

Pre-Antiretroviral Therapy Attrition Prevalence and Associated Factors  
in Six Antiretroviral Therapy Centers in Sudan

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## ABSTRACT

### Pre-Antiretroviral Therapy Attrition Prevalence and Associated Factors in Six Antiretroviral Therapy Centers in Sudan

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**Introduction:** Attrition of patients from care is a critical barrier toward an effective scale-up of HIV services in Sub-Saharan Africa. As part of the HIV care cascade, pre-Antiretroviral Therapy (ART) care is an important pre-requisite for early initiation of ART and optimal clinical outcomes. However, the body of evidence on pre-ART care attrition is limited in Sudan. Baseline data on the scale of pre-ART attrition and associated factors was needed to develop interventions as part of the Sudan National AIDS and STI control Program (SNAP) HIV care scale-up process.

**Methods:** Cross-sectional study using a questionnaire and facility checklist as study tools. The Study tools were filled from primary (study index cases) and secondary data sources (Patient HIV Cards, Pre-ART and Tracking/Appointment Registers) collected between November 1<sup>st</sup>, 2012 and May 31<sup>st</sup>, 2013 of pre-ART patients in six ART facilities in Sudan. Prevalence of retention was estimated using crude proportions. Bivariate and multivariate logistic regression analyses were performed to determine the factors associated with pre-ART attrition. Qualitative assessment was also conducted using phone interviews to determine possible causes of attrition.

**Results:** We found 78.5% of newly diagnosed patients (n=497) were registered in HIV care with 233 patients enrolled in pre-ART care. Out of which 64.8% (95% Confidence Interval, CI 58.8–70.8) were lost to follow-up (LTFU). Only 48 (31.8%) of those LTFU were successfully traced and out of which 45.8% were dead. Nondisclosure of HIV status (Odds Ratio, OR 2.69, 95% CI 1.09–6.62) and advanced HIV clinical staging (OR 5.94, 95% CI 2.84–12.44) were factors significantly associated with attrition in multivariate analysis. Non-adherence to guidelines and poor utilization of monitoring and follow-up tools at facility level also seem to attribute to pre-ART attrition. Qualitative analyses found that patient relocation and perception of good health were the main reasons cited for attrition.

**Conclusion:** Existent high rates of attrition are related to disclosure status, advanced disease stage, residence in state with treatment services and patients understanding of the disease. These factors from patients' records can be used as "early warning default indicators" to initiate ART rapidly, provide intensive counseling or transfer to nearby treatment center which may reduce attrition. The national program will also need to make concerted efforts to strengthen pre-ART quality of care. This will require further evaluation in future studies.

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## Definitions of Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CD	Cluster of Differentiation
CI	Confidence Interval
CTX	Co-trimoxazole
pMTCT	Prevention of Mother to Child Transmission
FMoH	Federal Ministry of Health
HIV	Human Immunodeficiency Virus
LTFU	Loss to Follow-Up
OR	Odds Ratio
PI	Primary Investigator
PLHIV	People Living with HIV
Pre-ART	Pre-Antiretroviral Therapy
PTB	Pulmonary Tuberculosis
SAP	State AIDS control Program
SFPA	Sudanese Family Planning Association
SMoH	State Ministry of Health
SNAP	Sudan National AIDS and STI Control Program
SPSS	Statistical Product and Service Solutions
STI	Sexually Transmitted Infection
UW	University of Washington
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

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## INTRODUCTION

### Background and Significance

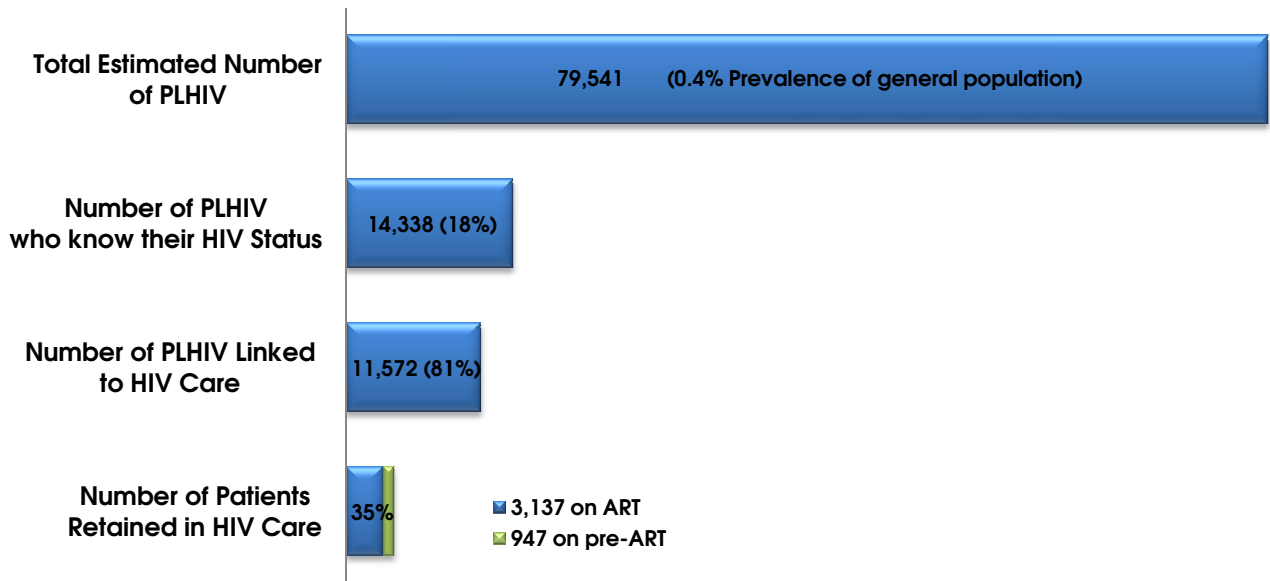
During the past decade, access to HIV/AIDS services has expanded dramatically in Africa. Sudan has a concentrated HIV epidemic with 0.4% HIV prevalence, a total HIV population of 79,541 and HIV incidence rate of 2,290 cases per year (SNAP 2013). HIV services have grown rapidly in the last five years to 143 Voluntary Counseling and Testing (VCT), 33 Antiretroviral Therapy and 250 Preventing Mother to Child Transmission (pMTCT) service delivery points managed through a national HIV program - Sudan National AIDS and STI Control Program (SNAP) with its 17 state office programs.

