ASSESSMENT OF LOSS-TO-FOLLOW-UP & ASSOCIATED FACTORS AMONG ART CLIENTS IN SWAZILAND

FINAL REPORT

MOH/WHO

December 2010

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Assessment of Loss-To-Follow-Up (LTFU) and associated factors among patients enrolled in ART Swaziland

Executive Summary

Background: Swaziland which has one of the highest HIV prevalence globally has implemented ART program since 2004, with about 56,587 patients ever put on ART whereas about 47,241 (83%) were still on treatment as at December 2009. This implies that about 17% of patients were lost to follow-up or dead. By the end of 2009, there were 30 ART initiation sites and 50 refill sites aimed at bringing ART services nearer to patients, and reduce rate of dropout from care.

Method: This was a retrospective operational research assessing the proportion of, and reasons for "loss-to-follow-up"(LTFU) among ART clients who dropped out of care within two years of ART initiation. A list was generated from facility databases of 946 patients initiated on ART during the period January to December 2007 in four Swaziland's referral hospitals, who met the study case definition for LTFU. Clients were contacted by phone and asked to participate in the study. Those who accepted to participate were visited at home or at pre-arranged locations by trained data collectors and administered a pre-piloted questionnaire. Analysis was done using Excel.

Results: Among the 946 originally classified as LTFU, 332 (35%) were reported dead, 428 (45%) could not be traced, while 186 (20%) were found alive. Among the 186 found alive, nearly 2/3 of them were either officially transferred out without proper documentations or had self-transferred to other ART sites and were still on ARV. The remaining 1/3 (n = 64) were found to have discontinued their ARV for periods equal or longer than 90 days from their last clinic appointment. The "untraceable" group made up a significant proportion of the original LTFU group. Being a subset of the original LTFU, the "untraceable" group were likely to comprise of clients who have died, those alive and still on ART as well as those who are alive but have discontinued their ART. In this study, the "untraceable" group combined with the "confirmed" LTFU, together form the "true" LTFU (diagram 1).

The peak period for loss was during the first 6 months of ART initiation (41%), while 71% of the losses occurred within the first 12mths. Of the 64 (confirmed LTFU) patients who were alive but had discontinued treatment, about 75% of them had been lost for a period of 12-24 months as at the time of the study. Major determinants for loss were family and social factors (57%), personal factors (33%), and programmatic factors (10%). Among the social factors, lack of transport money (34%), poor family support (30%) and lack of food to eat while on ART (14%) were the main reasons for the discontinuation of the treatment

About 59.2% (n = 38) of the 64 who were alive but had discontinued ARV treatment, reported that they had treatment supporters. Among these, 55% reported that their supporters either advised them to restart ART or reported them to clinic staff, while 45% of supporters did nothing when they learnt that their clients had stopped treatment.

About 90% of the 64 confirmed LTFU had disclosed their HIV status and 75% of the disclosures were to partners and/or parents. Respondents were more likely to disclose to more than one person. Over a quarter (28%) of the 64 confirmed LTFU clients reported ARV side effects, with males reporting higher (11/27 or 40.7%) than females (7/37 or 18%).

Conclusion: Over a third of all ART patients originally classified as LTFU were reported dead, while about 7% were alive but had discontinued treatment. Most frequent reasons for loss were lack of transport money to keep appointments, lack of food to eat while on ART and lack of family support. Program related reasons were the least reported cause for treatment discontinuation. Most respondents had treatment supporters almost half of whom took no action when patients stopped their ARV. There is need to clearly define the roles of treatment supporters, and educate them on these roles. Up-grading more ART refill sites in rural/remote areas to ART initiation/monitoring status will likely address the transport constraint of ART patients and probably reduce drop from care. Further, given the large proportion of patients that could not be traced, we recommend review and strengthening of the patient follow-up system through defaulter tracing at the national ART program.

1.0 BACKGROUND

1.1. The HIV epidemic in Swaziland

The first case of HIV was identified in Swaziland in 1986. Since then the number of newly infected persons has risen yearly. The HIV prevalence measured among pregnant women attending antenatal clinics grew from 3.9% in 1992 to 42% in 2008, being the highest in the world[1]. In 2006/7 it was estimated, through the Demographic Health Survey, that the HIV prevalence in the general population aged 2 years and above, was about 18,8% (22.1% for women and 14.4% for men).[2]

Presently, it is estimated that about 191,141 people in the country are living with HIV and AIDS, and according to the 2010 projections, about 65,418 to 70,000 of these are in need of ARVs. About 14,090 and 3,078 new infections are expected in adult and paediatric populations respectively in 2010. The total number of AIDS related deaths among adults and children are estimated at 9,512 and 2,783 respectively in 2010.[3]

Over 47,000 people were on ART at the end of December 2009. Of these, 4,772 were children, according to the ART annual report.[4]

1.2. ART and Adherence

The National ART programme started in Swaziland, January 2004, at Mbabane Government Hospital. This was followed by a rapid scale up of ART services to respond to the large numbers of PLWH who needed treatment. By the end of 2009, there were 30 ART initiation sites, with 50 refill sites. The increase in ARV refill sites, most of which are in the rural areas, was a response to the increasing numbers of people lost to follow-up in the ART Programme. The aim of this scale-up was to bring ART services nearer to patients, and help reduce the rate of patient dropouts from treatment.

At the time of this study, the eligibility criteria for ART in Swaziland was CD4 count <200 cells/mm^3 irrespective of the WHO clinical stage; WHO clinical stage 3 with CD4 <350cells/mm^3 or WHO clinical stage 4 irrespective of CD4 count; plus patients' attending at least two adherence counselling sessions, with a treatment supporter and expressing willingness and readiness to start ART.

The need for rapid scale up of ART services in Swaziland did not allow adequate time for the establishment of proper monitoring systems to capture all necessary patient information that will allow a proper follow up of patients enrolled in the ART

[1] 10th Round of National HIV Sero-surveillance among Women Attending Antenatal Care at Health Facilities, 2006
[2] Demographic and Health Survey, Swaziland, 2007
[3] Swaziland HIV Estimates and Projections.2007
[4] ART Annual Report

programme. The inability of health facilities to track patients who defaulted on ART, due to human resource and/or logistic constraints, resulted in loss of substantial number of patients from care. As a result, clinical outcome, including death, could not be determined for a sizable proportion of patients.

The ART annual report for end of 2008 showed that since January 2004, when the programme started, about 56,587 patients have ever been initiated on ART whereas about 47,241 (83%) were still on treatment by end of December 2009. This implies that about 17% of patients were lost to follow-up or dead. The cohort analysis for patients enrolled in 2007 showed that some ART sites had lost about 25% of their patients since they started providing ART services.

Reasons for these patient losses from care are poorly documented. Based on individual facility patient outcome tracking, about 49% of the patients classified as lost to follow-up were reported dead.

1.3. Assumption

This study assumes that only about half of the clients classified as "lost-to-follow-ups" (LTFU) are "true" LTFU, while the other half are probably dead.

2.0 AIMS AND OBJECTIVES

2.1. 1. Aims

The aims of this operational research are to determine the proportion of clients classified as lost-to-follow-up (LTFU) that are "true LTFU", and the factors associated with LTFU among HIV positive patients on ART in Swaziland.

2.1.2. Objectives

The objectives of the study are to determine -

- The proportion of patients lost to follow-up within the first two years on ARV treatment – 2007 to 2009.
- The rate of loss to follow up, within first two years on ART, among the cohort of patients initiated on ART in 2007
- The proportion of clients classified as LTFU that is 'true' LTFU and the proportion that is dead
- The factors associated with LTFU among HIV patients on ART in Swaziland

2.2. Research Question

What proportion of clients classified as "lost-to-follow-ups" are 'true' LTFU?

2.3. Definition of terms

According to the study -

2.3.1. "Lost to follow-up" is not keeping ART refill appointment for a period of 90 days or longer from the last booked refill appointment date, yet not classified in patient clinical outcome as 'dead' or 'transferred-out'.

