

**A study on antiretroviral
adherence in Tanzania:
a pre-intervention perspective, 2005**

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Acknowledgements

The ARV Tanzania Study Group acknowledges the financial support provided by WHO and technical support from the University of Amsterdam. The Tanzania Food and Drugs Authority in the Ministry of Health has provided a range of support, including organizing an international workshop in Bagamoyo to develop tools for data collection and facilitating the study process through data collection, data processing, analysis and documentation. The study team also wishes to thank the institutions where members of the study group are regular employees for allowing them to participate in this study. These include: the Tanzania Food and Drugs Authority, the Ministry of Health, the Muhimbili University College of Health Sciences, the African Medical Research Foundation, the National Institute of Medical Research and the University of Dar es Salaam. In addition, the study team greatly appreciates the contribution of the managers and heads of facilities where this survey was conducted, all ARV users involved, and the respondents who took time to talk to the researchers. Without their input, this study would not have been possible. While recognizing the contribution of the many individuals who have been involved in this study, we extend special thanks to our two research assistants, Jacqueline Makupa and George Ruhago.

We would also like to thank the ARV country study group coordinators, Anita Hardon and Trudie Gerrits, of the University of Amsterdam, and Richard Laing from WHO, Geneva, for their constructive criticism during both the development of the research proposal and the writing of the report. In addition, we thank John Kinsman of the University of Amsterdam and Kathleen Hurst from WHO, Geneva, for their various comments which helped to shape this report. We are grateful to Josien de Clerk for invaluable assistance in qualitative data analysis and to Monika Zwegarth of the Medical University of South Africa for designing the database which we used for quantitative data collection. In addition, we acknowledge the contribution of Mwemezi Ngementa, Sikubwabo Ngendabanka, Anna Mia Ekstrom and Nina Viberg during the development of the research proposal. Our colleagues from Botswana, South Africa and Uganda have been very supportive and gave us useful ideas throughout the project.

Lastly, we thank our families and the families of the research assistants and of all who supported and helped us in one way or another during the project period.

Acronyms and abbreviations

ADR	Adverse drug reaction
AIDS	Acquired Immune Deficiency Syndrome
AMREF	African Medical and Research Foundation
ART	Antiretroviral therapy
ARVs	Antiretroviral medicines
CTC	Care and Treatment Clinics (also known as ART clinics)
FGD	Focus group discussion
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GoT	Government of Tanzania
HIV	Human immunodeficiency virus
IEC	Information, education and communication
INRUD	International Network for Rational Use of Drugs
MDH	Muhimbili University College of Health Sciences (MUCHS), Dar es Salaam City Council and Harvard School of Public Health
MNH	Muhimbili National Hospital
MoH	Ministry of Health
MSD	Medical Stores Department
NACP	National AIDS Coordinating Programme
NGO	Nongovernmental organization
NIMR	National Institute of Medical Research
PASADA	Pastoral Activities and Services for AIDS in Dar es Salaam Archdiocese
PEPFAR	President's Emergency Plan for AIDS Relief (USA)
PLWHIV	People living with HIV
SIDA	Swedish International Development Agency
SSI	Semi-structured interview
TFDA	Tanzania Food and Drugs Authority
UDSM	University of Dar es Salaam
WHO	World Health Organization

Executive summary

In Tanzania, the burden of HIV is second only to malaria, with an estimated prevalence of 7% among adults (Tanzania Commission for AIDS, 2005). Today, the HIV epidemic is recognized not only as a major public health problem but also as a socioeconomic and developmental crisis that affects all sectors. The Tanzanian Government has recently initiated the roll-out of free antiretroviral therapy (ART). Although antiretroviral medicines (ARVs) can be effective in controlling the disease, they do not provide a cure and pose new challenges due to potential side-effects and the emergence of drug-resistant strains of HIV. However, the introduction of ARVs has dramatically reduced rates of mortality and morbidity, improved the quality of life for people living with HIV (PLWHIV), revitalized communities and transformed the perception of AIDS from that of a plague to a manageable, chronic illness.

Adherence to treatment is a critical factor in the success of ART. Patients must achieve at least 95% adherence in order to avoid treatment failure and the risk of developing drug-resistant strains of the virus. In Tanzania, up till now there has been no attempt to document the level of adherence to ARV treatment or to identify possible factors contributing to sub-optimal adherence. The present study was designed to help fill that gap. The aim has been to measure adherence and to identify possible factors and operational barriers facilitating or constraining adherence to ART among AIDS patients and to suggest possible ways of improving adherence.