With the expanded services and HIV population in care, challenges such as ensuring pre-Antiretroviral Therapy (ART) care retention has proven challenging in many African countries. A systemic review of 28 articles and abstracts on pre-ART care retention in Sub-Saharan African (Rosen and Fox 2011) suggested that less than one-third of patients not yet eligible for ART when diagnosed are retained continuously in care. Another study in South Africa (Lessells, Mutevedzi *et al.* 2011) showed that about 45% of patients enrolled in pre-ART care (n = 4,223) returned to the clinic within 13 months. The proportion retained in care was highest amongst females and older age groups. No data on the scale of pre-ART attrition in North Africa and the Middle East is available to our knowledge.

A situational analysis in Sudan (SNAP/WHO HIV Cascade Analysis 2013) found that out of 11,572 People Living with HIV (PLHIV) ever linked to care, 3,137 (27%) and 947 (8.2%) were registered into 2012 ART and pre-ART care records respectively suggesting high attrition rates in both ART and pre-ART populations (Figure 1). No descriptive data on durations of default or loss to follow-up (LTFU) or populations type prone to default is available.

Several factors have been associated with pre-ART attrition. According to Mugglin, Estill *et al.* 2012 systemic review, higher rates of LTFU are reported among men, patients with low CD4 cell counts and patients of low socioeconomic status. While patients eligible for ART were less likely to become LTFU and were more likely to die.

**Figure 1: HIV Care (Test-Treat-Retain) Cascade in Sudan (SNAP 2013)**



2012 data from Omdurman AIDS Clinical Unit - largest ART center in Sudan - showed that 81% of newly HIV diagnosed cases were either in stages III or IV (SNAP 2013) similar to Sub-Saharan findings of Kigozi, Dobkin *et al.* 2009. Qualitative data (SNAP/WHO HIV Cascade Analysis in Sudan 2013) identified several attrition factors associated with HIV care (not disaggregated to pre-ART and ART care). These included HIV services related factors (location, crowdedness, long waiting hours, frequent required visits e.g. monthly collection of co-trimoxazole pills, poor quality of counseling, weak HIV educational/awareness sessions, and inactive follow-up or early detection of defaulters) and patient related factors (self-stigma, high mobility, travel costs).

In summary, the body of evidence on pre-ART care attrition is limited nationally. Moreover, Sudan is in the process of HIV care rapid scale-up to improve HIV care/treatment crises, and requires timely reliable data to understand causes and factors associated with the current weak performance on pre-ART and ART care to develop rapid interventions. This study build on to the existent literature base and support the national response to address pre-ART care.

**General Objective**

The general purpose of this study was to generate data on pre-Antiretroviral Therapy (ART) attrition rates and its associated factors in six ART centers in Sudan.

## **Specific Aims**

1. Determine the prevalence of pre-ART attrition in six ART facilities in Sudan: Omdurman Teaching Hospital, Bashayer Teaching Hospital and Bahri Teaching Hospital in Khartoum state; El-Obeid Teaching Hospital in North Kordufan state; Kassala Teaching Hospital in Kassala state and the Sudanese Family Planning Association clinic in Red Sea state.
2. Determine the associated factors (demographic, clinical and facility) with pre-ART attrition in these six ART facilities in Sudan.

## **METHODS**

### **Study Setting**

Pre-ART care is defined as the period between enrollment at an ART clinic and initiation of ART. Pre-ART care is offered in all 33 ART sites in Sudan using SNAP guidelines mainly adopted from the World Health Organization (WHO) guidelines. The model of pre-ART care includes counseling, disclosure, partner notification and testing, transmission risk reduction measures, assessment for ART eligibility (mainly by clinical staging due to unavailability of CD4 testing) and provision of co-trimoxazole (CTX) pills as a prophylaxis for opportunistic infections.

This study was conducted in six ART sites (Figure 2); three ART centers in Khartoum state (Omdurman Teaching Hospital, Bashayer Teaching Hospital and Bahri Teaching Hospital), one ART center in North Kordufan state (El-Obeid Teaching Hospital), one ART center in Kassala state (Kassala Teaching Hospital) and one ART center in Red Sea state (Sudanese Family Planning Association clinic). These facilities were selected based on their high HIV patient load. For instance, about 53% of pre-ART patients in Sudan are enrolled in Omdurman Teaching Hospital VCT/ART center (SNAP 2013).

### **Study Design**

The study was cross-sectional using a questionnaire comprising of two sections, open and closed ended questions (Appendix A) and a facility checklist (Appendix B) filled from primary (study index cases) and secondary data sources (clinic records such as Patient HIV Cards, Pre-ART and Tracking/Appointment Registers).

**Figure 2: Map showing the location of the Research ART Clinics within Sudan (Epi-Info)**



### **Study Population and Sample**

Pre-ART cases were defined as all HIV positive patients enrolled at an ART clinic before initiation of ART between the periods November 1<sup>st</sup>, 2012 and May 31<sup>st</sup>, 2013. The study time period was selected as convenience sample based on the use and availability of pre-ART registers during this time interval.

Epi-Info (Version 7) was used to estimate a cross-sectional study sample needed to detect an expected overall default prevalence of 40% (95% confidence level and 80% power). The required minimum sample was 214 and a total of 233 cases were found during the study timeline.

## **Outcome Variables**

Pre-ART patients' outcomes were defined as:

1. Retained in care: those did not miss their last scheduled clinic appointment (less than three days deviation).
2. Defaulted from care: those who missed their last scheduled clinic appointment for more than three days and less than 90 days.
3. LTFU: those who missed their last scheduled clinic appointments for more than 90 days with unknown outcomes.

## **Data Collection**

In each of the six ART clinics, the Primary Investigator (PI) trained and supervised two team members (mostly counselors) to collect selected variables (Table 1) depicting demographic and clinical status as structured close ended questions (section 1 of Appendix A) from Patient HIV Cards that are routinely kept in the ART clinic. Counselors were also trained to collect additional variables from a qualitative assessment using phone interviews with patients identified as LTFU (section 2 of Appendix A). Facility related factors were collected by the PI using a checklist that examined quality of service from facility registries, direct observation and interviews with the facility staff (Appendix B).

ART facility staff involvement in this study was important to facilitate future operational interventions (strengthen their research skills and utilization of data for improvement), ensure confidentiality and obtain reliable qualitative data based on the existent counselor-patient relationship.

Data anonymity and non-linkage with patient cards was ensured by coding of study cases in the study tool. The counselors however had a separate sheet that linked study index cases with patient files for reference during data review and cleansing (Appendix C). The data collected from all sites was then translated back to English, entered into the PI's password protected computer and analyzed by the PI. To reduce any possibility of data collection bias, the PI randomly listened to about half of the phone interviews (audio speaker mode) and conducted frequent verification from source documents. Any discrepancies found were reconciled.

