent to first line ART continued to be non-adherent to second-line ART, suggesting that ART non-adherence is still a major concern in the management of HIV-infected patients [4]. Furthermore, in most resource-limited settings only two lines of ART are available. Advances in ART-based HIV treatment and preventive strategies such as “Treatment as Prevention” (TasP), including prevention of mother to child transmission (PMTCT) and pre-exposure prophylaxis (PrEP), have shown promising results in preventing HIV transmission. For example, treatment of the HIV-infected member in sero-discordant couple reduced the risk of new HIV infections in the un-infected partner [5]. However, the success of such strategies requires high degree of medication adherence. In this current study the issue of adherence was taken into consideration considering that St Gabriel mission hospital initiated a home visit program in order to enhance adherence.
to ART therapy. Barriers to adherence with ART have been explored; however, the association between the follow up home visit to clients on ART and adherence is not known.

Although it is widely recognized that adherence to antiretroviral medication regimens is vital to treatment success, rates of adherence to the regimen are often poor [3]. Adherence for patients on antiretroviral therapy includes not only taking antiretroviral drugs (“adherence to treatment”), but also attending all appointments as scheduled and following other instructions that the clinic, support staff and care providers may give (“adherence to care”) [4,5].

As HIV/AIDS prevalence rate continue to rise in developing countries, it is becoming increasingly necessary to scale up access to highly active antiretroviral therapy (HAART), especially in Africa where 95% of all new infections occur. However, in resource constrained settings where health care services are not well developed, poor adherence to treatment and defaulting from treatment are the two major challenges faced by the Antiretroviral Therapy (ART) programs.

In order to address, maintain and improve adherence levels in patients on antiretroviral therapy, St Gabriel’s Hospital developed a strategy of training community volunteers to provide adherence support at community level. Patients on ART are then allocated to these treatment helpers for adherence support services. Since its implementation in 2004 the program has not been evaluated to assess its effectiveness. The ambitious 3 by 5 initiative by World Health Organization set a target to put at least 80 000 Malawians living with HIV/AIDS on ART by December 2005. By December 2007, 110,000 clients had been started on ART with 90,000 clients predicted to be alive by end of the year 2007 [6]. Although there is rapid scale up in initiating antiretroviral therapy, Malawi still needs to deal with issues of adherence which remains largely unaddressed and poses a major challenge.

Specifically this study aimed at comparing the level of adherence to ART between patients who receive ambulatory treatment at a health facility with a home visit program and those receiving treatment at a health facility without home visit program.

Definition of variables

In this study, home visit program was assumed to be an independent variable while adherence to ART treatment was regarded as a dependent variable. In view of this clients adherence was compared by using the chi-squared test to determine the association of home visiting program with adherence. Other variables were also evaluated including age, gender, duration on ART, treatment sites, marital status, education, and other factors that were thought to be barriers to adherence by the participants.

Methods

An operational evaluation descriptive study using quantitative design was conducted from 2009 January to December 2010 at the ART clinics within the catchment areas of St Gabriel’s and Kapiri Mission Hospitals in Lilongwe and Mchinji districts, respectively. The clinics used standard data forms and registers recommended by the Ministry of Health. In addition, St Gabriel’s Hospital used community adherence registers whereas Kapiri Hospital did not; allowing patients from there to act as controls. The two ART clinics had been functional since June 2005 as low burden units. St Gabriel’s Hospital has been upgraded to a medium burden level as from October 2006 (Appendix 1 and 2).

Study population and sample size

The study populations were HIV patients, who had been on Triomune (combination of Stavudine, Lamivudine and Nevirapine) continuously for more than one year from the period of being initiated on antiretroviral drugs, and were living within the catchment area of the two Mission Hospitals namely St Gabriel’s and Kapiri. In addition, the population from St. Gabriel’s included only those who accepted to be visited at home and being paid a surprise follow up visit weekly by the treatment helper.

A sample size calculation was made to ensure sufficient numbers were available for the study. With a population difference of 4.5 to 1, using 95% confidence of identifying a difference and 80% power, an expected non-adherence rate of 25% in Kapiri and the ability to identify a difference of at least 12.5% at St Gabriel’s, the size of sample would need to be at least 402 in Kapiri and 107 in St Gabriel’s. Sufficient numbers that met the inclusion criteria were therefore available in 2009 and all were included in the study analysis.

Data collection

ART master cards and passport books of patients accessing antiretroviral therapy for 12 months and over from both hospitals and adherence registers of treatment helpers from St Gabriel’s Hospital were analyzed to assess adherence levels. Data were extracted from the clients’ ART master card, health passport booklet and treatment helpers registers (St Gabriel’s Hospital) regarding the number of doses of Triomune missed using the ART Adherence Surveillance Form (Appendix 3).