2.3.2. "Confirmed lost to follow-up" is not keeping ART refill appointment for a period of 90 days or longer from the last booked refill appointment date, and being found alive but not on ART.

2.3.3. "**True lost to follow-up**" means not keeping ART refill appointment for a period of 90 days or longer from the last booked refill appointment date, and being found alive but not on ART; or not being traceable to allow confirmation of definitive clinical outcomes such as 'dead' or 'transferred-out'.

3.0 METHOD

3.1. Study design

This operational research was conducted as a retrospective observational study using a cross-sectional study design. Following the selection of the study sample, a semi-structured questionnaire was used to capture "at-point" data relating to client's last ARV refill appointment and factors relating to respondents' failure to remain in care. There was no intervention or prospective follow-up on the participants and no control groups were involved.

3.2. Site Selection Criteria

Public health facilities offering ART services in Swaziland that met the following criteria were selected:

- Had provided ART services for at least 3 years
- Following up at least 4,000 clients on ART as at the time of the study
- Had reliable clinical database (client files, registers and electronic system)
- Having enough human resource capacity and skills to participate in the study.

3.3. Study Sites

Four hospitals were involved in the study. A regional hospital that offers ART services and met the site inclusion criteria was selected from each of the four geographic regions of the country. These were Mbabane Government Hospital, Raleigh Fitkins Memorial Hospital, Hlathikhulu Government Hospital and Good Shepherd Hospital.

3.4. Study population

The study population comprised of all HIV positive patients initiated on ART at the selected study sites during the period 1st January to 31st December 2007.

3.4.1. Sample population

The sample population comprised of all HIV positive clients initiated on ART at the selected study sites during the period under review - 1st January 2007 to 31st December 2007 – who, as at the time of commencing the study, 1st December 2009, had missed clinic appointment for 90 days or longer from the last booked appointment date. Of the 1126 names generated from the facilities' databases as clients lost to follow-up (LTFU) 946 (84%) of them were eligible for the study (Annex 1).

The sample size for the study was determined using the formula for sample size estimation for one group population proportion –

$$N = p*q/\sigma^2_p$$

Including a 10% adjustment for incomplete and inaccurate data or failure to trace respondents, the final calculated sample size was 288 + 28 = 316.

3.4.2. Sampling

In all the participating sites, the sample population was selected from a cohort of patients initiated on ART during the period 1st January 2007 to 31st December 2007. A list of all patients who met the study definition of "lost to follow-up" was generated from the current ART electronic medical register in each study site. The lists from the electronic registers were verified against the paper records at the respective study sites. Of the 1126 names generated from the facilities' databases as clients lost to follow-up (LTFU), 946 (84%) of them were found eligible for the study (Annex 1). At each study site, sequential study numbers were allocated to the identified study participants in order of enrolment into the study.

3.5.1. Eligibility criteria for study participants

Patients initiated on ART during the period 1st January 2007 to 31st December 2007 at the participating ART facilities, who met the study definition of "lost to follow-up" were eligible for the study.

All eligible participants also had to provide informed consent (age 18 years and above) or had to consent by proxy via parents, legal guardians or care-givers (for participants aged less than 18 years).

3.5.2. Inclusion criteria

- HIV positive client
- Initiated on ART during the period 1st January to 31st December 2007
- Missed refill appointment for 90 days or longer from last appointment date
- Willingly consented to participate in the study

3.5.3. Exclusion criteria

- Not tested HIV positive (e.g. clients put on post exposure prophylaxis, PEP)
- Initiated on ART outside the study period
- Missed refill appointment for less than 90 consecutive days from last appointment date
- Unwilling to participate in the study despite adequate information provided
- Too ill to participate in the study

3.6. Data collection

3.6.1 Identification and selection of human resources

The principal investigator was identified from the National ART Programme. A study coordinator was contracted for the duration of the study. From each participating ART site, one medical officer was selected to act as the site study supervisor; two expert clients were chosen as the questionnaire administrators, and a data clerk was selected to be responsible for daily data entry from PDA into a computer.

All staff involved in the study underwent a 2-day training on the research protocol, questionnaire administration and data collection using PDA. The training also included piloting the questionnaire in selected ART sites that were not participating in the study.

3.6.2. Logistic arrangements

Five vehicles with drivers were provided. One vehicle was used by the study coordinator for supervisory visits to the study facilities, while a vehicle was attached to each study facility and used to visit participants at home or at their preferred location, for questionnaire administration. The vehicles were used throughout the duration of the research.

Nine mobile phones and air-time vouchers were provided for calling potential study participants. Each study site had two mobile phones – one phone was permanently at the study facility while the other was used by the field officer to maintain constant communication with the facility while out at the field. Another phone was with the

study coordinator for communication with all the four study facilities and the four teams of field officers.

Questionnaires, consent forms and the study information leaflet (in both English and SiSwati), were available at the sites at all times.

3.6.3. Assessment of LTFU among ART patients

Electronic files of patients who were initiated on ART between 1st January 2007 and 31st December 2007 were reviewed to identify those who failed to keep scheduled appointments for 90 days or more during the course of 2 years (and had not restarted ART as at the time of data collection). A list of these "LTFU" patients was generated from the electronic medical register and compared with paper-based records at the study sites. The enlisted patients were contacted through phone calls to ascertain whether they were alive and agreed to participate in the study. Those patients that could not be contacted via their landline and mobile phones were traced using their physical addresses. Where applicable, further attempts to trace and/or obtain information about potential participants were made using the contact details of their treatment supporters as captured in the facility databases. Those reported dead by their treatment supporters were recorded as dead and more information sought regarding whether or not they were still taking ARVs as at the time of death.

For those who agreed through the phone to participate in the study, an appointment date for a visit at home or at any preferred location was set and a detailed physical address was obtained to allow visit by the trained questionnaire administrators. During the visit, detailed information about the research was provided to the participant using participant's information leaflet. The participant's information leaflet used in participants' education contained a concise explanation of the objectives of the study; its benefits to the prospective participant, and participant's rights to or not to participate in the study. All concerns and questions raised by the participant were addressed. Following this, an informed consent was obtained from participant before questionnaire administration. The consent form was in both SiSwati and English for participants' convenience.

3.6.4. Administration of the Questionnaire

Data were collected using a close-ended semi-structured questionnaire which was translated to SiSwati and back translated to English, and was test-piloted in two health facilities that were not involved in the study. The questionnaire was entered in a PDA which was used for the actual data collection by the field officers. Data collection using PDA was decided on because it was anticipated to be less time consuming, less prone to human errors, and data collected would be easily exported into Excel database without mistakes, hence, ensuring data accuracy from collection to analysis. The main variables collected by the researchers were participant's demographic, baseline CD4 cell count

and WHO clinical staging, and information on participant's adherence to ARV, including disclosure of HIV status to family members and others.

Face to face interviews were conducted and data entered direct into the PDA. Information collected was checked for completeness by the questionnaire administrator before leaving the interview site. Upon return to the respective study site, the medical doctor at the site cross-checked the data captured in the PDA to confirm completeness and accuracy.

3.6.5 Ensuring Data Quality

Data quality was ensured via the following –

- The use of standardized predetermined semi-structured questionnaire
- Use of expert clients - who were both educationally qualified and experienced in facility data collections - as data collectors
- Two-day training of the data collectors on the questionnaire and logistics of data collection were conducted to further improve their data collection skills
- Practical training of the data collectors on the use of PDA for data collection was undertaken
- Piloting of the questionnaire at two facilities not involved in the actual study – and validating the questionnaire based on the findings of the pilot
- Using the same data collectors for the pilot further enhanced their skills and proficiency for the actual study
- Data collection tools were reviewed with the statistician at the Monitoring and Evaluation department of the Ministry of Health for quality assurance
- Having the questionnaire both in English and SiSwati languages for participants' preferences, understanding and user-friendliness
- On-going supervision of the data collection process by the doctors at the ART sites, the Principal investigator and study coordinator.
- Use of PDA also ensured data quality by eliminating data entry errors while transferring from paper questionnaires to the computer. Data captured with PDA was exported directly to Excel database daily by the data clerk.