**Table 1: Study Aims, Variable Definitions and Data Sources**

Study Component	Variable Definitions	Data Sources
<b>Study Aim 1:</b> Determine the prevalence of pre-ART attrition in six ART facilities in Sudan		
<b>Study Population</b>	<b>Pre-HIV Care</b> The period between testing for HIV and enrollment in HIV care	VCT Records and Pre-ART Register
	<b>Pre-ART Care</b> The period between enrollment at an ART clinic and initiation of ART.	Patient Card and Pre-ART Register
<b>Study Population Subgroups</b>	<b>Pre-HIV Care Attrition</b> Pre-HIV care patients who were not enrolled in care after HIV diagnosis	VCT records and Pre-ART Register
	<b>Retained in Pre-ART Care</b> Pre-ART cases who did not miss their last scheduled clinic appointment (less than three days deviation)	VCT records, Pre-ART Register, Patient Card and Tracking/Appointment Register
	<b>Defaulted from pre-ART care</b> Pre-ART cases who missed their last scheduled clinic appointment for more than 3 days and less than 90 days	
	<b>LTFU</b> Pre-ART cases who missed their last scheduled clinic appointment for more than 90 with unknown outcomes	
<b>Pre-ART Attrition Prevalence</b>	$\frac{\text{Number of patients who discontinue pre – ART care (Defaulter + LTFU)}}{\text{Total Number of patients in pre – ARTcare in the same time period}}$	Pre-ART register and Tracking/Appointment Register
<b>Study Aim 2:</b> Determine associated factors (demographic, clinical and facility) with pre-ART attrition in six ART facilities in Sudan		
<b>Demographic Factors</b>	Age, Gender, Marital status, State of Residence, Occupation, Education	Patient Card
<b>Patient Factors</b>	Pre-ART care entry point (self or medical referral), Clinical status (stage, CD4 count), Family disclosure status and other Factors identified from qualitative assessment	Patient Card, Counselor’s Records and Responses from open-ended interviews with pre-ART defaulters
<b>Facility Factors</b>	Quality of care (Adherence to pre-ART care national guidelines, Facility staff to patient number ratio and other factors identified from qualitative assessment	Facility Records, Direct observation and Responses from open-ended interviews with pre-ART defaulters and facility staff

### Data Analysis

Descriptive analysis was used to define study population characteristics. Prevalence of retention at facility level was estimated using crude proportions. Study pre-ART subpopulations included patients who retained in pre-ART care while “defaulters” and “LTFU” were grouped

under “discontinued care” since they showed similar characteristics. Bivariate logistic regression analysis (crude odds ratios) was carried out to compare both pre-ART population groups against demographic and clinical variables. Variables exhibiting significance (P-value < 0.05) or borderline significance (P-value < 0.1) with the outcome were entered into multivariate logistic regression models to determine the adjusted odds ratios (ORs). Facility factors were assessed based on the data quality of the records and utilization of tools. A score of poor, fair or complete denoted the quality of care. This was then evaluated using bivariate correlation. Quantitative data analyses were performed using IBM Statistical Product and Service Solutions (SPSS Version 20.0).

Qualitative data was transcribed in Arabic and translated into English. Interviews were systemically reviewed and coded into Microsoft Office Excel (Edition 2010). Common themes were identified and axial coding was used to categorize and subcategorize findings.

### **Ethical Considerations**

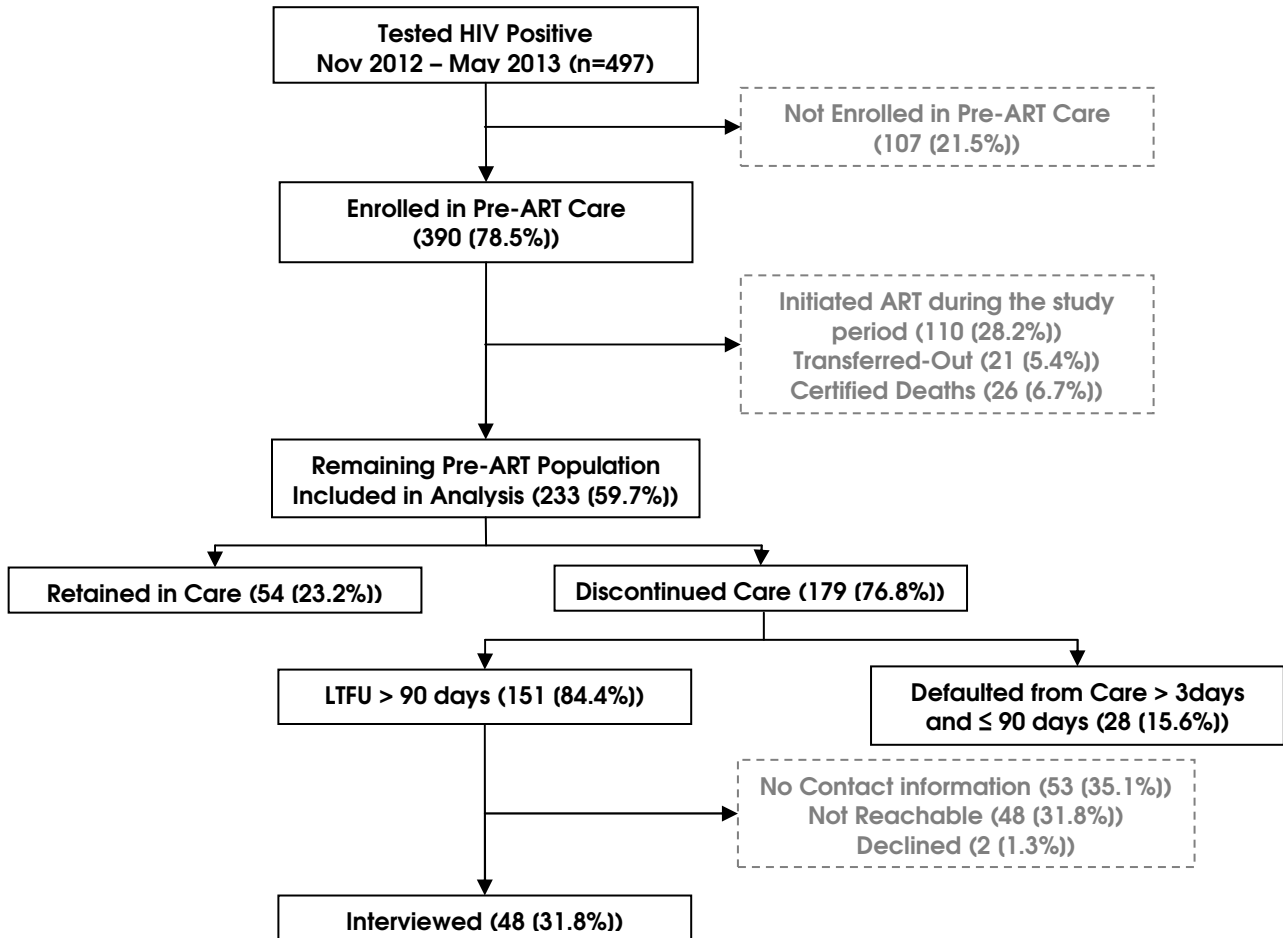
The ethical approval for the study was obtained from Human Subject Division, University of Washington (No. 45643). The study was designed as part of a validation exercise of the HIV test, treat and retain cascade situational analysis conducted by SNAP in collaboration with WHO and was exempted from ethical approval from the FMOH National Health Research Ethics Committee. The data in this study did not include patient identifiers and will be destroyed after five years.