Data analysis

Quantitative Data were entered on SPSS version 11.5 for analysis after creating a database for data entry. Frequencies and cross tabulations tables were prepared to generate relationships between variables for not adhering to ART as follows; Patient related factors (illness, forgetfulness, feeling better, fear of disclosure); Medication related factors (side effects); Health delivery system related factors (problems with delivery); Social related factors (funeral) and Other related issues. Chi square test was applied to test for statistical differences in proportion between the two groups (Table 3).

Ethical consideration

Ethical approval was sought from research and publications committee of College of Medicine. Further; permission to conduct the study was obtained from the two hospitals (Appendix 4 and 5).

Results

Characteristics of the study participants

Of the 107 and 482 participants enrolled from St Gabriel’s and Kapiri Hospitals, 55(51%) and 226 (47%) were female respectively. The age range is represented in four categories (15-29, 30-44, 45-59 and >60 years) (Tables 1 and 2). A majority
of them were local peasants or tenants living on subsistence farming. Most of the participants (89%) lived more than 15 km from the health facility. All the participants had undergone ART counseling and education with their preferred guardians. Participants understood the need to take the ARVs for the rest of their lives and that treatment was free. The participants also understood very well that complications would develop, cost of transportation to the treatment centers, the daily treatment regimen and what optimal adherence meant.

Discussion

While all patients clearly understood the importance of taking the ARVs throughout the rest of their lives, the average rate of non-adherence to ART ranged between 14% and 35%. Non-adherence to ART in adult population has been shown to range from 33% to 88% depending on how adherence is defined and evaluated [7]. Repeated defaulting and missing appointment dates from treatment among Kapiri patients participated contributed largely to the non-adherence rates. The attention the patients received in the community follow up cohort at St Gabriel’s visit. The Chi square test results showed that there was a significant difference in the ART adherence between HIV patients who received ambulatory treatment at health facility with no follow up (Kapiri) and that of a follow up visit (St Gabriel’s). The results further showed that 93 (86.9%) from St Gabriel’s and 309 (64%) from Kapiri Hospitals were ≥ 95% adherent to their treatment regimen (Figure 1). Patients who had suboptimal adherence rate were 14 (13.1%) and 173 (36%) for St Gabriel’s and Kapiri Hospitals respectively.

Comparison on levels of ART adherence between St. Gabriel’s and Kapiri Mission Hospitals

In this study it was hypothesized that there is no significant difference on the level of adherence to ART between HIV/AIDS patients who receive ambulatory treatment at health facility with no follow up (Kapiri) visit program and those with a follow up (St Gabriel) visit. The Chi square test results showed that there was a significant difference in the ART adherence between HIV patients who received ambulatory treatment at health facility with no follow up visit (Kapiri) and that of a follow up visit (St Gabriel’s). χ² (1) = 21.02, p=0.001, α=0.05 with effective size = 0.189 (Table 3).

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Table 1: Characteristics of Patients not adhering to ART Regimen

<table>
<thead>
<tr>
<th>Health Facility</th>
<th>No of patients ≥ 95% adherence rate</th>
<th>No of patients &lt; 95% adherence rate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>St Gabriel</td>
<td>93 (86.9)*</td>
<td>14 (13.1)*</td>
<td>107</td>
</tr>
<tr>
<td>Kapiri</td>
<td>309 (64.1)*</td>
<td>173 (35.9)*</td>
<td>482</td>
</tr>
</tbody>
</table>

*Represent percentages of adherence and non adherence at the two health facilities

Table 2: Number of Adherent and Non Adherent Patients to ART at the Two Health Facilities

<table>
<thead>
<tr>
<th>Health Facility</th>
<th>Value</th>
<th>df</th>
<th>Asymp. Sig. (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
<th>Exact Sig. (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>21.021(b)</td>
<td>1</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity Correction(a)</td>
<td>19.982</td>
<td>1</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td>23.881</td>
<td>1</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fisher’s Exact Test</td>
<td></td>
<td></td>
<td></td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>Linear-by-Linear Association</td>
<td>20.985</td>
<td>1</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N of Valid Cases</td>
<td>589</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) Computed only for a 2x2 table
b) 0 cells (.0%) have expected count less than 5. The minimum expected count is 33.97.

Table 3: Chi-square Test for Proportion of Adherence at the Two Hospitals.
Studies on antiretroviral therapy have demonstrated a correlation between the patients’ self-reported adherence levels and virological efficacy of the therapy [9].

The average self-reported adherence level in this study at both hospitals was 92%. Although the average self-report adherence levels was equally high, only 63% of the population achieved >95% adherence levels as set by the National AIDS Control program. This is similar to Mills and others [10] whose pooled analysis of 71% of North American studies, and 66% of African studies using patient self-report to assess adherence indicated a pooled estimate of 55% (95% confidence interval, 49%-62%; 12, 98.6%) and 77% (95% confidence interval, 68%-85%; 12, 98.4%) of the population respectively achieving adequate levels of adherence. These studies used similar thresholds for adherence monitoring (e.g. 100%, >95, >90%, >80%) [11-16].

