

Reference: N08/05/124

“Causes of non-adherence to antiretroviral therapy in Wellness Clinic, Tshepong Hospital, Klerksdorp”

(As part of fulfillment of MMed at University of Stellenbosch)

Studied in
Tshepong Hospital Complex, Klerksdorp
North West Province
Republic of South Africa

By
Dr. C. R. Das

Supervisor: Dr. Strini Govender

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“Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature:

Date:

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Index of abbreviation

AA:	Alcohol Anonymous
ADC:	AIDS Defining Conditions
AIDS:	Acquired immunodeficiency syndrome
ART:	Anti-retroviral therapy
ARV:	Anti-retroviral
CCM:	Cryptococcal Meningitis
DM:	Diabetes Mellitus
FBO:	Faith based organization
HAART:	Highly active anti-retroviral treatment
HIV:	Human immunodeficiency virus
HTN:	Hypertension
MSF:	Médecins Sans Frontières
NGO:	Non-governmental organization
NNRTI:	Non- nucleoside reverse transcriptase inhibitor
NRTI:	Nucleoside reverse transcriptase inhibitor
PI:	Protease inhibitor
RuDASA:	Rural Doctor Association of South Africa
SA:	South Africa
SANCA:	South African National Council of Alcoholism and Drug Dependence
STI:	Sexually transmitted infection
TB:	Tuberculosis
UNAIDS:	United Nations Programme on HIV/AIDS
WHO:	World Health Organization

Introduction

HIV/AIDS is the leading cause of death in Sub-Saharan Africa.¹ According to 2001 estimates, there are 28.5 million people living with HIV in Africa, comprising more than 70% of the world's HIV-infected population.¹ HIV/AIDS remains one of the most important social and public health threats in Sub-Saharan Africa.¹ UNAIDS 2006 estimates that 5.5 million people are living with HIV, and almost 1,000 AIDS deaths occur every day in South Africa.¹ South Africa is currently one of the most severely affected countries in the world.¹

The South African government has recently applied a three pronged strategy of information, education and communication to encourage behavioral change. Despite these efforts, the number of people living with HIV/AIDS continues to rise.

Antiretroviral therapy (ART) is currently the only treatment available for HIV. It does not cure HIV infection, but reduces HIV related mortality and morbidity.² Nucleoside reverse transcriptase inhibitors (NRTIs) inhibit virus replication by directly blocking chain extension during reverse transcription using nucleoside analogues as chain terminators; Non-nucleoside reverse transcriptase inhibitors (NNRTIs) inhibit virus replication by binding directly to the reverse transcriptase and prevent reverse transcription and Protease inhibitors (PIs) inhibit formation of mature infectious virus particles by blocking protease activity and thereby preventing cleavage of the gag-pol polyprotein. Patients with AIDS defining conditions (ADCs) take longer to regain their CD4 count due to the defect in the immune system. This may increase their risk of morbidity and mortality.²²

Adherence to a medication is generally defined as the extent to which a patient takes medication as prescribed by their health care provider. The word "adherence" is preferred by many health care givers in place of "compliance", because "compliance" suggests that patient is passively following doctor's suggestions, and that the treatment plan is not based on a therapeutic alliance or a contract established between the patient and health care provider.¹⁶ Contrary to that, adherence is regarded as implying an active role of the patient in their health care. The success of Highly Active Antiretroviral Therapy (HAART), Tuberculosis (TB) treatment or Sexually Transmitted Infection (STI) treatment is dependent on close to 100% adherence to the treatment.

Adherence to ART is the most important determinant of treatment success. Adherence levels of less than 95% are associated with the development of viral resistance and virological failure, and subsequent risk of transmission of resistant virus to others.² Patients should be treated with ART for the rest of their lives and this level of adherence is therefore difficult to sustain. Optimal treatment adherence has been closely correlated with viral suppression,⁵⁻⁷ while non adherence has contributed to progression to AIDS,⁸ the development of multidrug resistance and death.⁹⁻¹¹ Even short-term non adherence (as little as 1 week) may result in a rapid increase in viraemia, leading to treatment failure.¹²

ART is increasingly available within public and private sectors in many countries. The South African government started rolling out ART within the public sector in 2004. With a growing numbers of patients on ART, it is of utmost importance to

ensure high levels of adherence to have the desired effect and to avoid the risk of spreading drug resistant viruses.