### **RESULTS**

Between November 2012 and May 2013, 497 patients tested positive for HIV at these six ART facilities in Sudan. The entry points for the HIV positive population were either VCT referral (22.6%) which includes partner testing or testing children of infected parent(s); self-referral (24.9%) or medical referral (52.5%). 390 patients (78.5% [95% CI 74.6 – 82.3]) enrolled in pre-ART care. Out of which 110 (28.3%) started ART during the study period, 21 (5.4%) were registered as transfer-out and 26 (6.7%) as certified death cases and were excluded from the study population. The remainder 233 cases were sufficient to meet the required sample size and were included in the analysis. 141 patients (60.5% [95% CI 53.7 – 67]) were eligible for ART.

Out of the study sample, we attempted to contact all LTFU patients or their treatment supporters through phone for qualitative assessment. However, only 48 (31.8%) LTFU patients were successfully interviewed since phone contacts were not available for about two-thirds of the cases or were not reachable via phone due to mainly inactive phone numbers (Figure 3).

**Figure 3: Enrollment of the Study Population**



**Characteristics of the Study Population**

The study pre-ART population had 134 (57.5%) men with median age of 34 years (IQR 27-42 years). It is important to indicate that pediatric cases represent only 4.7% of the study population. Half of the 233 patients were married (49.3%) and more than one-third (37.7%) had primary level education. The majority of employed cases (83.2%) were nonprofessional.

Across the six facilities, the gender distribution varied from one clinic to another. Yet, the figures were small thus the variation may not be significant. We observed for instance a high

proportion of female cases in El-Obeid, SFPA and Bahri ART clinics, while Kassala ART clinic had the highest proportion of male cases (78.8%). It is important to mention that only 3.6% female cases were referred from pMTCT sites since the guideline recommends ART management within pMTCT sites except in smaller sites with no ART available. We also noted that the study population from the Red Sea SFPA was younger (27.8 years mean age) compared to other ART clinics.

Another important difference was that higher levels of education and employment status were observed among patients enrolled in ART clinics within Khartoum state compared to other states. This may be explained by the fact that Khartoum is the country's capital and major cities usually offer better job and education opportunities. The basic summary information on key patients sociodemographic characteristics stratified by ART facility are provided in Table 2.

### **Attrition in Pre-ART Care**

Around two-thirds (151) of the cases enrolled in the study were lost to follow-up (64.8% [95% CI 58.8 – 70.8]). While 28 (12% [95% CI 8.2 – 16.3]) defaulted from pre-ART care (6.4% for > 3days and ≤ 30 days; and 5.6% for > 30 days and ≤ 90 days).

Variations in the pre-ART care attrition rate were noted across the six facilities (Figure 4). The lowest attrition rate was noted in Bahri ART clinic (27%) while Omdurman ART clinic had the highest proportion of 76%.

### **Factors Associated with Attrition in Pre-ART Care**

#### **Demographic/Patient Related Factors**

Bivariate analysis findings showed illiteracy, primary level education, nonprofessional employment status and patients who live in another state where the ART clinic is located were more likely to default from care. There was also a statistical significant correlation between pre-ART care attrition and WHO stage III or IV patients and those who did not disclose their HIV-positive status to family members (Table 3).

Only nondisclosure of HIV status and advance clinical staging associations with pre-ART attrition remained significant in the multivariate model, while residence showed borderline association (Table 3).

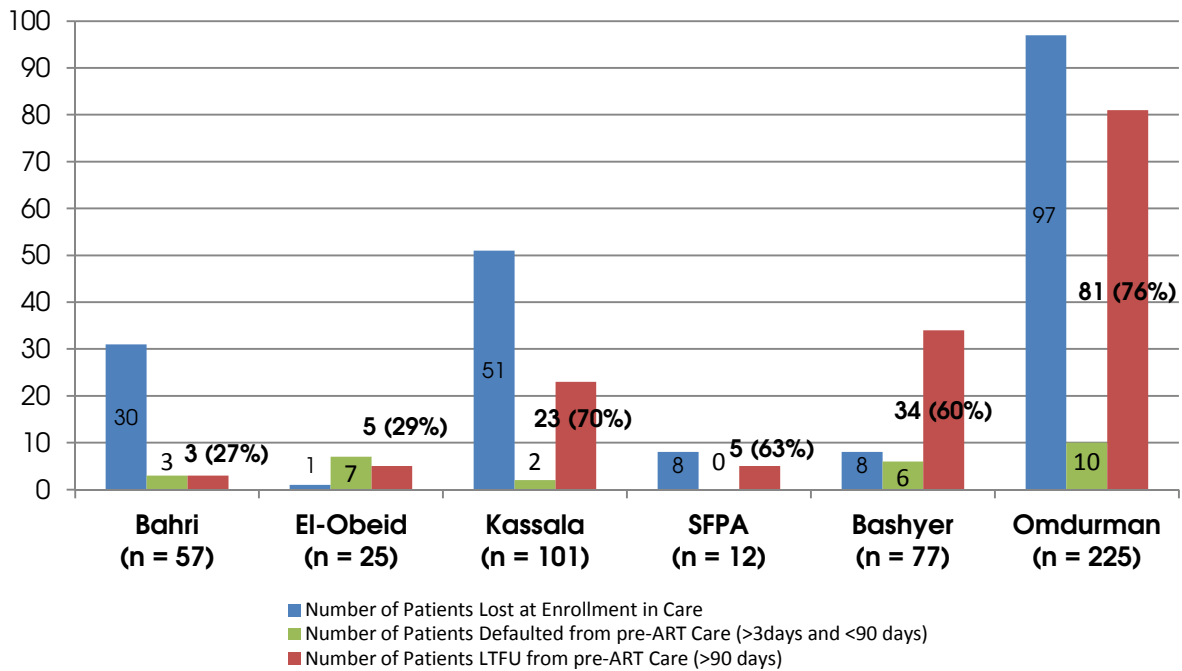
**Table 2: Descriptive Characteristics of Patients Enrolled in Pre-ART Care across 6 ART Facilities in Sudan (November 2012 - May 2013)**