Study limitations

Measure of compliance in the two Hospitals was based on oral reports and pill counts; there is no other objective way of verifying patients’ level of adherence. This might not give a true reflection of the actual drug adherence as some patients may give false or half - true response about their adherence in order to give the clinical staff a good impression. This has the potential of skewing the data obtained. Some patients who are initiated on ART are already motivated in adhering to prescribed treatment. Placing such patients under the supervision of treatment helpers may have little effect on drug adherence levels.

Recommendations

Basing on the results of this study, ART adherence, monitoring and counseling can be shifted to lay cadres without compromising the effective implementation of ART program, as is the case with other programs like tuberculosis programme which uses Health Surveillance assistance (HSAs) to monitor and administer anti-TB drugs.

Conclusion

The results of the study have shown that there is significant difference between the two groups of patients on ART. Given the apparent relatively low levels of ART adherence in patients who were not attached to treatment helpers, one of the most important emerging issues is to come up with a feasible intervention which will influence optimal ART adherence. There is an urgent need for universal access and sustainability of antiretroviral therapy particularly in resource-limited settings. Hence, follow-up of clients by treatment helpers within the community appears to be a good way to improve retention of clients on ART.

List of abbreviations

AIDS: Acquired Immune Deficiency Syndrome
ART: Antiretroviral Therapy
ARVs: Anti-retroviral Drugs
ASW: Adherence Support Workers
DOT: Directly Observed Therapy
FGD: Focus Group Discussion
HAART: Highly Active Antiretroviral Therapy
HIV: Human Immunodeficiency Virus
HCW: Health Care Workers
MENS: Medication Event Monitoring System
PMTCT: Prevention of Mother to Child Transmission
PLWA: People Living with HIV/AIDS
SPSS: Statistical Package for the Social Sciences
TB: Tuberculosis

Competing Interests

The author(s) declare that they have no competing interests.

Authors Contribution

HK, designed the study, developed the protocol, organized and collected data, analyzed and interpreted the results. MOG, drafted the manuscript, reviewed and edited the study protocol and critically reviewed and revised the manuscript. Both authors read and approved the final manuscript.

Acknowledgement

The authors gratefully acknowledge the assistance from numerous individuals without necessarily mentioning their names for contributing to this study. We also thank the management of the two hospitals for providing site for the study.

References


16. Wood E, Hogg RS, Yip B, Harrington PR, O'Shaughnesy MV, Montaner JS. Effects of medication adherence on survival of HIV-infected adults who start highly active antiretroviral therapy when CD4+ Cell count is 0.200 to 0.350 x109 cells/ml. Ann Intern Medical Journal. 2003;810-316.
Appendix 1: Map 1 St Gabriel’s Hospital and the Catchment Area

Appendix 2: Map 1 Kapiri Mission Hospital and the Catchment Area
### Appendix 3: ART Adherence Surveillance Form

<table>
<thead>
<tr>
<th>Patient code number</th>
<th>Hospital/Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 2. Caretaker Information

<table>
<thead>
<tr>
<th>ID</th>
<th>SEX</th>
<th>TESTED HIV</th>
<th>POS.</th>
<th>TREATMENT STARTED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### 3. Adherence Codes


#### 4. Dispensing Frequency

<table>
<thead>
<tr>
<th>Duration</th>
<th>Weekly refills</th>
<th>Bi-Monthly</th>
<th>Monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

#### 5. Why did patient miss doses?

Fill in adherence reasons code:

- 1: Forgot
- 2: Side effects
- 3: Feeling sick
- 4: Illness in family
- 5: Perceived lack of need
- 6: Sharing medication
- 7: Funeral
- 8: Delivery/travel problems
- 9: Dispensary out of stock
- 10: Program stopped
- 11: Unable to pay for meals
- 12: Work conflict
- 13: Other

### Appendix 4: Permission Letter from St Gabriel's Hospital

15th November 2008

Miss H. Kamara
College of Medicine
Private Bag 360
Chichiri
BLANTYRE 3

Dear Miss Kamara,

**RE: PERMISSION TO CONDUCT A RESEARCH AT ST GABRIEL’S HOSPITAL**

Following your letter regarding your request to conduct a research on Effects of Home follow up visit in enhancing Antiretroviral Therapy Adherence among HIV/AIDS patients in a rural setting at St Gabriel’s Hospital, we are pleased to inform you that the hospital management team has granted permission to your request.

We hope you will take into consideration all ethical issues.

Yours sincerely,

Dr. A Kiromera
Hospital Director

Tel: 01 923 432/01 205 920
Email: administrator@stgabrielshw.org