3.6.6. Validity

Validity, defined as the degree to which the result of a measurement (test, procedure, finding, or deduction) actually and truly reflects the exact state of the phenomenon being measured, was ensured in this study through the following -

- Strict application of predetermined inclusion and exclusion criteria for both study sites and study samples
- Use of standardized and pre-piloted close-ended questionnaire on all respondents for uniformity in data collection

- Assessing the same parameter by rephrasing some questions at different points of the questionnaire to determine consistency in participants' responses
- Using multiple questions to assess a given parameter of interest in the questionnaire
- Allowing participants option of preferred language, either English or SiSwati, to enhance understanding and accuracy in response
- Using properly trained and qualified data collectors questionnaire administration
- Using the same trained data collectors at a given study site for the entire data collection process eliminated inter-collector errors and enhance validity
- Continued supervision and verification of both the data collection process and the collected data by the ART doctors at the study sites, the Principal Investigator and the Research Coordinator

3.6.7. Data analysis

The Excel spread sheet was used to conduct basic descriptive statistical analysis with assistance from the M&E unit of the Ministry of Health.

4.0 ETHICAL CONSIDERATION

4.1. Ethical clearance

Ethical clearance from the Science and Ethics Committee of the Ministry of Health was sought and obtained prior to the start of the research. A letter of approval to conduct the study was issued by the Committee.

4.2. Informed consent

Written informed consent was obtained from the participants. Participants aged 18 years and above signed their own consents while consent was obtained by proxy from parents / guardians / care-givers to those aged below 18 years. Refusal to participate in the study did not affect the clinical care provided to such patients. To ensure confidentiality, no questionnaire had participant's names, and all collected data were analysed in group.

4.3. Psychosocial support for emotional trauma

Provisions were made to address the psychosocial needs of emotionally traumatised relatives of deceased patients enlisted for the study. Relatives of deceased patients who were emotionally traumatised by inquiring about the deceased were arranged to receive counselling and support from the regional psychologists nearest to them. Due arrangements were made with the regional psychologists to provide these services should the need arise.

Provisions were also made for counselling and debriefing of any data collectors who might become emotionally traumatised on learning of the death of some of their clients during the data collection process. The management and duration of these counselling and support services were left to the professional discretion of the psychologists.

5.0. IMPLEMENTATION PLAN AND TIME FRAME.

The duration of the operational research was 12 weeks; that included data collection, data analysis, report writing and sharing the findings with national authorities and stakeholders.

6.0. LIMITATIONS OF THE STUDY

Being a retrospective study, recall bias might have been introduced by failure of participants to accurately remember the facts surrounding their stopping ARVs. It was difficult to reach some potential participants lost to follow-up due to lack or change of contact details. Also, participants might not have provided full and accurate information for fear of reprimand by the study team despite reassurances against this.

7.0. BENEFITS OF THE STUDY

It is hoped that the results of this operational research will inform and guide program direction and implementation. Lost-to-follow-up patients who were located were encouraged to return to the health facility for step-up adherence counselling and possible re-initiation on ART if willing to re-enrol into care.

8.0. RESULTS

8.1. Categories of patients originally classified as LTFU

Table 1: Categories and Sub-categories of clients classified as LTFU

Categories	Sub-categories	Numbers	Percentages
1. Alive (n=186), 19.7%	Confirmed as LTFU	64	6.76 %
	Transfer out	75	7.92 %
	Refused to participate	15	1.59 %
	Incomplete data for analysis	7	0.7 %
	Out of the country	25	2.64 %
2. Dead (n=332), 35.1%	Dead + information from relatives	287	30.33 %
	Dead + no information	45	4.76 %
3. Untraceable (n=428), 45.2%	Untraceable	428	45.2 %
	Total	946	100%

Table 1 shows the 3 major categories of clients originally classified as “Lost-to-follow-up” (LTFU). These include clients who were found alive (19.7%), those who were reported dead (35.1%), and those who could not be traced or the “untraceable” (45.2%).

The alive group is composed of 2 sub-groups of patients - (i) those who were alive but had stopped their ARV and (ii) those who were alive and were still on ARV because they either self-transferred to other facilities, or because they were officially transferred out but were not captured in the facility’s database as such. Those participants who were found alive but who had discontinued their ARVs for a period of 90 days or longer are considered as the “confirmed” lost-to-follow-up (6.76%). The dead group also comprised of 2 sub-groups – (i) patients who were confirmed dead but the study was able to obtain basic information about them from relatives (30.33%) and (ii) patients who were confirmed dead but there were no reliable persons to provide information about them (4.76%).

The patients who were “untraceable” made up a significant proportion (45.2%) of the original LTFU group. Being a subset of the original cohort classified as LTFU, the “untraceable” group is likely to comprise of patients who have died, those transferred out without documentation, those alive and on ART as well as those who may be alive but have discontinued their ART.

The “untraceable” group combined with the “confirmed” lost-to-follow-up group are together classified as the “true” lost-to-follow-up.

The table 1 and Figure 1 show that among the 946 clients eligible for the study, 25 (2.64%) were out of the country during the study period and so could not be interviewed; 15 (1.59%) declined to participate; while 7 (0.7%) had incomplete data and were not included in the analysis.