A cross-sectional study on ARV adherence was conducted in Arusha and Dar es Salaam in June and July 2005, involving a total of seven health care facilities in the two regions. A multi-disciplinary team of researchers collected the data from ARV users through exit interviews, semi-structured interviews, adherence measurement, focus group discussion (FGD) and key informant interviews. In seeking information from health care staff, the tools used were semi-structured interviews, observation of staff while conducting consultations, and pharmacy stock controls.

A total of 207 ARV users were involved in the study, 26 observations were made, 28 staff were interviewed, 8 FGDs and 10 key informant interviews were conducted, and 6 pharmacy stock checks were carried out in health care facilities.

The mean age of ARV users studied was 43 for males and 37 for females and most of the ARV users studied were females (64%). Most male ARV users were either employed in the private sector or self-employed in a small-scale business, while female ARV users were either not employed or involved in minor trade. Of the staff interviewed, most were nurses.

In this study, adherence is considered from the perspective of both the ARV user and the health worker. From the ARV users' perspective (based on two-day recall, visual analogue and the pill count method) the mean level of adherence was 95%, while from the health workers' perspective it was found to be 88% (range 60%-100%). The composite measure of adherence using 28-day visual analogue and pill count method was 90%. However, only 21% of ARV users interviewed reported achieving the optimal level of adherence (over 95%) as measured by the composite adherence rate. The remaining 79% self-reported to achieve only moderate adherence (85%-95% adherence rate) and are therefore at risk of treatment failure and the development of drug-resistant forms of the virus.

While most patients seemed to be knowledgeable about ART, a few patients were not well-informed about treatment and the consequences of sub-optimal adherence to ARVs. The main ways of providing this information at the health facilities involved in the study included leaflets, seminars, adherence counselling, verbal counselling, television and video.

The standard of counselling was considered to be good in Dar es Salaam but there was less satisfaction with the counselling services provided in Arusha. Despite widespread information about HIV and AIDS, the idea of bewitchment as the source of HIV was still reflected in the perception of some patients. And although most of the 30 ARV users interviewed during semi-structured interviews (93.5%) had disclosed their HIV status, social stigma was said to be widespread. Respondents said that PLWHIV are often stigmatized both at home and in the workplace (especially in the private sector).

The cost of once-monthly travel to the clinic for ARV users was significant, ranging from Tshs 200-30 000 (approximately 20 US cents to US\$ 30.00), while the distance patients had to travel ranged from 1 km to 246 km.

Both ARV users and key informants said that lack of food was a problem for most ARV users. This was exacerbated by a treatment-related increase in appetite and by the additional demands of needing to take some medicines together with food. However, this did not appear to affect treatment adherence among the ARV users involved in the study. Of the ARV users who cited lack of food as a problem, all maintained that they had persisted in taking their ARVs. Other interviewees remained concerned at the potential impact of hunger on adherence to ART. For example, it was reported that some patients take their medication only once a day, in the evening, because that is the time when they have food, and that some patients were selling ARVs in order to buy food. This implies that food scarcity can be a drawback to adherence.

The study identified a number of structural problems in the health facilities involved. For example, it was found that consultations carried out in some of the public facilities in Arusha were not as conducive to confidentiality as consultations in the public facilities in Dar es Salaam. Elsewhere, at the private facilities in both Dar es Salaam and Arusha, confidentiality was said to be satisfactory. In addition, ARV users reported that they could spend up to 10 hours in the health care facility waiting to be attended to during their monthly visits.

According to both ARV users and staff, laboratory services were inadequate in some of the public facilities surveyed. Problems cited included the unavailability of CD4 reagents and machines, thus delaying the required tests. The private facilities were better equipped than the public facilities.

The prescribed ARV medicines were generally available in the health care facilities involved. Only five of the staff interviewed (including four from Government facilities) reported occasional shortages of prescribed medicines. Although medicines for opportunistic infections were reported to be available in most of the facilities, these were not always dispensed free of charge.

The staff involved complained of low motivation, inadequate training, and of being overloaded with work. Other complaints included long waiting times for patients due to the limited number of staff.

Suggestions for ways of improving the ARV programme included: providing food and financial loans to ARV users; adequate counselling; using education and information to help reduce stigma; efforts to reduce waiting times; an increase in the number of ART clinics and in staffing levels; ensuring a reliable medicine supply chain; improvements in staff motivation and training; providing transport for staff involved in home-based care (i.e., treatment monitoring and adherence counselling); and an increase in laboratory services.