The 'estimate of average rate of non adherence to ART range from 50% to 70% in many different social and cultural settings, and the risks associated with non adherence are dire for both the individual and society at large'.^{3, 4} Adherence is perceived as a significant barrier to the delivery of ARV therapy in sub-Saharan Africa.^{13, 14} Adherence to ART and TB therapy of HIV-positive patients in South Africa depends on several different factors, such as community participation, a parallel TB control programme, case identification, treatment modalities, drug supply, adherence support, monitoring, the clinical setting, nature of the doctor-patient relationship, and non-disclosure to family.¹⁹ The psychological and social consequences of HIV/AIDS also affect adherence, e.g. anxiety during HIV testing, difficulties adjusting to an HIV positive test result, disclosure of status, depression, suicidal ideation, and psychiatric illness caused directly by HIV infection (e.g. AIDS dementia).²⁰ It must be noted that the gold standard for adherence assessment and intervention strategies is elusive and "one size does not fit all".¹⁵ The experience of Médecins Sans Frontières (MSF) in Khayelitsha demonstrated that adherence can be improved with the use of special pill boxes, cards showing pills and their accompanying water or food needs, and technology like beepers and SMSs.²¹

This study aimed to investigate the adherence rate for patients on ART after more than three months, via a pill count, and to explore reasons for non adherence. The study was carried out at the Wellness Clinic, Tshepong Hospital, Klerksdorp, North West Province, South Africa.

Methods

The study was designed as a cross sectional survey of patients under treatment at the HIV Clinic in Tshepong Hospital.

A sample size of 150 patients out of the 7,000 patients was considered adequate by the Centre for Statistical Consultation. Patients needed to be on ART for 3 months or more, willing to give written consent and over the age of 18 years. Every consecutive patient that met the inclusion criteria was invited to participate until the sample size was obtained over a 5 month period (November 2008 to March 2009)

The best methods of adherence measurement are pill counts and electronic monitoring, but electronic monitoring is unavailable in our setting.²⁴

The nurse conducted a pill count on each patient as they attended the clinic with their pill packets and patients missing more than 3 pills (<95%) in the previous month were categorized as non-adherent.

All selected patients completed a semi structured questionnaire. Research assistants, who were nurses at the hospital, interviewed participants confidentially in consultation room, to maintain a free and unbiased environment. The questionnaire collected data on the patient's demographic profile, clinical status and perceived

obstacles to adherence. Clinical data, such as ART commencement date, CD4 count and viral load, were crosschecked using the hospital records.

Study data were stored in Microsoft Excel and were analyzed by Prof. Martin Kidd of Centre for Statistical Consultation, University of Stellenbosch and Engr. Tahir Choudhury of Development Bank of Southern Africa.

Ethical approval was obtained from the Human Research Ethics Committee of the University of Stellenbosch (Project Number: N08/05/024).

Results

Demographic results

A total of 150 participants were interviewed of whom 19 (12.7%) were non-adherent and 131 (87.3%) were adherent to ART. The participants' ages ranged from 17 to 65 years. The demography of the participants is presented in Table I.

Table I: Demography of participants

Category	Variable	Frequency N and (%)
Gender	Male	52 (34.7%)
	Female	98 (65.3)
Marital status	Single	97 (64.7%)
	Married	30 (20.0%)
	Widow/ Widower	17 (11.3%)
	Others	6 (4.0%)
Country of origin	South African	149 (99.3%)
	Non South African	1 (0.7%)
Ethnicity	African	150 (100%)
Age group	18 – 34	39 (26.0%)
	35 – 65	111 (74.0%)
Employment status	Employed	32 (21.3%)
	Unemployed	52 (34.7%)
	Social grant	52 (34.7%)
	Others	14 (9.3%)
Shift worker	Yes	7 (4.7%)
	No	143 (95.3%)
Household income	< R 600	67 (44.7%)
	R 601 - R 1,000	65 (43.3%)
	R 1,001 - R 2,000	11 (7.3%)
	R 2,001 - R 4,000	5 (3.3%)
	> R 4,000	2 (1.3%)
Family size	1	19 (12.7%)
	2 – 3	70 (46.7%)
	4 – 5	35 (23.3)
	> 5	26 (17.3)

Clinical status

The clinical status of the participants in terms of their CD4 counts and viral loads is shown in Figures 1 and 2 below. The figures confirm the benefit of ART on improving the CD4 count and suppression of viral load. Figure 1 and 2 show that the CD4 count increased from a mean of 140 at initiation to 413 (p< 0.01) at the time of the study; and that viral load decreased from a mean of 290,828 at initiation to a mean of 1,550 (p<0.01).