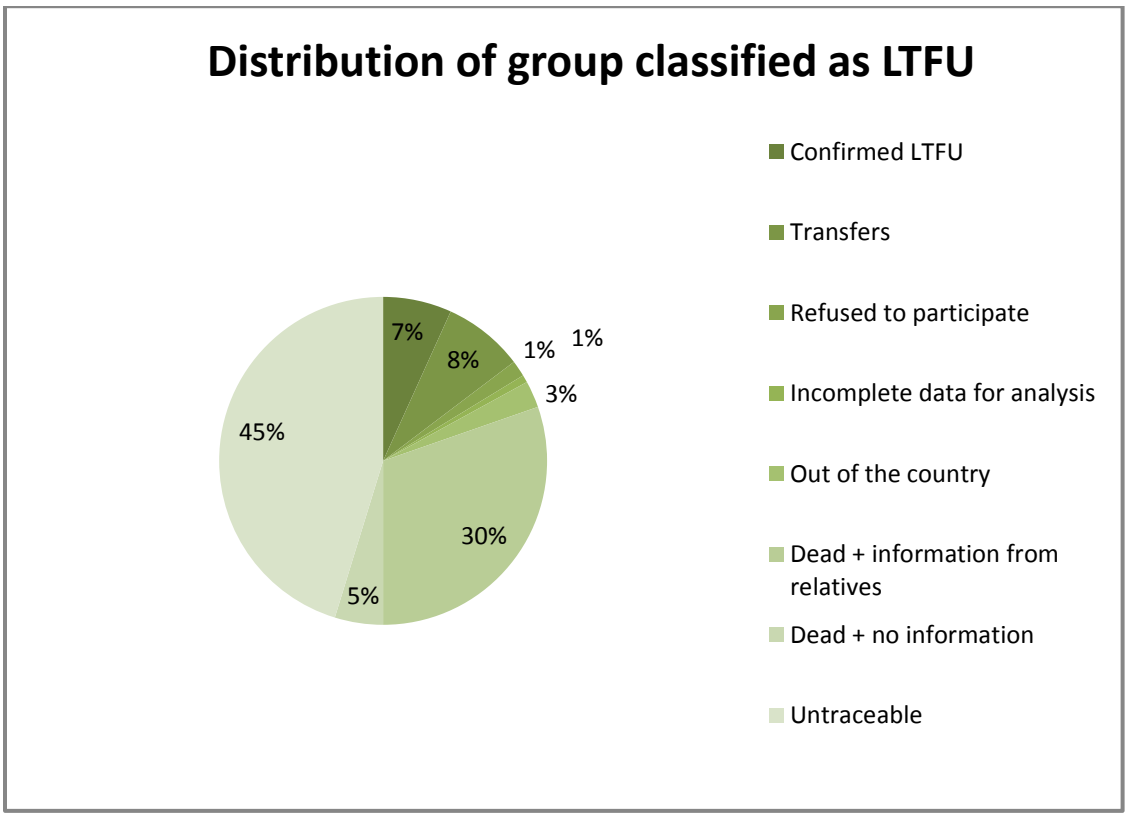

Figure 1: Distribution of the group originally classified as LTFU

Diagram 1: Breakdown of the original LTFU cohort

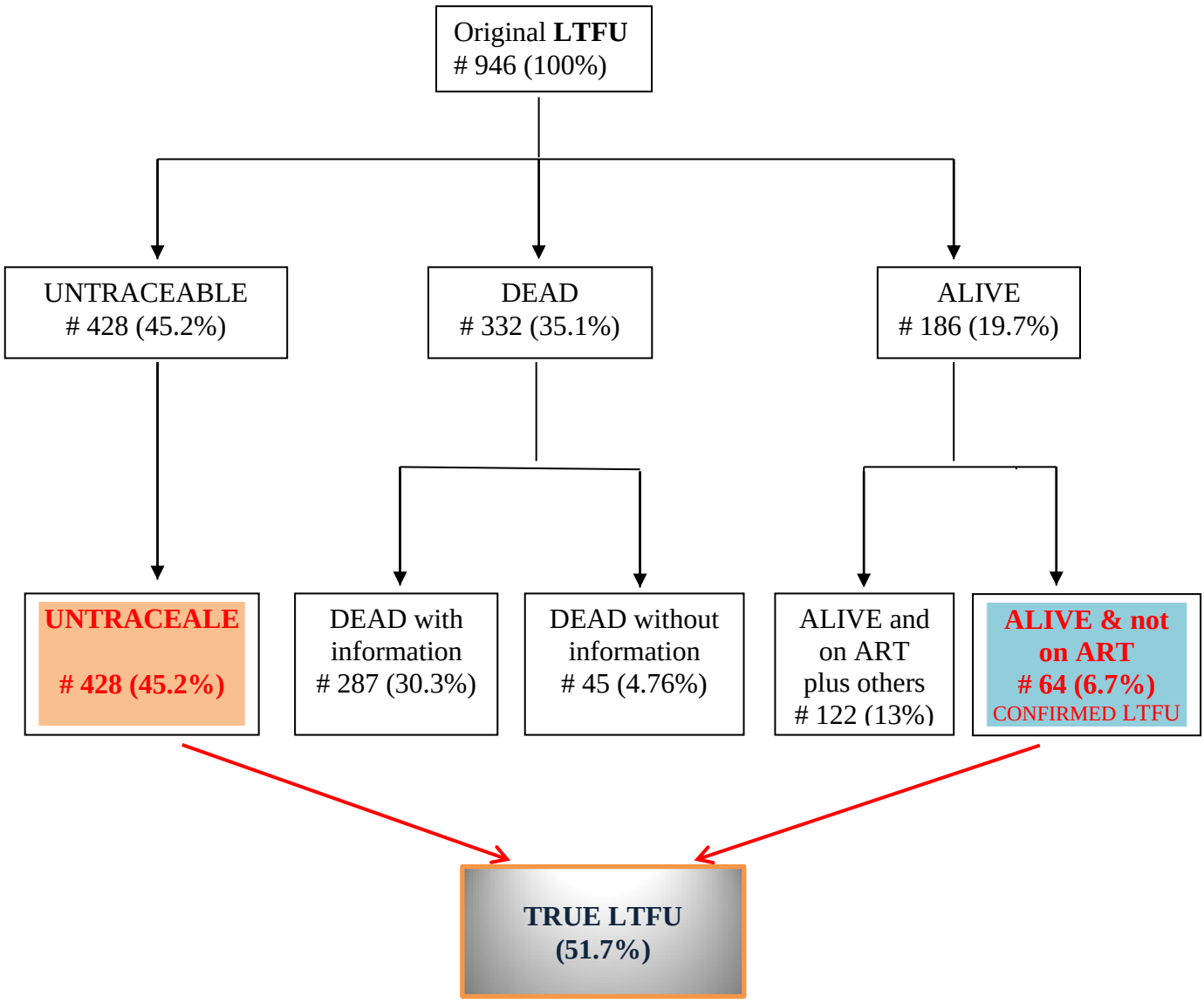

Diagram 1 further illustrates the breakdown of the cohort of 946 clients originally classified as lost-to-follow-up. Those who could not be traced (n = 428) plus those confirmed to be alive but had discontinued their ARVs (n = 64) together constitute the "true LTFU" (n = 492), and account for over half (51.7%) of the group originally classified as LTFU.

8.2. Rate of LTFU among study cohort

Table 2: Rate of LTFU among patients initiated on ART 24 months or longer

Facility	Number of clients initiated on ART from 1st Jan to 31st Dec 2007 by facility	Total # of clients lost to follow-up from 1st Jan 2007 to 1st Dec 2009			Calculated Rate of lost to follow-up	
		Confirmed LTFU	Untraceable	Confirmed LTFU plus untraceable (true LTFU)	Using only confirmed LTFU	Using true LTFU (confirmed LTFU plus untraceable)
MGH	1330	11	267	278	0.8%	21%
RFM	1134	22	64	86	1.9%	7.6%
GSH	1103	20	74	94	1.8%	8.5%
HGH	690	11	23	34	1.6%	4.9%
All	**4257**	**64**	**428**	**492**	**1.5%**	**11.6%**

The true LTFU rate (using "confirmed LTFU" plus the "untraceable" as the numerator) equals 11.6% or 116 per 1000 patients per 24 months of ART initiation.

8.3. Duration on ART before dropping out of care among confirmed LTFU

Table 3: Proportion of loss from care by duration on ART among confirmed LTFU patients

Duration on ART (months) before loss	Number of LTFU	Percentage LTFU
<6mths	26	40.7%
6 to 12mths	19	29.7%
13 to 24mths	12	18.7%
Above 24mths	6	9.4%
Unspecified	1	1.5%
Total	64	100.00%

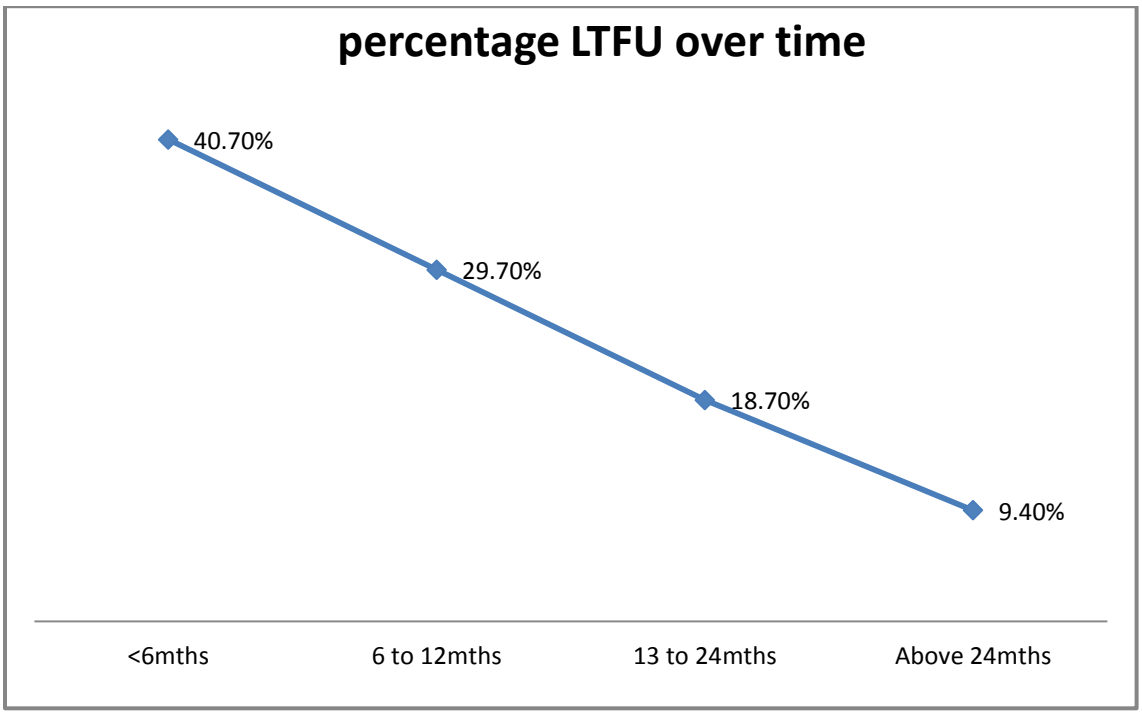

Figure 2: Percentage distribution of confirmed LTFU by duration on ART

Table 3 and figure 2 show that the greatest proportion of drop from care (n = 26; 40.7%) among the confirmed LTFU patients occurred within less than 6 months of initiating ART, while less than a third of the respondents (n=19, 29.7%) were on ART for a period of between 6 and 12 months before dropping out. Cumulatively, about 71% of ART drop-outs among the study subjects occurred within the first 12 months of starting treatment. Patients who had been on ART for longer than 24 months constituted less than a tenth (n=6; 9.4%) of all confirmed LTFU clients. As patients stayed on ART longer, the likelihood of their dropping out of care gradually reduces.