While the relatively high rate of adherence reported in this study is encouraging, more efforts are needed to ensure optimal adherence among the large group (79%) of ARV users who are currently taking less than the critical 95% of their dosage. There is much that could be done to sustain and improve the current adherence rate. Many potential activities or interventions could be implemented and evaluated to determine which are most effective. As ARVs are rolled out to meet the challenging targets set by the Government, it is critically important to determine how to ensure optimal adherence for good clinical outcomes and to prevent the emergence of drug-resistance.

Chapter 1: Introduction

1.1 Background

The United Republic of Tanzania is one of the world's poorest countries. It has a gross domestic product of US\$ 600 per capita, and life expectancy at birth is 44 years (CIA World Factbook, 2003). HIV is a serious public health problem in Tanzania, second only to malaria, with an estimated prevalence of 7% among adults (Tanzania Commission for AIDS, 2005). HIV is a major development crisis that affects all sectors. It has had a major impact on health, economic and social progress – reducing life expectancy, deepening poverty, and contributing to and exacerbating food shortages (National AIDS Coordinating Programme (NACP), 2003).

The advent of ART in 1996 changed the way people in the world's richest countries view HIV (UNAIDS, 2004). Although ARVs do not provide a cure and pose additional challenges due to potential side-effects and the emergence of drug-resistant strains of HIV, they have dramatically improved rates of mortality and morbidity, improved quality of life, revitalized communities and transformed the perception of AIDS from that of a plague to a manageable, chronic illness (UNAIDS, 2004).

Tanzania receives various sources of funding for HIV from organizations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), the US President's Emergency Plan for AIDS Relief (PEPFAR), the Clinton Foundation, the Swedish International Development Agency (SIDA) and the Tanzania Multi-country HIV/AIDS Programme. The Government of Tanzania (GoT) has been vigorously engaged in efforts to combat HIV and has launched initiatives to increase the availability of ARVs as well as other medicines for the management of HIV-related opportunistic infections. The Tanzania Food and Drugs Authority (TFDA) has registered more than 50 ARV formulations, enabling private pharmaceutical companies and hospitals to stock and sell ARVs (TFDA, 2004). Government efforts are also supported by an increasing number of nongovernmental organizations (NGOs) and private companies which are promoting and establishing HIV policies and treatment programmes for their employees (e.g. the African Medical and Research Foundation (AMREF) and the Tanzania Cigarette Company).

Over the past few years, the price of ARVs has fallen dramatically. In 2000, the price of a first-line WHO-recommended ARV regimen to treat one patient for one year was between US\$ 10 000 and US\$ 12 000 on world markets. By 2004, the price for some generic combinations was approximately US\$ 300 per person per year (UNAIDS, 2004). The decrease in prices is attributed to increased funding from the Global Fund and PEPFAR and competition from generic manufacturers.

The GoT has ambitious plans to put more than 400 000 people on ARVs within a five-year period (October 2004-September 2009). The Government's interim goal of putting 44 000 people on ART by end-2005 was not met. The National AIDS Control Programme reported that, as of January 2006, an estimated 25 300 people were on treatment. As ART is scaled up in Tanzania, there is a need for community mobilization and empowerment in order to address social factors that constrain adherence to ART. An understanding of these factors is crucial in order to plan for the scaling up of access to ART.

1.2 Rationale

As more people gain access to ART, new initiatives are needed to help ensure that patients adhere to treatment. The maintenance of viral suppression requires maximum adherence (at least 95%) to ART (Parades, 2000; Garcia et al., 2003). Insufficient adherence to ARVs may result in treatment failure and the emergence of drug-resistant strains of HIV and require a change to second-line treatment regimens, thereby greatly increasing treatment costs (Bangsberg et al., 2000).

The availability of ARVs in Tanzania is relatively recent. Therefore this study was designed to investigate key factors associated with adherence and non-adherence to ARV medication, with a view to suggesting possible intervention measures to sustain or improve adherence. The study focused on health facilities where ARVs had been provided for at least three months. It is part of a multi-country study also carried out in Botswana and Uganda.