Figure 1: Comparison of CD4 Count at initiation of ART and currently

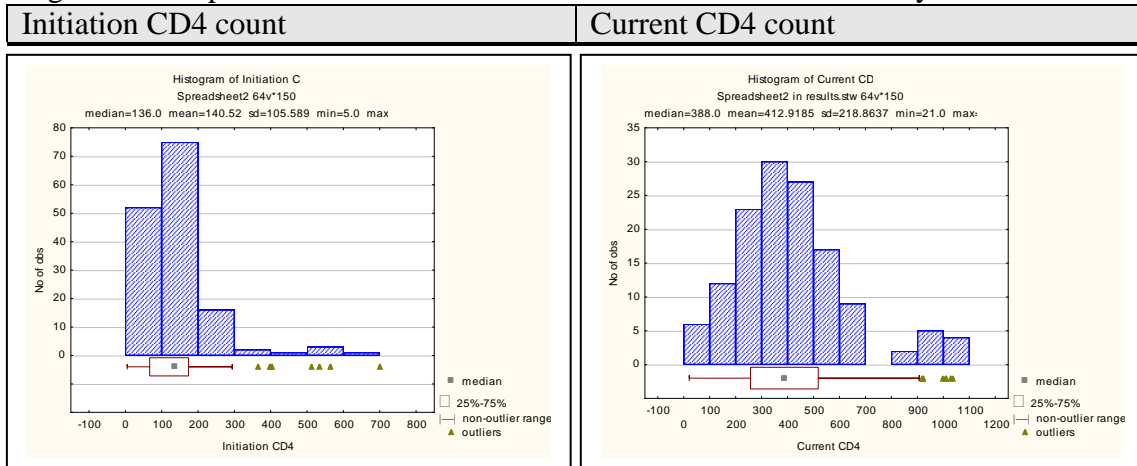


Figure 2: Comparison of Viral load at initiation of ART and currently

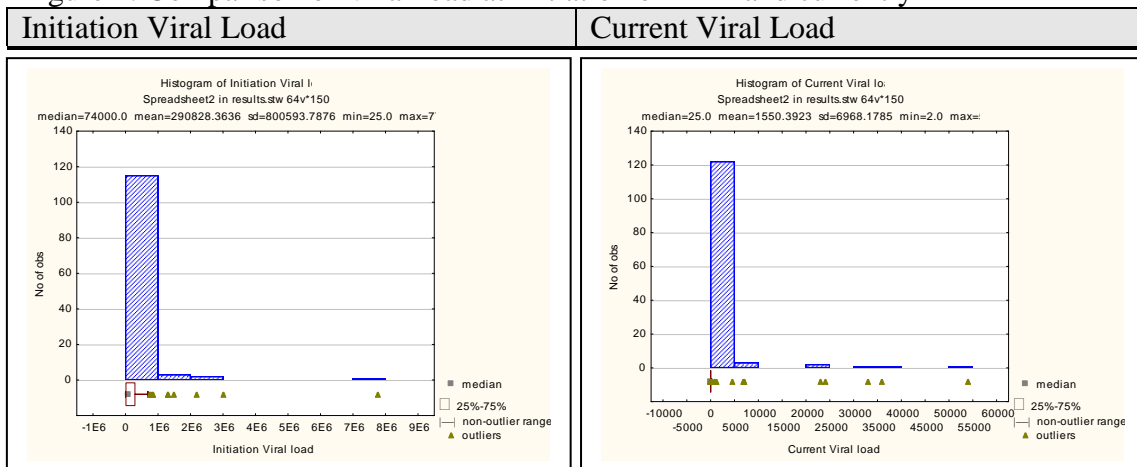


Table II presents the medical history of the participants and techniques used for improving adherence. The Table shows that more than half of the participants (n=81, 54.0%) were under treatment for longer than 24 months. Out of 150 patients 97 (64.7%) were in WHO Stage III, oro-oesophageal candidiasis was identified as the main opportunistic infection (n=31, 20.7%). Psychological issues were uncommon but this relied on self-reports. Co-morbidity with TB was common (n=81, 49.7%).

Although patients used pill boxes and treatment supporters to improve their adherence, the cell phone reminder was the most commonly used technique (n=65, 35.3%).