8.4. Total duration of lost-to-follow-up among confirmed LTFU patients

Table 4: Average length of time lost to care among confirmed LTFU patients

Duration in months of Loss-to-follow-up	Number	Per cent
<6mths	11	17.2 %
6 to <12mths	5	7.8 %
12 to < 24mths	22	34.4 %
24mths/above	26	40.6 %
Total	64	100 %

Table 4 and figure 3 indicate that as at the time of the study, 40.6% (n=26) of respondents had been lost to follow-up for a period of 24 months or longer, while 75% (n=48) were lost to follow-up for a total period exceeding 12 months.

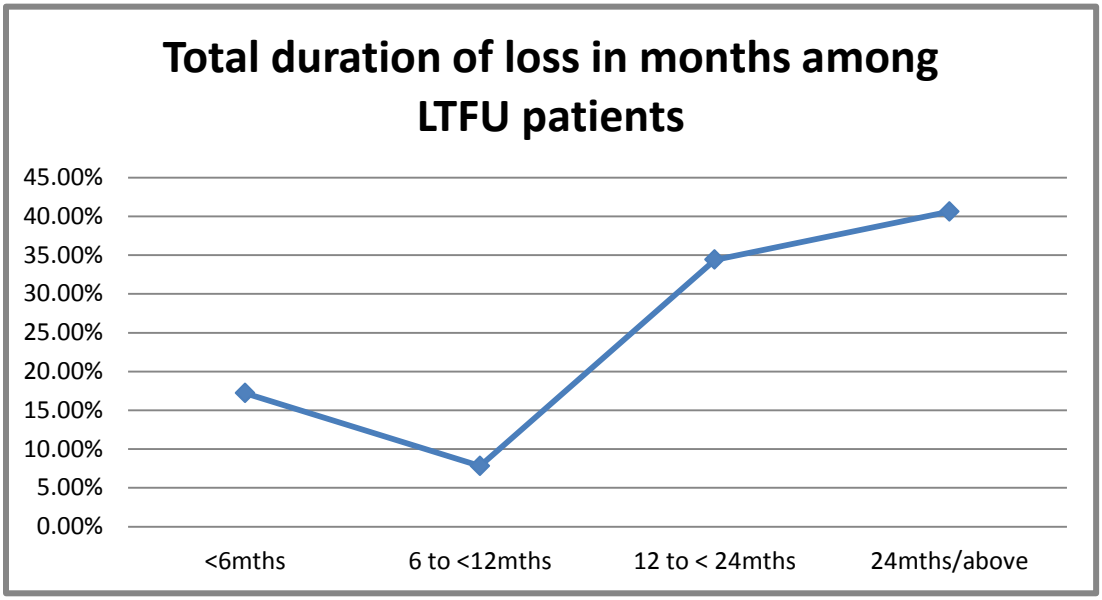

Figure 3: Duration of loss in months among confirmed LTFU patients

8.5. Reasons for stopping ART among confirmed LTFU patients

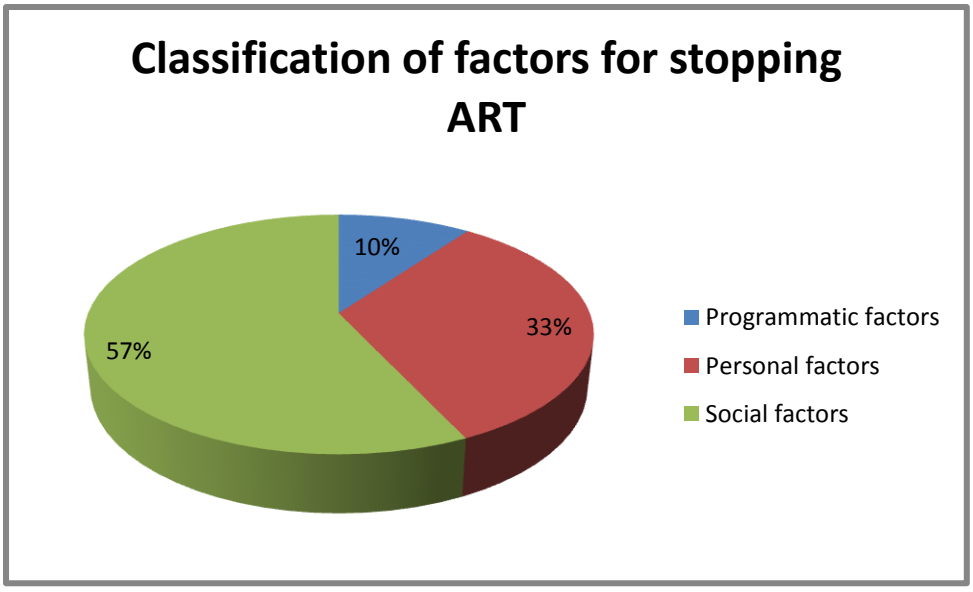

Figure 4: Major determinants of stopping ART among confirmed LTFU patients

Table 5: Reported reasons for stopping ART among confirmed LTFU patients

Categories of reason	Reported Reasons for stopping ART	Number	Percentage
1. Personal reasons for stopping ART	No belief in ARV	8	**12.5%**
	Traditional healer better	6	**9.4%**
	Prayer cures HIV	2	3%
	Don't care for my life	1	1.5%
	Did not disclose my status	7	11%
	Felt better so stopped	2	3%
	Immune boosters better	2	3%
	Too many pills to take	0	0%
	Emigrated out	4	6.3%
2. Social/Family reasons for stopping ART	Lack of transport money	22	34.4%
	Lack of food to eat while on ARV	9	14%
	Lack of family support	19	30%
	Stigma from family and friends	1	1.5%
	Lack/change of care-giver	2	3%
	Problems at workplace	3	4.7%
3. Program related reasons for stopping ART	Stigma/discrimination from healthcare worker	1	1.5%
	Drug stock-out at ART site	0	0%
	Treatment complications/side effects	9	14%

Figure 4 shows the major determinants of LTFU. Family and social factors (57%) constituted the most frequently reported reasons by respondents for stopping treatment, about a third (33%) of the reported reasons were related to personal factors, while only 1 in 10 of the reasons identified by respondents was related to the ART Program.

About 12.5% of respondents reported that they had no faith in ART, with some believing rather in traditional medications (9.4%), prayers (3%) or immune boosters (3%), while one in every ten of the respondents reported non-disclosure of their HIV status as reason for their dropping out of treatment. Respondents did not report pill burden as a reason for stopping ART

Prominent among the social reasons for stopping ART were lack of transport money (34.4%) and lack of family support (30%), while lack of food to eat while taking ARV medications accounted for 14%.

About 14% of respondents reported treatment complications and/or drug side effects as their reason for stopping ART. This was the main program-related reason reported by patients. None of the respondents reported drug stock-out, while only 1.5% reported stigma and discrimination from healthcare providers (table 5 and figure 5).