1.3 Literature review

Adherence is described as the engagement and accurate participation of an informed patient in a plan of care (Rabkin et al., 2003). The concept of 'adherence' has a broader meaning than compliance. It encompasses the extent to which a patient follows instructions and implies understanding, consent and partnership. It also includes entering into and continuing in a programme or care plan, as well as keeping appointments and tests as scheduled (Rabkin et al., 2003). In low-income countries, adherence can be a problem for a number of reasons. Yet studies have shown no significant difference in adherence between resource-limited and resource-rich countries, which suggests that patients in all environments have trouble adhering to medicines 100% of the time. It is therefore recommended that all ARV programmes worldwide should have a concurrent plan for adherence assessment and support (Rabkin et al., 2003; Weiser et al., 2003).

For the purposes of this study, '*Near perfect adherence*' has been defined as 95% and above adherence. The ability to consistently take the medicines at exactly or approximately the same times each day depends on the individual's frame of mind as well as the support of family members, the people around them, and the community at large. Administration of ARVs imposes constraints on the daily schedule and lifestyle and it can be difficult for individuals to adapt to these demands, especially on a long-term basis.

Previous studies in Tanzania on other diseases have indicated that patients often do not have enough knowledge and/or do not remember how to use various prescribed medicines, contributing to their irrational use (Mnyika et al., 1995; Masele et al., 1993; MoH, 2002). This has also been observed in settings where ARVs are used. For example, in a previous study in Botswana, 54% of patients reported optimal adherence (defined as completing greater than or equal to 95% of prescribed doses) and 56% were seen as achieving optimal adherence on the basis of provider assessment (Weiser et al., 2003). The main factors affecting ARV use in Botswana were structural, disease-related and treatment-related factors, and socioeconomic and cultural factors. For instance, patients lacked funds and had to travel long distances to the clinics providing ARVs. If cost was eliminated as a barrier, then the adherence rate was predicted to increase to 74% (Weiser et al., 2003). The Botswana Government has taken several initiatives to improve adherence, including increasing access to ARVs in the public sector, improving the distribution of ARVs, increasing the availability of clinical and laboratory monitoring, and strengthening health infrastructures for delivering care.

The role of sociodemographic characteristics, such as gender, race, age, exposure category and educational level as predictors of adherence has produced largely inconsistent results (Horne et al., 1998). The tendency to ascribe low adherence to (often deprived) social groups is a well established trend in the general literature, dating back to 1990 when tuberculosis control occupied public health officials (Lerner et al., 1998). However, as later experience with antibiotics demonstrated, low adherence is not restricted to certain social classes but is widespread and unpredictable. Research in the HIV field supports this perspective. Moreover adherence rates vary not just between individuals but also for the same individual over time (Carrieri et al., 2001). Adherence is therefore best thought of as a variable behaviour rather than as a constant characteristic of an individual. Most people will exhibit low adherence some of the time (Horne et al., 1998).

Psychological factors, including mental health problems such as depression, have been associated with low adherence in HIV-infected adults and adolescents, as have other psychological variables such as perception of one's ability to follow a medication regimen, or self-efficacy (Singh et al., 1996; Murphy et al., 2001; Eldred et al., 1998; Tuldra et al., 2000). Beliefs about health and illness, in particular about the necessity of medication to ward off illness and concerns about potential adverse events, have been found to be influential in both HIV and other disease areas (Horne et al., 2001 and 2002).

1.4 Problem statement

A comprehensive study of ARV adherence and possible factors facilitating or constraining adherence to ART in Tanzania has not yet been attempted. Elsewhere, studies in other countries have described a range of factors affecting ARV treatment adherence at various levels, including individual, community and health facility levels (Weiser et al., 2003; Horne 1998; Eldred et al., 1998). These factors can be broadly grouped into three categories: structural factors, disease and treatment factors, and social and economic factors. The structural factors include inadequate support services,

limited accessibility of treatment, long distances to the health facility, lengthy waiting times, and the attitudes and quality of care of the health care staff. The disease and treatment factors include the seriousness of the disease, adverse drug reactions, and side-effects. The socioeconomic factors include poor patient knowledge and information, illiteracy, lack of social support, poverty, stigma, misconceptions about HIV and AIDS, and communication barriers between patients and doctors/care-givers (see Figure 1 below).

1.5 Objectives

1.5.1 Broad objective

The purpose of this study was to identify possible factors which constrain or facilitate adherence to ART among AIDS patients and suggest possible ways to improve adherence.