Table II: Medical history of participants

Category	Variable	Frequency N and (%)
Duration of medication	3-6 months	15 (10.0%)
	6-12 months	23 (15.3%)
	12-24 months	31 (20.7%)
	> 24 months	81 (54.0%)
WHO stage on initiation	Stage I	14 (9.3%)
	Stage II	18 (12.0%)
	Stage III	97 (64.7%)
	Stage IV	21 (14.0%)
Opportunistic Infection	Cryptococcal meningitis	5 (3.3%)
	Oro-oesophageal candida	31 (20.7%)
	Kaposi sarcoma	3 (2.0)
	Others	8 (5.3%)
Psychological Complaint	No complaint	103 (68.3%)
	Depression	7 (4.7%)
	Anxiety	1 (0.7%)
	Others	2 (1.4)
Other Chronic Disease (n = 163) [†]	No complaint	141 (93.3)
	Hypertension	22 (13.5%)
	Diabetes	3 (1.8%)
	TB	81 (49.7%)
Remembrance (n = 184) [†]	Others	6 (3.7%)
	No complaint	51 (31.3%)
	Pill box	40 (21.7%)
	Support/ Caregiver	36 (19.6%)
	Cell phone alarm	65 (35.3%)
	Others	43 (23.4%)

[†] Number of participants responded more than one disease condition and remembrance

Reasons for non-adherence

All the obstacles to adherence selected from the questionnaire and reported by the participants were coded and are presented in order of frequency in Table III. Altogether 50 different obstacles to adherence were identified.

Table III: Responses as obstacles to adherence

	Choice	Count of yes	% of yes
1	Unemployed/ no income	71	47%
2	No regular food supply at home	62	41%
3	Side effects of medication (nausea, vomiting)	26	17%
4	Forgot because drunk with alcohol/took drugs	23	15%
5	Forgot to take medication	12	8%
6	Transport problem –clinic too far from the home	11	7%
7	Problem with HIV disclosure to employer	11	7%
8	Lack of social and family support	10	7%
9	Income not sufficient	9	6%
10	Spent time on the street looking for a job	9	6%
11	Lack of commitment	8	5%
12	Social engagement (attending funeral)	8	5%

	Choice	Count of yes	% of yes
13	Drug burden (Use other chronic medication)	7	5%
14	Ignored their treatment	6	4%
15	Perception that HIV is incurable or non-curable	5	3%
16	Stigma/guilty feeling	4	3%
17	Non disclosure made it difficult	3	2%
18	Couldn't get medication from clinic/pharmacy	3	2%
19	Too ill to come to the clinic	2	1%
20	Lack of understanding about disease (language/knowledge).	2	1%
21	Not believing that ART can suppress virus/no confidence on ARVs treatment	2	1%
22	Work relationships	2	1%
23	Family matters/family problems	2	1%
24	Forgot clinic appointment	2	1%
25	Problem with employer to adjust time schedule	2	1%
26	Family related stress	2	1%
27	Problem with date adjustment for clinic appointment	1	1%
28	Irresponsibility/lack of responsibility to take medication	1	1%
29	Bad influence from peers	1	1%
30	Patient feels that she/he is no longer sick	1	1%
31	Belief in tradition medication)	1	1%
32	Bought other medication and forgot to take ARV	1	1%
33	Depression and stress	1	1%
34	Migration from one place to another	1	1%
35	Forgot to set reminder on the cell phone	1	1%
36	Family member forgot to remind them	1	1%
37	Too many pills	1	1%
38	Treatment is not delivered at the referral site	1	1%
39	Emergency cases	1	1%
40	No money to collect medication from clinic	1	1%
41	Not eating well	1	1%
42	Don't think medication was needed	1	1%
43	Difficult to adjust timing with work	1	1%
44	Shared medication with others	1	1%
45	Don't want others to notice	1	1%
46	Didn't want to mix pills with alcohol/drugs	1	1%
47	To many people at home to keep confidentiality	1	1%
48	Shifting duty is a problem to carry medication at work	1	1%
49	Children give problem	1	1%
50	Spend time at the shebeen	1	1%

These 50 obstacles were then re-categorised into 4 main themes and 13 sub-themes as shown in Table IV. The Table reveals that socio-economic factors are perceived to be the biggest obstacles, in particular financial and food related problems. Medication related issues and personal behaviour are the next most important issues.