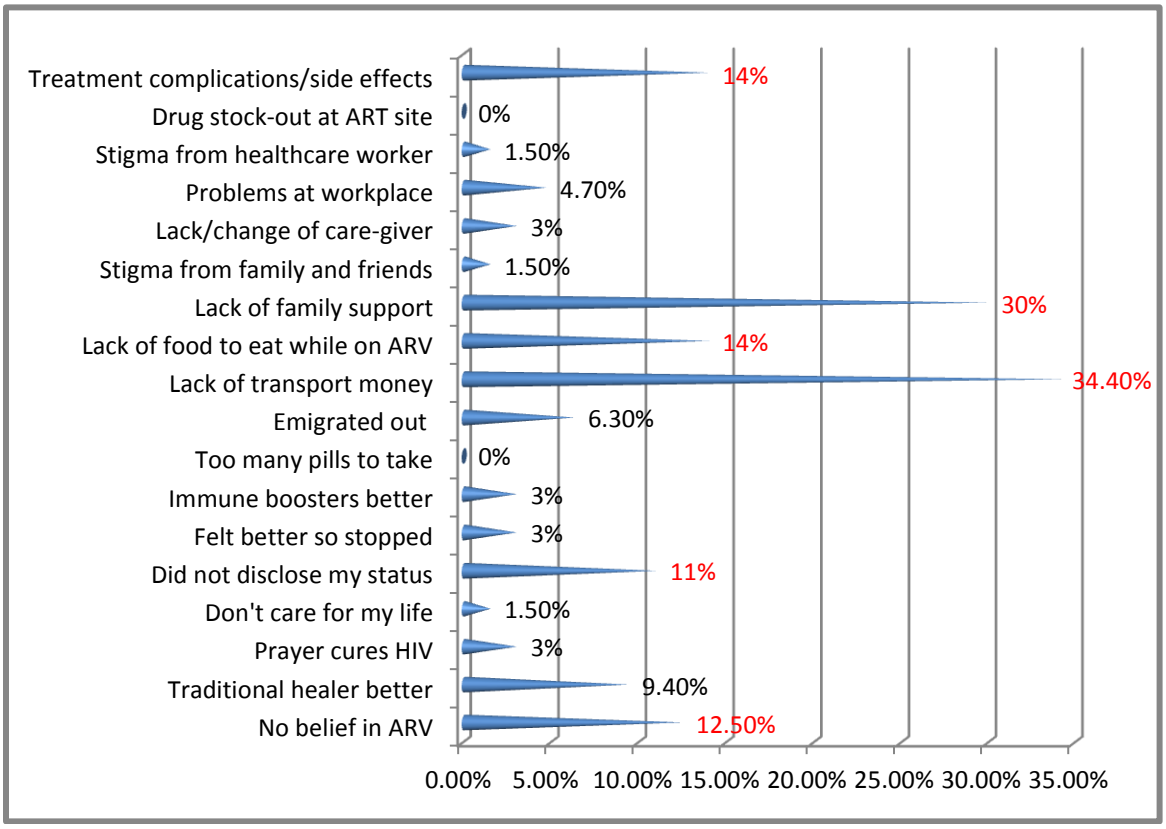

Figure 5: Reported reasons for stopping ART among confirmed LTFU patients

8.6. Profile of Treatment Supporters to confirmed LTFU patients

The 51 responses profiling treatment supporters (figure 6 and table 6) indicate that about 70% of supporters were partners and/or parents to the respondents. Some respondents reported having more than one treatment supporter. No respondent reported the use of friends and/or PLWHIV for treatment support. About 6% of respondents had their sibling as treatment supporters. All the other forms of supporters including neighbours, work-mates, Rural Health Motivator, and healthcare workers together make up about a quarter (24%) of the treatment supporters engaged by respondents.

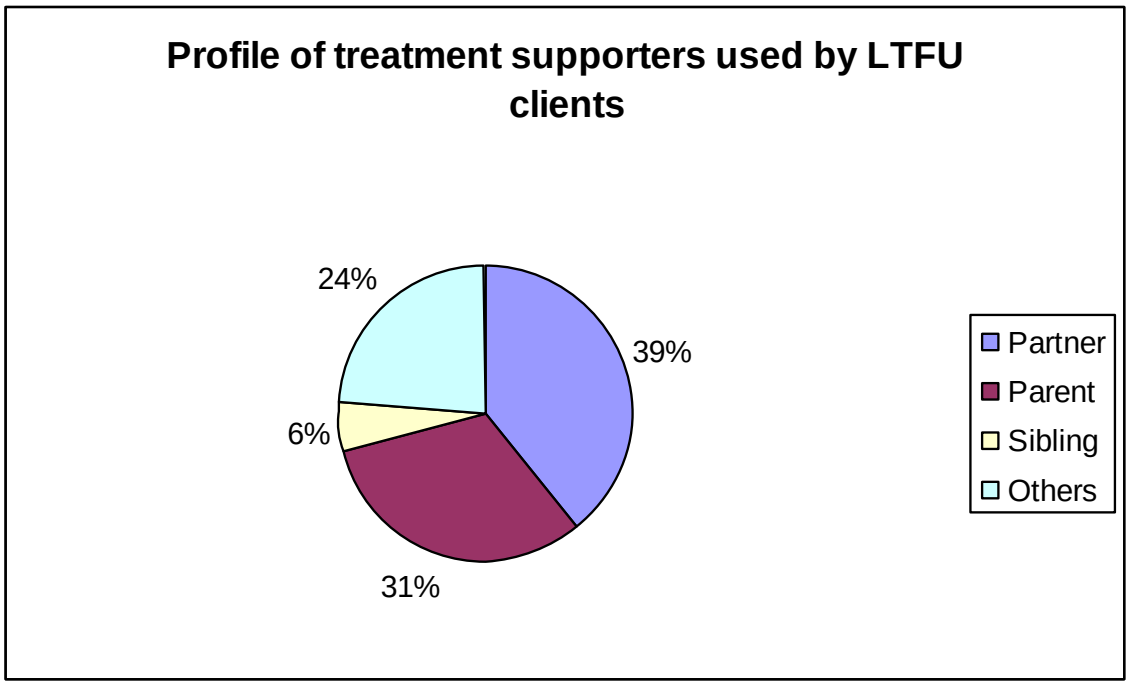

Figure 6: Profile of treatment supporters to confirmed LTFU patients

Table 6: Profile of Treatment Supporters for responding confirmed LTFU patients

Age group	Partner	Parent	Sibling	Others	Total
0 to 19	0	6	0	2	8
20 to 29	8	7	2	2	19
30 to 39	9	3	0	6	18
40 to 49	3	0	1	2	6
50+above	0	0	0	0	0
Total	20(39%)	16(31%)	3(6%)	12(24%)	51

8.7. Effectiveness of Treatment Support among confirmed LTFU patients

Table 7: Effectiveness of treatment support to confirmed LTFU patients

	Number	Percentage
Knew & advised I restart ART	18	28.1%
Knew & reported to ART staff	3	4.8%
Knew & did nothing	17	26.5%
I had no Rx support	18	28.1%
Unspecified	8	12.5%
Total	64	100.0%

Table 7 and figure 7 indicate that among the respondents, about two-fifth (40.6%) either had no treatment supporters or did not indicate that they had, while 59.4% (n = 38) reported having treatment supporters.

Among the 38 respondents that had treatment supporters, 21 (55%) of the supporters knew that their clients had defaulted ART and acted positively by either advising them to restart ART or reporting them to ART clinic staff for action; while in 18 others (45%) the treatment supporters knew of the drop from care but did nothing to have clients restart ART.