1.5.2 Specific objectives

The study aimed to:

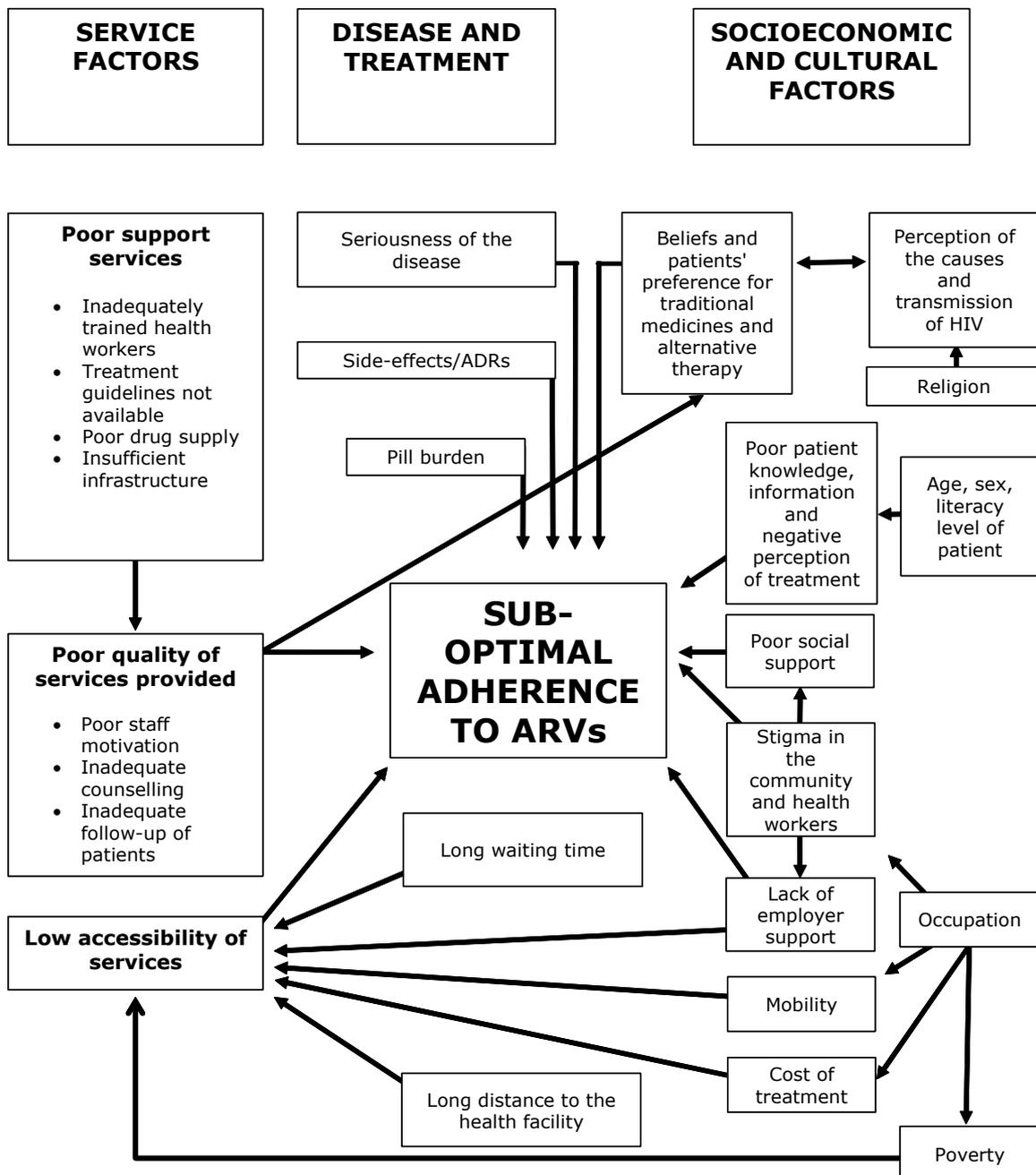
- ◆ determine the proportion of patients who achieve/do not achieve optimal adherence to ART in selected health facilities in Tanzania
- ◆ identify factors (structural, socioeconomic, cultural and disease-related) contributing to sub-optimal adherence
- ◆ assess the quality of the operating structures for the provision of ARVs in the selected health facilities
- ◆ assess the quality of the processes involved in providing ART services for patients attending the selected sites
- ◆ document suggestions and proposals for improving ART adherence from ARV users, health care providers and key informants.