		ART Facility by State						
		North Kordufan	Kassala	Red Sea	Khartoum		Total	
		El-Obeid (n = 17)	Kassala (n = 33)	SFPA (n = 8)	Bahri (n = 11)	Bashayer (n = 57)	Omdurman (n = 107)	(n = 233)
<b>Sex</b>	<b>n (%)</b>							
Female		12 (70.6)	7 (21.2)	6 (75)	8 (72.7)	21 (36.8)	45 (42.1)	99 (42.5)
Male		5 (29.4)	26 (78.8)	2 (25)	3 (27.3)	36 (63.2)	62 (57.9)	134 (57.5)
<b>Age</b>	<b>Median (IQR)</b>							
		33 (29-38)	32 (24-41)	26.5 (24-35)	32 (26-56)	38 (31-45)	32.5 (27-40)	34 (27-42)
<b>Marital Status</b>	<b>n (%)</b>							
Single		1 (7.1)	16 (50)	2 (28.6)	1 (9.1)	17 (30.4)	14 (16.3)	51 (24.8)
Married		9 (64.3)	8 (25)	2 (28.6)	6 (54.5)	27 (48.2)	55 (64)	107 (51.9)
Divorced/Separated /Widow		4 (28.6)	8 (25)	3 (42.9)	4 (36.4)	12 (21.4)	17 (19.8)	48 (23.3)
<b>Education</b>	<b>n (%)</b>							
Illiterate		9 (69.2)	11 (33.3)	6 (85.7)	7 (70)	15 (26.8)	22 (23.4)	70 (32.9)
Khalwa <sup>a</sup> /Primary		3 (23.1)	15 (45.5)	1 (14.3)	1 (10)	14 (25)	57 (60.6)	91 (42.7)
Secondary or higher		1 (7.7)	7 (21.2)	0 (0)	2 (20)	27 (48.2)	15 (16)	52 (24.4)
<b>Employment</b>	<b>n (%)</b>							
Not employed		7 (53.8)	10 (30.3)	5 (71.4)	7 (63.6)	18 (32.1)	29 (31.2)	76 (35.7)
Nonprofessional		5 (38.5)	16 (48.5)	2 (28.6)	4 (36.4)	25 (44.6)	62 (66.7)	114 (53.5)
Professional		1 (7.7)	7 (21.2)	0 (0)	0 (0)	13 (23.2)	2 (2.2)	23 (10.8)

**Abbreviations:** SFPA, Sudanese Family Planning Association; IQR, Interquartile Range.

<sup>a</sup>Informal elementary Islamic schools

**Figure 4: Pre-ART Care Attrition by ART Facility**



Immunological factors were not assessed in this analysis as only 29 (12.4%) of the study population had a CD4 test done. Although other clinical factors were also associated with pre-ART care attrition such as Diarrhea and >10% weight loss, however these variables were strongly correlated with the WHO clinical stage. They were not considered as variables in the model because they are components of WHO staging and cannot be analyzed as separate indicators.

Qualitative assessment found that nearly half (45.8%) of the LTFU patients successfully traced were deceased, while 10 (21%) patients reported moving to another location mainly due to work related reasons. 6 (12.5%) patients transferred to the ART clinic in their original state of residence (silent transfer) and another 6 patients said they did not need to show up to the clinic since they are feeling better. Out of these last 6 cases, 4 were buying CTX from other pharmacy outlets and one patient reported taking traditional medicine. 2 (4.2%) patients suffered from CTX side effects. Only one patient reported being too ill to attend to the clinic and another lacked transport money.

Denial was also cited by 2 patients for missing their scheduled appointments as stated by one 40 years old female:

*“I don’t have the disease (HIV) – I’m fine and don’t need any treatment”*

**Table 3: Logistic Bivariate/Multivariate Analysis for Factors Associated with Pre-ART Attrition**

<b>Variable</b>	<b>Pre-ART Attrition (%)</b>	<b>OR (95% CI)</b>	<b>P-value</b>	<b>Adjusted OR<sup>a</sup> (95% CI)</b>	<b>P-value</b>
<b>Sex</b>					
Female	75.8%	Ref.			
Male	77.6%	1.11 (0.60 – 2.1)	0.740		
<b>Age</b>					
≤ 25	76.1%	Ref.			
26 – 35	74.7%	0.93 (0.40 – 2.15)	0.861		
≥ 36	79.6%	1.23 (0.54 – 2.81)	0.629		
<b>Marital Status</b>					
Single	72.5%	Ref.			
Married	76.6%	1.24 (0.58 – 2.66)	0.578		
Divorced/Separated /Widow	81.2%	1.64 (0.63 – 4.24)	0.308		
<b>Education</b>					
Illiterate	84.3%	3.09 (1.31 – 7.27)	0.010	1.56 (0.53 – 4.59)	0.423
Khalwa/Primary	81.3%	2.51 (1.16 – 5.43)	0.020	1.94 (0.71 – 5.29)	0.197
Secondary or higher	63.5%	Ref.			
<b>Employment</b>					
Not employed	72.4%	1.68 (0.63 – 4.47)	0.296	2.10 (0.51 – 8.66)	0.304
Nonprofessional	84.2%	3.43 (1.29 – 9.11)	0.013	3.12 (0.74 – 13.13)	0.122
Professional	60.9%	Ref.			
<b>Residence in the Same State Where the ART Clinic is Located</b>					
Yes	74.6%	Ref.			
No	87.8%	2.45 (0.91 – 6.60)	0.076	2.89 (0.99 – 8.42)	0.051
<b>Entry Point</b>					
VCT-referral	72%	Ref.			
Self-referral	80%	1.56 (0.63 – 3.84)	0.338		
Medical-referral <sup>b</sup>	78.4%	1.42 (0.66 – 3.03)	0.370		
<b>Family Disclosure Status</b>					
Yes	67.4%	Ref.			
No	84.9%	2.72 (1.18 – 6.26)	0.019	2.69 (1.09 – 6.62)	0.032
<b>WHO Clinical Stage</b>					
Stage I & II	58.2%	Ref.			
Stage III & IV	88.7%	5.65 (2.9 – 10.9)	<0.001	5.94 (2.84 – 12.44)	<0.001

**Abbreviations:** ART, Antiretroviral Therapy; OR, Odds Ratio; CI, Confidence Interval; Ref., Reference; VCT, Voluntary Counseling and Testing which include referral from other VCT facilities, partner testing or testing children of infected parent(s); WHO, World Health Organization

<sup>a</sup>Adjusted odds ratios are only presented for variables included in the multivariate model.