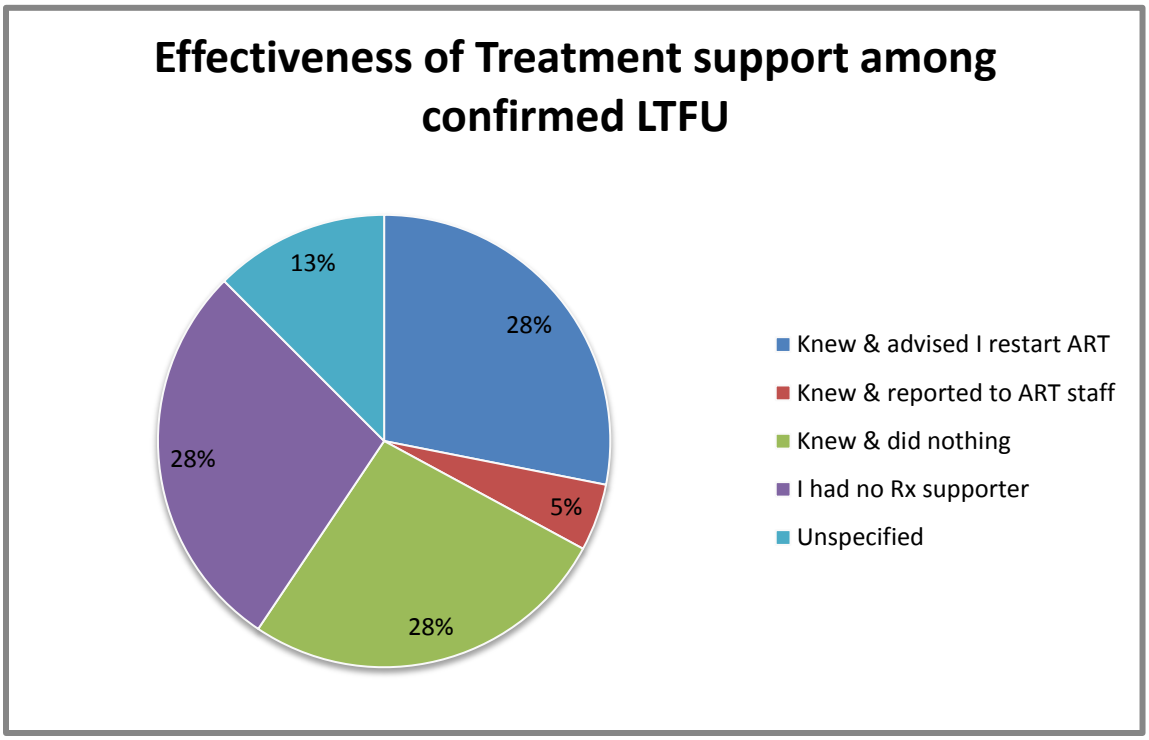

Figure 7: Effectiveness of treatment support to confirmed LTFU patients

8.8. Disclosure of HIV status among confirmed LTFU patients

Table 8: Disclosure of HIV status among confirmed LTFU patients by Gender

	To partner	To parent	To sibling	To friend	To others	Not disclosed	Total
Male	11	12	4	1	6	3	37
Female	18	19	10	5	9	0	61
Total	29	31	14	6	15	3	98

A total of 98 responses were obtained among the 64 respondents interviewed – indicating that some patients disclosed to more than one individual (table 8). Approximately 96% disclosure was reported by the participants, while only 3% non-

disclosure was volunteered. The 3 reported non-disclosures were all from male participants. About 3 in 4 (75.5%) of the responses indicated disclosure to close family member (partner, parent, and siblings).

8.9. ARV refill appointment keeping by confirmed LTFU patients prior to defaulting

Table 9: ARV refill appointment keeping among confirmed LTFU patients prior to stopping ART

ARV refill indicators	Total
I refilled when I remembered	6 (9.3%)
I refilled when I had transport money	8 (12.4%)
I used to miss my appointment by less than 7days	2 (3.1%)
I used to miss my appointment by weeks	2 (3.1%)
I kept my appointment when my ARV is finished	2 (3.1%)
I sent somebody to refill for me when I could not go	2 (3.1%)
I did not miss my refill appointments	36 (56.2%)
Unspecified	6 (9.3%)
Total	**64 (100%)**

Among respondents, about 59.3% (n=38) kept their refill appointments either by attending refill visits themselves or by sending others to refill for them when they could not attend. About a third (31%) of respondents either missed their refill appointments or kept them only when they remembered or when they had transport money. The remaining 9.3% of the respondents did not specify on their ART refill appointment keeping.

9. DISCUSSIONS

The study found that a third of all the people originally classified as lost to follow-up (LTFU) were actually dead. A large proportion (45%) of the original LTFU group could not be traced while a sizable proportion (8%) were transferred out and were still on ART at other ART sites but were not so documented in facility records. The confirmed LTFU constituted about 6.7% while the true lost to follow-up, a combination of the confirmed lost to follow-up and the untraceable, is about 52%. This means that among the cohort of patients initiated on ART in 2007, 52% of them were either alive but had stopped their ART or could not be traced to allow proper classification into treatment outcomes.

The large proportion of deaths among the group originally classified as LTFU may be related to the documented late entry into care observed among our HIV population. With large proportion of our HIV patients enrolling into care at WHO clinical stages 3 and 4, and/or very low CD4 cell count, they progress to fatal outcome in spite of ART. These deaths were not captured in the ART facility database possibly because some of the deaths occurred at home. Some of the deaths that occurred in the hospitals were not also captured possibly due to the weak link between the hospital wards and the ART clinics in terms of patient tracking. These weaknesses have implications both to the national program and the country in areas of reliable vital statistics.

The high proportion of potential study participants that were untraceable may be an indication of some challenges in the data capturing system within the ART facilities. Detailed contacts of patients and treatment supporters were not fully captured at enrolment into care, and were not updated with time. It equally could be as a result of the high mobility of patients and the frequent change of contacts especially phone numbers. Further, it is equally known that some patients deliberately provide false contacts during enrolment for fear of stigma. Also, most of our patients come from rural areas without structured physical addresses, hence, patient tracking is difficult. The fact that nearly half of the potential study participants were untraceable has some negative implications on the national program because these patients cannot be followed up.

Though it could be inferred that being a subset of the original LTFU cohort, the untraceable group is likely to comprise of the dead, the transferred-out on ART, and those who had actually stopped their ART, however, such inference may lack credibility in the absence of documented evidence. With such a large proportion of patients that could not be traced, accurate determination of patient treatment outcomes and the actual rate of drop from care becomes a programmatic challenge.

The transferred-outs, both the officially transferred-out without proper documentation and the self-transfers, also point to weaknesses in the patient referral system within the ART program. This may be indicative of challenges in the area of data capturing and proper documentation of patient management decisions by data managers and clinicians. It could also imply weak communication links between the different ART sites. Some cases of self-referrals may be because some of the patients admitted in the

hospital wards and initiated on ART while in the ward actually come from faraway places from the ART initiation point. On recovery and discharge from the ward they decide to transfer themselves to the ART sites nearest to them without informing the initiating site. Besides impacting on proper classification of patient outcome, undocumented official and self-transfers could also impact on accurate drug forecasting at facility level in respect of both ARVs and drugs for opportunistic infections.

The confirmed "lost-to-follow-up" (LTFU) group comprised of patients found alive but who had missed their booked appointments for 90 days or longer. Although the proportion of the confirmed LTFU in this study is less than what was originally hypothesized – being less than one tenth – this group is, however, of significant importance to the ART program because they are potential breeding ground for HIV drug resistance (just as the untraceable) and the transmission of primary ARV drug resistance in the communities.

The average confirmed LTFU patient in this study is a male or female, aged between 25 and 39 years, most likely single, had completed secondary or primary education, and is very likely unemployed. Most had enrolled into ART program with a baseline WHO clinical stage 3.

Among the confirmed LTFU group, early drop from care was noted. A large proportion of them dropped from care within first year of ART. The peak period for dropping, however, was the first six months of starting ART. The possible reasons for this early drop may include, but not limited to, initiating patients who are not really ready or well prepared for ART; drug side effects; Immune Reconstitution Inflammatory Syndrome, IRIS; lack of transport fare to continue with refill visits; lack of disclosure with associated difficulty hiding the medications from relatives, among other possible reasons.