1.6 Output

The study addressed:

- ◆ The degree of ART adherence and sub-optimal adherence in two regions of Tanzania
- ◆ Possible factors (structural, socioeconomic, disease-related) contributing to sub-optimal adherence to ART
- ◆ Possible operational barriers to ART adherence
- ◆ Possible interventions to be undertaken to improve ART adherence.

Figure 1: Problem analysis diagram on factors affecting ARV adherence



Chapter 2: Methodology

2.1 Study design

The study was based on a cross-sectional study design using rapid appraisal techniques for collecting both qualitative and quantitative data.

2.2 Study population

The study population included:

- ◆ ARV users from seven health care facilities who met the criterion of being on ART for at least three months
- ◆ staff at the seven health care facilities who were involved in counselling and providing ARV medicines (e.g., nurses, doctors) and the pharmacists who were dispensing and stocking drugs
- ◆ key informants who were identified from among the communities to which the ARV users belonged (e.g., AIDS activists from NGOs, coordinators of HIV programmes and representatives of local government).

2.3 Inclusion and exclusion criteria for interviewees

Inclusion criteria:

Patients

- Adult, 18 years or over and willing to participate in the study
- On ART for at least three months

Health care workers

- Staff working at the ART clinic and willing to participate in the study
- Well-informed about ARV users

Exclusion criteria

Patients

- Not willing to be interviewed
- Below age 18
- Not on ARV treatment

Health care workers

- Not willing to be interviewed
- Working at the ART clinic for less than one month
- Not directly interacting with ARV patients.

2.4 Quantitative data

Most of the quantitative data were collected using an adherence tool and some were collected using exit interviews, semi-structured interviews and a checklist for pharmacy stock. The adherence tool was administered before the patients collected medication from the pharmacy. The exit interview was conducted after the patient had been attended to.

2.5 Qualitative data

Qualitative data were obtained using an observation checklist, semi-structured interviews, exit interviews, focus group discussions (FGDs) and interviews with key informants.

2.6 Data collection tools

A combination of data collection tools were used to gather the information in this study. Tools used for data collection from ARV users were exit interviews, semi-structured questionnaires, adherence tool and FGDs. These tools were originally developed at a multi-country workshop held in Bagamoyo in February 2005, and were then adapted after pilot testing. They are included in this report as Annexes. The following tools were used with other population groups: semi-structured interviews with staff, observation, pharmacy stock controls and key informant interviews with identified community members.

Instruments used to measure adherence were:

- ◆ Two-day recall, involving the use of 'sun and moon' charts to measure the consistency of the times respondents took their medicine over the previous two days (Annex 4).
- ◆ Visual analogue, in which ARV users were asked to pour beads from one glass into another to indicate the number of pills they would have taken over a one-month period. The remaining beads in the first glass were deemed to be the pills which the ARV user had forgotten to take during the course of the month. Adherence was recorded on the basis of the line marked from 0-10 on the first glass (Annex 4).
- ◆ Pill count method undertaken by the dispensing pharmacist, in which the numerator was the number of pills supposed to have been taken over a given period minus the number of pills missed and the denominator was the total number of pills supposed to have been taken (Annex 4).
- ◆ Health workers' assessment, comprising the estimate of the level of adherence to treatment by ART clients over a period of not less than three months (Annex 6).

2.7 Pilot study

Following the multi-country workshop to develop instruments in early 2005, a planning meeting of Tanzanian medical and social scientists was held at the FDA at Mabibo in Dar es Salaam. The purpose of this meeting was to review research tools, to train the research assistants and conduct a pre-test of the tools in a selected health facility in Dar es Salaam. Amana Hospital in Ilala municipality was used as the pilot site. The pilot study was done two weeks prior to the main study, to determine the suitability of data collection instruments, sampling frame and techniques, and estimates of mean adherence, so as to calculate the sample size required for the adherence tools. The research tools were modified and finalized for the Arusha and Dar es Salaam data collection.

Following the pilot study results, the tools were refined into a good Kiswahili translation to make them clearer for the study population. The visual analogue method for estimating adherence level was modified from weekly to monthly recalls. In addition, a new category denoting the occupation of the respondent was added to the ARV user tools, as this was found to be important.

2.8 Sample size and sampling strategy

The sample size calculation for ARV users using the adherence tool was based on the results of the pilot study (mean overall adherence rate = 98%, $p*(1-p) = 0.015605$, and α at 95% confidence interval) which gave 24 per each health facility (estimated total of 168 ARV users for seven facilities). The adherence tool was used for 107 ARV users, while 100 ARV users were studied through exit interviews and semi-structured interviews (see Table 1). In some health facilities, the sample size was smaller than planned for the adherence tool because some identified users did not meet the criteria of being on treatment for at least three months. ARV users were randomly chosen using the outpatient attendance register. Each ARV user chosen was administered a single tool.