Table IV: Categorical analysis of responses of obstacles to adherence

Theme	Count of yes n=348	%
Socioeconomic related factors e.g. poverty, unemployment, costs of transport etc.		
Financial problems	90	25.9
Food problems	62	17.8
Distance / access	12	3.1
Employer / work related problems	17	4.4
Patient-related factors e.g. beliefs, mental disorders, alcohol abuse etc.		
Personal behaviour	32	9.2
Mental disorders / substances	24	6.8
Concerns / fears	6	1.7
Beliefs / ideas	12	3.4
Family related	26	7.5
Social group / friends related	1	0.3
Health care team/health system-related factors e.g. poor service, poor relationship with health workers, etc.		
Health care team / health system related factors	5	1.5
Condition-related factors e.g. symptoms, side effects, complexity of treatment, knowledge about meds, etc		
Medication	35	10.0
Illness	4	1.1

These 13 sub-themes were then analysed for any association with adherence or non-adherence at the last visit as shown in Table V. None of these sub-themes showed a statistically significant association with adherence.

Table V: Analysis of sub-themes for their association with adherence

Theme		Adherent		P value
		n	%	
1) Financial	Yes (n=78)	70	89.74	0.35
	No (n=72)	61	84.72	
2) Food	Yes (n=62)	57	91.94	0.14
	No (n=88)	74	84.09	
3) Distance/access	Yes (n=11)	8	72.73	0.17
	No (n=139)	123	88.49	
4) Employer/work related	Yes (n=13)	11	84.62	0.76
	No (n=137)	120	87.59	
5) Personal behaviour	Yes (n=28)	25	89.29	0.72
	No (n=122)	106	86.89	
6) Mental disorders (including substance abuse)	Yes (n=22)	18	81.8	0.42
	No (n=128)	113	88.3	
8) Family related issues	Yes (n=13)	10	76.92	0.27
	No (n=137)	121	88.2	
9) Social group/friends	Yes (n=23)	18	78.26	0.18
	No (n=127)	113	88.98	
12) Medication	Yes (n=32)	27	84.38	0.57
	No (n=118)	104	88.14	

Discussion

Main findings of the study

Overall 87.3% of patients were adherent to ART during the previous month.

The main challenges to adherence identified by patients were socio-economic and related to a lack of income and food. Medication related issues such as side effects and complex regimens were also important along with a range of more personal behavioural issues. Mental disorders, substance abuse and family-related issues were also identified as relevant.

Discussion of results in relationship to the literature

The level of non-adherence to ART among the patients of Wellness Clinic is far below reported levels of non-adherence that range from 50% to 70% in many different social and cultural settings.^{3,4}

Other studies have identified health care team and health system factors as being important.¹⁹ These factors were seldom reported here; however, this may be due to the questionnaire design and a reluctance to report these factors when being interviewed by a health worker. Psychological factors have been highlighted in other studies, but may have been underreported here.²⁰

The use of cell phones, pill boxes and social support as ways of improving adherence were also found to be helpful in this community and confirm the findings of MSF in Khayelitsha.²¹

Socio-economic related factors came out as a prominent threat to adherence in the study and point to the interaction between poverty and adherence to medication. For example the struggle to survive and provide food for the family may take precedence over clinic attendance and a lack of income may limit the ability to travel to the clinic on a regular basis. Even those who had employment however struggled with a range of issues related to disclosure and accessing their treatment.

Family relationships and social support were also identified as important and confirm the value of building social capital in poor communities.²⁵

The importance of the patients underlying beliefs, family support, current illness and employer related issues have also been reported in other studies..^{26,27}

Strength and weakness of the study

The use of both open and specific questions to elicit all perceived obstacles to adherence is strength of the study.

Main weaknesses of the study were i) non-inclusion of completely defaulted (not attending the clinic) patients; ii) small sample that lacked the power to test for the association of identified factors with adherence iii) interviewing by health workers may have influenced some of the responses especially related to the health services iv)

adherence was only measured over the previous month v) use of a self developed questionnaire.

Recommendation and Conclusion

The study implies that improving socio-economic conditions through job creation, skills development, social grants and food parcels may be beneficial to adherence.

Access to treatment for those who are employed also needs to be improved and health services should look at ways of accommodating the needs of this group as well as interacting with employers to improve their understanding of the ART requirements.

Attempts should be made to keep prescriptions as simple as possible and to monitor closely for side effects. Cell phones and other technologies should be promoted as ways of coping with complex and chronic regimens.

Counselling should be open to discuss personal behaviour, beliefs and concerns and to motivate behaviour change. Counselling should also be family orientated and willing to assist where possible with family related issues that impair adherence.

Health workers should be vigilant for mental problems, alcohol and substance abuse and be in a position to assist patients with these problems.