However, the actual reasons reported by the study subjects for dropping from care were largely related to personal factors, with minimal contribution from program related issues. The major reported reasons were lack of transport fare to keep refill appointments; lack of food to eat while on ART; poor family support; belief in alternative therapy; and lack of faith in ARV. The later may be due to negative publicity on ARV; influence of culture and tradition; poor support for ART from religious organizations and traditional healers; weak marketing strategy for ART among healthcare providers; and the stigma that goes with ART.

About three-quarters of the confirmed LTFU patients had stopped treatment for a duration of between 12 and 24 months. This indicates a serious weakness in defaulter tracing program within ART sites. Reasons could be because the hospital telephone lines were not authorized to be used to call patients, or because there are no specific cadre of staff assigned to undertake this critical responsibility and be accountable to someone. Further, ART sites have problems with vehicles to embark on physical tracing of patients. Some of the transport problems include ART vehicles being under the direct

supervision of the main hospital administration with little control by the ART team; and too many outreach visits relying on one vehicle.

Other possible factors that may impact on the decision to stay in care or otherwise may include disclosure status and the presence and quality of treatment support received by patients on ART. While a limited proportion of the LTFU patients reported non-disclosure, those who disclosed were more likely than otherwise to disclose to more than one individual. Non-disclosure, therefore, may have played a marginal role in patients' drop from care.

About 40.6% (n = 26) of the 64 confirmed LTFU respondents either had no treatment supporters or did not indicate that they had one. Among the other 59.4% (n = 38) who reported having treatment supporters, it was observed that a large majority of the treatment supporters are either parents or partners to the patients. It was further noted that almost half (45%; n = 18) of these treatment supporters did nothing to have patient return to ART care when they discovered that patient had dropped from treatment. This failure on the part of the treatment supporters might be because being close relatives to the patients, they were not firm enough with supervising patients' adherence to care. It could equally be because the treatment supporters actually lacked understanding of what their actual roles should be, or because they were not empowered enough to play those roles. Effectively, therefore, it translates to about 32.8% or 21 of the 64 confirmed LTFU group actually had effective treatment support while the other two-thirds either had no treatment support at all or had ineffective support. The implication is that patients are not offered the type of support they are supposed to receive to keep them in care.

Over half of the confirmed LTFU patients reported that, while they were still on ART, they kept their refill appointments on time either by self or surrogate visits. Hence, refill appointment-keeping may not be a reliable predictor of possible subsequent drop from care.

10. RECOMMENDATIONS

1. Due to the high proportion of "the untraceable' clients (45%) among the group of clients originally classified as LTFU, we recommend the strengthening of the data collection mechanisms within the ART sites to achieve a real-time 100% capture of all client demographic information, and to update all outstanding data on subsequent visits.
2. Improving and strengthening information flow between the various hospital wards and the ART clinics on one hand; and the ART clinics and the community structures on another, to properly capture information relating to deaths and/or complications in respect of admitted and discharged ART clients. Enlisting toll-free numbers that will assist relatives and patients to timely and freely communicate with ART sites

regarding clients' mobility, change of addresses, self-transfers or death is recommended.

3. Strengthen communication and transfer mechanism between transferring and receiving ART sites with reliable feedbacks on every transferred patient - either official or self – will help account for every patient. Use of national identity number for ART clients should be explored, since this will likely assist in patient tracking and easy identification between ART sites.
4. Interventions aimed at limiting loss to follow-up of ART clients must be started early prior to ART initiation, and must be sustained for up to twelve months to take care of the peak period of dropout from care. These may include monthly step-up adherence counselling at each refill visit for the first 3 – 4 months, and then three monthly thereafter. The presence of treatment supporters during the counselling sessions will compliment this effort.
5. Follow-up logistics like phone contacts and home visits using cars and motor-bikes have to be discussed with partners who may be willing to support such strategies like providing mobile phones and air-time vouchers for patient tracking. Also MTN, SPTC and other companies could be approached for assistance through discounts, donations and free air-time. Permission to call or visit defaulting patients at home should be obtained and documented in their medical records at the time of enrolment into care.
6. The roles of treatment supporters should be clearly defined, and what actions they are expected to take in cases of drug side effects, defaulting treatment, client relocation or self-transfer, and death, should be stated. They must be thought what actions to take in these circumstances, and empowered to do them. Having treatment supporters present during initial and subsequent adherence counselling session for ART patients might also be beneficial.
7. In order to identify HIV positive persons and to channel them in HIV care before it is too late, strengthening HIV testing including door to door and provider initiated HIV testing and counselling is strongly recommended

ANNEX 1: The Study Population tally sheet

	HGH	GSH	RFM	MGH	TOTAL
N^{O} IN ORIGINAL LIST from M&E	**132**	**269**	**285**	**440**	**1126**
ORIGINAL N^{O} – DUPLICATIONS	132-6 (126)	269-28 (241)	285-70 (215)	440-6 (434)	1126-110 (1016)
BALANCE – PTS NOT ON ARV	126-0 (126)	241-5 (236)	215-0 (215)	434-3 (431)	1016-8 (1008)
BALANCE – PTS ACTIVE on ARV	126-5 (121)	236-59 (177)	215-1 (214)	431-5 (426)	1008-70 (938)
BALANCE – PTS OFFICIALY TRANSFERRED OUT	121-16 (105)	177-11 (166)	214-2 (212)	426-0 (426)	938-29 (909)
BALANCE – OFFICIALLY DEAD	105-0 (105)	166-10 (156)	212-0 (212)	426-0 (426)	909-10 (899)
BALANCE – RESTARTED on ARV	105-0 (105)	156-0 (156)	212-0 (212)	426-0 (426)	899-0 (899)
BALANCE – PTS @ OUTREACH	105-29 (76)	156-0 (156)	212-0 (212)	426-0 (426)	899-29 (870)
BALANCE – Pts too ill for study	76-0 (76)	156-0 (156)	212-1 (211)	426-0 (426)	870-1 (869)
BALANCE + SITE generated LIST	76+0 (76)	156+53 (209)	211+24 (235)	426+0 (426)	869+77 **(946)**
N^{O} ELIGIBLE FOR STUDY	**HGH 76**	**GSH 209**	**RFM 235**	**MGH 426**	**SD 946**
Not traceable	23	74	64	267	428
Officially T/F but not documented	0	5	0	14	19
Self-transferred & on ART	5	21	10	20	56
Out of the country	2	3	16	4	25
Refused to participate in study	0	9	2	4	15
Incomplete data for analysis	0	0	4	3	7
Dead (relative interviewed)	35	70	93	88	286
Dead (but no information)	0	7	24	15	46
Alive & not on ART **(confirmed LTFU)**	**11**	**20**	**22**	**11**	**64**
Total	76	209	235	426	946

ANNEX 2: PROFILE OF THE CONFIRMED LTFU PATIENTS

Demographic Indicators		#	%
Age Group	0-4	6	9.4
	5-14	1	1.6
	15-19	0	0
	20-24	5	7.8
	25-29	16	25
	30-39	25	39
	40-49	9	14
	50-59	1	1.6
	≥60	0	0
	Unspecified	1	1.6
	TOTAL	**64**	**100%**
Gender	Male	27	42.2
	Female	37	57.8
	TOTAL	**64**	**100%**
Marital Status	Married	24	37.4
	Single	32	50
	Co-habit	1	1.6
	Widowed	4	6.2
	Divorced	1	1.6
	Others	1	1.6
	Unspecified	1	1.6
	TOTAL	**64**	**100%**
Education level	None	12	18.8
	Primary	15	23.5
	Secondary	29	45.3
	Tertiary	4	6.2
	Unspecified	4	6.2
	TOTAL	**64**	**100%**
Employment status	Employed	23	36
	unemployed	40	62.4
	Unspecified	1	1.6
	TOTAL	**64**	**100%**
Baseline CD4	<100	22	34.4
	100-199	26	40.6
	200-299	10	15.6
	≥300	5	7.8
	Unspecified	1	1.6
	TOTAL	**64**	**100%**
WHO Stage	I	12	18.8
	II	7	10.9
	III	42	65.6
	IV	3	4.7
	TOTAL	**64**	**100%**