Twenty-six observations were made to see how the patient was received and dealt with in the ARV clinics and 28 health workers were also interviewed. The health workers interviewed were those who were working in the ART clinics. However, the number of staff varied between the different health facilities and therefore the expected sample size was not consistent in all facilities.

Eight FGDs were conducted with ARV users and 10 key informant interviews were carried out. In six of the health care facilities, stocks of ARV medicines were checked to assess availability.

Table 1 shows the total study population in the seven health facilities in both Arusha and Dar es Salaam according to data collection tools.

**Table 1:
Study population of selected health facilities in Arusha and Dar es Salaam**

Facilities		Adherence tool	Exit interview	SSI client	SSI staff	FGD	Key informant	Observation consultation	Stock check
ARUSHA	Selian	15	17	3	4	1	2	5	1
	St Elizabeth	10	5	5	2	1	1	-	-
	Arumeru	5	5	5	5	1	1	4	1
	Mt. Meru	19	9	1	2	1	1	2	1
DAR ES SALAAM	M/nyamala	23	15	5	5	2	2	5	1
	PASADA	22	14	5	5	2	2	5	1
	Hindu Mandal	13	5	6	5	-	1	5	1
Total		107	70	30	28	8	10	26	6

SSI: Semi-structured interview. FGD: Focus group discussion

2.9 Data collection

Data were collected by the research team and research assistants. Research assistants dealt with the adherence measurement tools and exit interviews under the supervision of the research team. Research team members conducted semi-structured interviews, FGDs, key informant interviews, observation of consultation and pharmacy stock checking. Review meetings were conducted each evening in order to share the daily experiences. In addition, the principal investigator checked the completeness of the collected data on a daily basis. In order to maintain consistency, the same team collected data in both Arusha and Dar es Salaam.

2.9.1 Data entry and analysis

Data for the adherence tool were entered into the prepared MS Access database while the remaining data were entered into Epi Info 2000. Data entry was checked by the principal investigator. Analysis was undertaken using both MS Access and Epi Info 2000. Descriptive analysis was done for the basic demographic characteristics. Means and standard deviation were calculated for quantitative data. For qualitative data, coding was done and data were summarized using themes. Methods used for estimating adherence included both ARV users' self-assessment, health workers' perception, pill count and visual analogue.