<sup>b</sup>In-patients, Out-patients (including private clinics), Tuberculosis and pMTCT referral.

## Facility Related Factors

Four ART clinics out of the six included in this study scored poor on pre-ART Registers and HIV Cards data quality. Patient Tracking Registers were not utilized in three ART clinics to trace pre-ART defaulters. While in the other clinics the tracking registers were incomplete and proper codes were not recorded to indicate the attrition outcome. Appointment Books were only available/utilized in two ART clinics. Omdurman ART clinic was the only clinic where the Patient Appointment cards were not well utilized and patients needed to memorize their next appointment date. In addition, non-standardized or weak archiving/filing system for pre-ART patients HIV Card was also observed in El-Obeid, SFPA, Bashayer and Omdurman ART clinics. For instance, files were stacked alphabetically, by gender or according to patients' recent visits.

Bivariate analysis revealed no statistical correlation between the attrition rate and the ART clinic quality of care score (Table 4).

**Table 4: Bivariate Correlation Analysis for Facility Factors Associated with Pre-ART Attrition**

	<b>Pearson Correlation</b>	<b>P-value</b>
<b>Adherence to National Guidelines</b>	<b>- 0.739</b>	<b>0.093</b>
<b>HIV Card Data Quality/Completeness</b>	<b>0.404</b>	<b>0.427</b>
<b>Pre-ART Register Data Quality/Completeness</b>	<b>- 0.146</b>	<b>0.783</b>
<b>Staff-to-Patients Ratio</b>	<b>0.552</b>	<b>0.256</b>
<b>Utilization of Tracking Register</b>	<b>- 0.630</b>	<b>0.180</b>
<b>Utilization of Appointments Book</b>	<b>- 0.207</b>	<b>0.694</b>
<b>Utilization of Appointment Cards</b>	<b>- 0.513</b>	<b>0.298</b>

Nonetheless, we identified a number of facility related factors that may contribute to the pre-ART care attrition. Quality of care evaluation in these ART facilities revealed that although defined guidelines exist, huge gaps remain in implementing these guidelines. This was seen for instance in the ART centers of Kassala, Bahri and Bashayer where Patient HIV cards were filled for newly diagnosed patients in their third visit with counselors' own rationale that a newly diagnosed patient needs to indicate commitment for follow-up demonstrated by fulfilling criteria such as ability to attend all three post counseling sessions. Another example of implementation

weakness observed was that routine tracing of pre-ART defaulters was not carried out on a regular basis in all facilities nor was it conducted as per SNAP guidelines. Defaulters were traced at least one week accounting for working days lag from guideline recommendation which is three days. Even though all phone costs are provided by the State AIDS control Program (SAP), only one phone call is usually made to trace defaulters instead of three as per national guidelines.

The quality of HIV education also seems to attribute to pre-ART care attrition, a 29 years old male patient stated:

*“Is the immunity test (CD4) available now? I didn’t know I had to return to the clinic without it”*

## **DISCUSSION**

To our knowledge, this is the first study that reported retention rates among patients enrolled in pre-ART care in Sudan. Our findings suggest that 78.5% of newly diagnosed patients are linked to HIV care, consistent with the national figure of 81% (SNAP 2013) and higher than enrollment rate of 57% as reported by Micek, Gimbel-Sherr *et al.* 2009. The differences could be explained by the definition of pre-ART enrollment for instance, some facilities register pre-ART patients in their third visit which could cause selection bias, or register all patients without necessarily initiating CTX. The difference could also be explained by the proximity of the testing site to treatment clinic. One facility in particular had a low enrollment rate of 47.7% and was explained by the fact that most of patients tested were inpatients and it was difficult to link them to care after their discharge. More research is needed to explore definitions of enrolments in sites and understand enrollment pathways for patients, in addition examine the profile of 21.5% of the patients who did not enrolled into pre-ART care following diagnosis.

The proportion of pre-ART patients retained in care in these facilities was very poor (23.2%) compared to about 80% pre-ART care retention suggested by Geng, Bwana *et al.* 2013. We also noted that facilities under study performance varied as reflected by the wide range in pre-ART attrition rates. This can be justified by the different approaches in each clinic to identify and follow-up pre-ART patients. Furthermore, we noted that the higher patient load a facility had, the higher proportions of pre-ART population discontinued care. We were unable to demonstrate significant correlation because of the small number of clinics included in this study but this could be explored in future research.

The factors that were significantly associated with pre-ART care discontinuation included WHO clinical staging, disclosure status and residence in state with treatment services. The major contributory factor to the high pre-ART attrition was HIV disease severity. Around 81% of pre-ART attrition was observed among ART eligible patients in our study which was substantially higher than the reported 26% in Uganda (Amuron, Namara *et al.* 2009). This broad variation in the results can also be explained by the different study approaches for each research since Amuron, Namara *et al.* 2009 was designed as a two years prospective cohort study. Advance clinical staging was associated positively with attrition in agreement with previous findings from literature that showed active Pulmonary Tuberculosis (PTB), prolonged unexplained fever and severe bacterial infections, which are components of late clinical staging, to be associated with pre-ART attrition (Tayler-Smith, Zachariah *et al.* 2011). Consequently, a number of those identified as LTFU might actually be unascertained deaths and we believe this may contribute most to the pre-ART attrition observed. Moreover, the mortality rate of 45.8% reported among LTFU patients supports the late suggestion. Even though, it is important to point out that the 68% untraceable LTFU population may express different characteristics than those interviewed.

Similarly, our data add to those from other studies where disclosure status is associated with attrition (Sarna, Sebastian *et al.* 2013). Non-disclosure of positive HIV status leads to weak social support system to seek health care and treatment.