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Anti - Retroviral and Adherence: Descriptive Study Questionnaire

Section 1A Demographic details. (Ask patient)	
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1.	Study number <input type="text"/> <input type="text"/> <input type="text"/>
2.	Date enrolled to study: dd____ / mm____ / yy_____
3.	Gender: M <input type="checkbox"/> F <input type="checkbox"/>
4.	Marital status: Single <input type="checkbox"/> Married <input type="checkbox"/> Widow/Widower <input type="checkbox"/> Others <input style="width: 100px;" type="text"/>
5.	What is your country origin (country of birth) 1. SA <input type="checkbox"/> 2. Non South African <input type="checkbox"/>
6.	What is your Ethic group: 1. African <input type="checkbox"/> 2. White <input type="checkbox"/> 3. Coloured <input type="checkbox"/> 4. Indian <input type="checkbox"/> 5. Other <input style="width: 100px;" type="text"/>
7.	What is your year of birth: <input style="width: 100px;" type="text"/> Do not know <input type="checkbox"/> What is your age <input style="width: 100px;" type="text"/>
8.	What is your current employment status: 1. Employed <input type="checkbox"/> 3. Social grant (disability) <input type="checkbox"/> 2. Unemployed <input type="checkbox"/> 4. Other <input style="width: 100px;" type="text"/>
9.	Are you a shift worker? Yes <input type="checkbox"/> No <input type="checkbox"/>
10.	On average how much money do you get in your household every month: 1. < R600. <input type="checkbox"/> 4. R2001 –R4000 <input type="checkbox"/> 2. R601 – R1000. <input type="checkbox"/> 5. > R4000 <input type="checkbox"/> 3. R1001 – R2000. <input type="checkbox"/>
11.	What is your family size? Single <input type="checkbox"/> 2-3 <input type="checkbox"/> 4-5 <input type="checkbox"/> more than 5 <input type="checkbox"/>

Section 1/B Medical history (Ask patient)	
1.	Date initiation (ART) dd____mm____yy_____
2.	Duration of medication(ART) 1. 3-6 Months <input type="checkbox"/> 3. One to two years <input type="checkbox"/> 2. 6-12 Months <input type="checkbox"/> 4. More than two year <input type="checkbox"/>
3.	WHO stage on initiation Stage I <input type="checkbox"/> 3. Stage III <input type="checkbox"/> Stage II <input type="checkbox"/> 4. Stage IV <input type="checkbox"/>
4..	Initiation(With date) CD4: <input type="checkbox"/> Viral Load: <input type="checkbox"/>
5.	Current(With date) CD4: <input type="checkbox"/> Viral Load: <input type="checkbox"/>
6.	Any opportunistic Infection 1. Cripto meningitis <input type="checkbox"/> 3. Kaposi Sarcoma <input type="checkbox"/> 2. Oro-esophageal Candida <input type="checkbox"/> 4. Others <input type="text"/>
7.	Psychological information 1. Depression <input type="checkbox"/> 2. anxiety <input type="checkbox"/> 3. Others <input type="text"/>
8.	Any other chronic disease 1. HTN <input type="checkbox"/> 4. CCM <input type="checkbox"/> 2. DM <input type="checkbox"/> 5. Others <input type="text"/> 3. TB <input type="checkbox"/>
9.	How do you remember to take your pills Pill box <input type="checkbox"/> Cell phone alarm <input type="checkbox"/> Support/caregiver <input type="checkbox"/> Others <input type="checkbox"/>

10. What you think is/are primary obstacle(s) to take your pills regularly?

Participants

response.....

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11.

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What do you think are other obstacle(s)? (you can answer more than one with a tick mark)

a) Side effects of medication (nausea, vomiting)	
b) Transport problem –clinic too far from the home	
c) Lack of social and family support	
d) Drug burden (Use other chronic medication)	
e) Lack of understanding about disease (language/ knowledge).	
f) Cultural diversity (believe on tradition medication)	
g) Perception that HIV is incurable or non curable	
h) Short of regular food supply at home	
i) Problem with HIV disclosure (to employer)	
j) Economic (financial) limitation of unemployment	
k) Social engagement (attending funeral)	
l) Change in daily routine	
m) Forgot to take medication	
n) Migration one place to other	
o) Medication was stolen	
p) Couldn't get it from clinic/pharmacy	
q) Slept through the dose	
r) Forgot because drunk alcohol/took drugs	
s) Shared medication with others	
t) Uncertain about how to take medication	
u) Don't think medication was needed	
v) Don't want others to notice	
w) Didn't want to mix pills with alcohol/drugs	
x) Any other comments	