The actual distance between patient's residence and the hospital has been shown to be directly correlated with pre-ART attrition in other studies (Hassan, Fielding *et al.* 2012), similar to our findings where we found patients who live in the same state where the ART clinic is located are less likely to default from pre-ART care. Although of borderline significance, this finding could explain the high attrition rate in Omdurman ART clinic since the proportion of cases who reside out state was the highest (29%) compared to the other ART clinics.

Other factors including age, gender, marital status, education level, employment status, CTX initiation and entry points to care showed no association in multivariate model with pre-ART attrition unlike findings from other studies in Africa (Larson, Brennan *et al.* 2010; Losina, Bassett *et al.* 2010; Kenneth, Mohammed *et al.* 2012). These factors may not be directly comparable to other literature due to the different population characteristics of this study.

Because of the small sample of pediatric patients in this study, we could not determine the rate of LTFU among this group in contrast to an estimated range of 0% – 37% loss to follow-up among children in Mugglin, Wandeler *et al.* 2013 systemic review.

We were unable to demonstrate a significant association between the quality of care per facility and pre-ART attrition as exhibited in other studies (Scott, Zweigenthal *et al.* 2011). This difference could be attributed to the sample of facilities included in this study or the scoring system used to assess quality of care. Nevertheless, we identified a number of facility related factors that may contribute to the pre-ART care attrition. We found non-adherence to the existing monitoring and follow-up guidelines or use of tools, and contact information completeness that impeded identifying defaulters early and easily. In addition, findings from the qualitative assessment of pre-ART cases who discontinued care indicated weaknesses in patients' understanding of pre-ART care and presence of self-denial that reflect the quality of services. Although we anticipated that a lag or delay in pre-ART care to be associated with attrition, this could not be validated because of the uniformity of findings since most of the patients (76%) were found to start pre-ART care in the same day of diagnosis. Again, this finding could be a result from selection bias based on practice of registration of pre-ART patients who demonstrated high attendance.

Weaknesses in the quality of service delivery could be explained by the fact that pre-ART care is usually ignored at program level because routine reporting of care outcomes is traditionally restricted to ART patients. This aspect should be addressed critically since most of newly diagnosed patients are in advanced stages of disease in much need of pre-ART care and rapidly initiated on ART. The national program will need to make concerted efforts to strengthen pre-ART quality of care by allocating additional resources on pre-ART service delivery. ART clinic staff needs to understand their roles and responsibilities in the context of pre-ART care which could be addressed through improved training. The clinic staff also needs to record correct and comprehensive addresses and contact information of patients to enable timely tracing of defaulters, and most importantly build a rapport with them and earn their trust. Our findings are important to guide facility staff to identify pre-ART patients more likely to discontinue care to provide additional effort to prevent this outcome.

New and existing protocols of pre-ART service delivery must be adapted on a national and state level. We also recommend regular periodic follow-up and audits of records and filing/archiving of data at the State AIDS control Program (SAP) and facility level. In addition, facility staff needs to critically review their performance in pre-ART care on a regular basis for quality improvement.

These results should be viewed in light of the study's limitations. Firstly, the cross-sectional study methodology does not indicate causality but association. Secondly, the quality of data collected from secondary sources was incomplete. Missing data may bias the distribution of the study findings especially the population characteristics. Even though this could have been substantiated from the primary data sources (pre-ART LTFU cases), their number was too few to fill the gap. Thirdly, the utilization of facility staff to collect data had the strength of providing research ownership, while on the other hand using different data collectors from each facility runs the risk of affecting the study tool's reliability as well as introduction of bias. However, this effect was minimized by the use of a guideline to standardize the questions, training of data collectors by the PI and provision of random oversight/listening into interviews to monitor quality and provide guidance where needed. Fourthly, qualitative data collection could be affected by recall and respondent bias. We believe this was limited in most facilities because of low patient load to counselors (recall bias) and the existent relationship between the facility staff and patient (respondent bias). Fifthly, generalizability of findings from these ART centers to others may not be possible because of potential variation of PLHIV and state population characteristics such as health seeking culture and existent HIV stigma within community in these states compared to others. Lastly, the censoring of patients in some facilities who should be registered in care immediately following HIV diagnosis and weaknesses in recording transfer-out and/or self-transfer may introduce misclassification bias during analysis. The scale of this bias was limited by active tracing of defaulters to determine their status.

None of these limitations is sufficient to alter one of the core finding of this study, which is the majority of patients are lost from pre-ART care. In addition, the study main strength includes involvement of the center staff which will facilitate the utilization of the clinic's data for future operational interventions and ensured reliability and confidentiality of the data. The study also

covered six ART facilities across four states and results are likely to reflect the operational reality.

In conclusion, our study suggests that attrition from care is a major problem during the pre-ART period. The majority of patients lost to follow-up were eligible for ART and therefore we believe that death may explain an important part of pre-ART care attrition, while perception of good health may be attributed to attrition among ineligible patients. The findings can be used as early default indicators. Existent high rates of attrition were related to disclosure status, advanced disease stage, residence in state with treatment services, patients understanding of the disease and facility preparedness to identify defaulters effectively. These factors from patients' records can be used as "early warning default indicators" to initiate ART rapidly, provide intensive counseling or transfer to a nearby treatment center and effective defaulter identification and tracking which may improve pre-ART retention. These interventions need to be evaluated in further studies.

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APPENDIXES

Appendix A: Study Questionnaire

<input type="checkbox"/>	Khartoum الخرطوم			
<input type="checkbox"/>	Kassala كسلا	الولاية	<input type="text"/>	مركز العلاج ART Facility
<input type="checkbox"/>	North Kordufan شمال كردفان	State		
<input type="checkbox"/>	Red Sea البحر الأحمر			

<input type="text"/>	<input type="text"/>	<input type="text"/>	Date التاريخ	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Patient code رمز المريض
السنة	اليوم	الشهر								

Demographic Factors العوامل الديموغرافية												
Section 1: Close-ended questionnaire	<input type="checkbox"/>	Not applicable غير قابل للتطبيق		الحالة الاجتماعية Marital status	العمر (سنة) Age (years)	<input type="checkbox"/> ذكر Male	<input type="checkbox"/> انثى Female	الجنس Gender	<input type="checkbox"/> Yes نعم <input type="checkbox"/> No لا الإقامة في نفس الولاية التي يقع فيها مركز العلاج Residence in the same state where the ART clinic is located			
	<input type="checkbox"/>	Married متزوج										
	<input type="checkbox"/>	Never married لم يسبق له الزواج										
	<input type="checkbox"/>	Separated منفصل										
	<input type="checkbox"/>	Divorced مُطلق										
	<input type="checkbox"/>	Widow أرمل										
	<input type="checkbox"/>	المهنة Occupation		غير متعلم Illiterate خلوّة Khalwa أساس Primary ثانوي Secondary جامعي Undergraduate فوق جامعي Graduate			التعليم Education					
	<input type="text"/>	<input type="text"/>	<input type="text"/>	تاريخ الإلتحاق بالرعاية الصحية Date of enrollment in HIV care			<input type="text"/>	<input type="text"/>	<input type="text"/>	تاريخ تشخيص الإصابة بفيروس نقص المناعة Date of HIV diagnosis		
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	<input type="checkbox"/>	Self-referred (طوعي) تحويل ذاتي			نقطة الدخول Entry point	عدد جلسات الإرشاد النفسي التي تلقاها المريض بمركز العلاج Number of counseling sessions completed in current ART center						
<input type="checkbox"/>	:Referred by تحويل بواسطة											

العوامل المتعلقة بالمريض Patient Factors							
<input type="checkbox"/> Yes نعم	<input type="checkbox"/> No لا	مكاشفة الأسرة Family disclosure status		عدد الزيارات للعيادة خلال الفترة المحددة Number of clinical visits during study period			
<input type="checkbox"/> Monthly شهري	<input type="checkbox"/> Three monthly كل 3 أشهر	<input type="checkbox"/> Six monthly كل 6 أشهر	<input type="checkbox"/> Other أخرى	موعد زيارة العيادة الذي حدده مقدم الخدمة الصحية Provider request clinic visits in file	<input type="checkbox"/> Yes نعم	<input type="checkbox"/> No لا	فحص CD4 خلال 30 يوماً من الإلتحاق بالرعاية الصحية CD4 testing done within 30 days of enrollment
المرحلة السريرية عند تشخيص الإصابة WHO stage at HIV diagnosis			فحص CD4 عند تشخيص الإصابة CD4 count at HIV diagnosis				
<input type="checkbox"/> Tuberculosis درن	الوزن كجم Weight Kgs	<input type="checkbox"/> حمى أكثر من 3 أسابيع Fever > 3 weeks	الأمراض الإنتهازية/الحالة الصحية Opportunistic Infection/Medical conditions	<input type="checkbox"/> Yes نعم	<input type="checkbox"/> No لا	سعال أكثر من 3 أسابيع Cough > 3 weeks	صرف السبترين Received CTX
:Other conditions حالات/أمراض أخرى							

بيانات المقابلة الهاتفية مع المرضى المتخلفين عن العيادة Phone Interview Data with Traced defaulter					
<input type="checkbox"/> لم يتم الوصول للمريض أو الداعم له Neither patient nor treatment supporter could be reached					
<input type="checkbox"/> تم الوصول إلى المريض أو قريب/الداعم له Patient or treatment supporter contacted					
<input type="checkbox"/> أجريت المقابلة معه Interviewed			<input type="checkbox"/> رفض إجراء المقابلة Declined		
End time زمن نهاية المقابلة		Start time زمن بداية المقابلة		Date التاريخ	
				يوم	شهر
				سنة	
:Interviewee name اسم الكادر الذي أجرى المقابلة					
لماذا لم تعد لأخر موعد زيارة حُدد لك بالمركز؟ Why did you not return for your last schedule appointment?					
<input type="checkbox"/> Lack of transport money عدم توفر تكلفة الحركة			<input type="checkbox"/> Deceased توفي المريض		
<input type="checkbox"/> Feeling better تحسنت صحته			<input type="checkbox"/> Buy CTX from pharmacy يتلقى العلاج من الصيدلية		
<input type="checkbox"/> Taking traditional medicine يتناول علاج بلدي			<input type="checkbox"/> Side effects آثار جانبية		
العنوان Location	<input type="checkbox"/>	انتقل إلى مكان آخر Moved to another place		<input type="checkbox"/> Unknown location إنتقل إلى مكان غير معروف	
<input type="checkbox"/> ART center مركز العلاج			<input type="checkbox"/> Moved to another clinic تحول إلى مركز علاج آخر		
:Other (specify) أخرى (حدد)					
عوامل مرتبطة بالمريض Patient Factors					
عوامل مرتبطة بمركز العلاج Facility Factors					

## Appendix B: Facility Quality Checklist and Pre-ART Attrition Prevalence

ART Facility:

State:

Date:

Number of Patients registered at the facility						Pre-ART				ART			
Number of Facility Staff (throughout the study period)						Clinicians							
						Counselors							
						Lab technicians							
						Pharmacists/dispensers							
						Clerks							
						Others							
<b>Number of patients registered in HIV care (November 1<sup>st</sup>, 2012 – May 31<sup>st</sup>, 2013)</b>													
November		December		January		February		March		April		May	
Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care	Tested positive for HIV	Enrolled in care
<b>Number of patients enrolled in pre-ART care (November 1<sup>st</sup>, 2012 – May 31<sup>st</sup>, 2013)</b>													
November		December		January		February		March		April		May	
Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART
<b>Number of patients on pre-ART care who missed appointments (&gt; 3days and ≤ 90 days) (November 1<sup>st</sup>, 2012 – May 31<sup>st</sup>, 2013)</b>													
November		December		January		February		March		April		May	
Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART	Eligible for ART	Not eligible for ART
> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days	> 3 days ≤ 30 days >30 days ≤ 90 days

**Number of patients on pre-ART care who are lost to follow-up (> 90 days)  
(November 1<sup>st</sup>, 2012 – May 31<sup>st</sup>, 2013)**

<b>November</b>		<b>December</b>				<b>January</b>				<b>February</b>				<b>March</b>				<b>April</b>				<b>May</b>					
<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>		<b>Eligible for ART</b>		<b>Not eligible for ART</b>	
Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU	Dead	LTFU
<b>Adherence of Health Care Providers to pre-ART care national guidelines</b>				<b>Copies of guidelines</b>																							
				<b>Patient HIV Card</b>																							
				<b>Pre-ART Register</b>																							
				<b>Other registers (ART, Monthly and Referral Forms)</b>																							
				<b>Patient flow</b>																							
				<b>Others</b>																							
<b>Availability of tools and their use to identify/trace defaulters</b>				<b>Patient Appointment card</b>																							
				<b>Appointment book</b>																							
				<b>Patient Tracking Register</b>																							
				<b>Others</b>																							