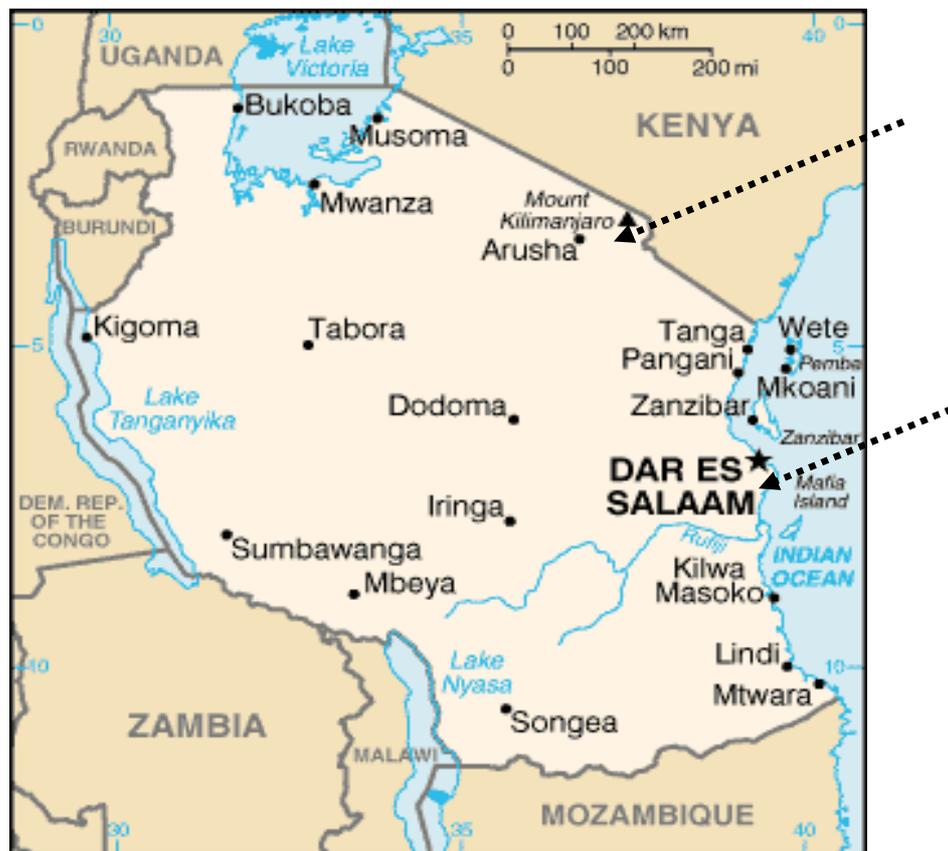
2.10 Ethics

The National Institute for Medical Research Committee issued ethical clearance for this study. Permission was also obtained from the respective regional health authorities and from the facilities involved. Consent was obtained from all the clients interviewed and from staff and key informants.

Chapter 3: Study areas

The study was conducted in Arusha and Dar es Salaam. Arusha is situated in a highland area in the north of Tanzania and has a population of almost 1.3 million, while Dar es Salaam lies in the coastal region and has a population of almost 2.5 million (National Bureau of Statistics, United Republic of Tanzania, 2003). These two cities were chosen because they had already been providing ARVs for at least three months at the time of the study. Arusha is a major tourist city which is known as the “Geneva of Africa” because it hosts many national and international conferences and meetings. Dar es Salaam is the major commercial city in Tanzania, which attracts many people both from other parts of the country and from abroad.

Figure 2: Map of Tanzania showing the study areas of Arusha and Dar es Salaam



ARV adherence study sites shown by arrows.

3.1 Health care facilities

Seven health care facilities were selected, including both public facilities and private/faith-based facilities. In Arusha, four health care facilities were involved in the study: Selian and St Elizabeth Hospitals (both faith-based facilities) and Mount Meru and Arumeru Hospitals (both public facilities). Selian is operated by the Lutheran Church, while St Elizabeth is run by the Roman Catholic Church. Both hospitals are located within Arusha City and are beneficiaries of PEPFAR funding. The Selian Hospital launched its ART programme in 2003, while the St Elizabeth programme started in early 2005. At the time of the study, Selian had a total of 535 registered ARV users, of whom 353 were females and 182 males. At St Elizabeth Hospital there were 299 (215 female and 84 male) ARV users. Community counsellors were helping ARV users in Selian and St Elizabeth Hospitals.

Of the public health facilities, Mt. Meru is a regional hospital located in the centre of Arusha City. At the time of the study, it had 344 (212 female and 132 male) registered ARV users. Arumeru, a Government district hospital, is located 15 km outside the city and had only registered 87 ARV users (42 females and 45 males). Both hospitals started an ART programme in late-2004 and are funded by the Government and the Global Fund. Some of the facilities in Arusha did not operate on a daily basis, leading to time constraints for the research team as well as for ARV users.

In Dar es Salaam, three health care facilities were studied: Mwananyamala Hospital, Hindu Mandal Hospital, and PASADA (Pastoral Activities and Services for AIDS in Dar es Salaam Archdiocese) Hospital. Mwananyamala is a public district hospital, located in Kinondoni municipality; Hindu Mandal is a private hospital in Ilala municipality, which is owned and run by Tanzanians of Indian origin; and PASADA is a faith-based hospital run by the Roman Catholic Church in Temeke municipality. PASADA and Mwananyamala started their ART programmes in 2003 and 2004 respectively, while Hindu Mandal Hospital started in 2002. The Mwananyamala programme receives support from both the Government and the Global Fund, and is also a beneficiary of a HIV project run jointly by three institutions: Muhimbili University College of Health Sciences (MUCHS), Dar es Salaam City Council and Harvard School of Public Health (known as the MDH project). Funding of study facilities is shown in Table 2 below. At the time of the study, Mwananyamala Hospital had 1791 registered ARV users (907 females and 884 males); PASADA had 508 registered ARV users (364 females and 144 males); and Hindu Mandal had 178 ARV users (102 females and 76 males).

Table: 2 Summary of characteristics of the surveyed health care facilities

	Facilities	Public/ Private	Initiation of ART	ARV funding sources	ARV users	No. of clinics per week
ARUSHA	Selian	Private/ Lutheran	2003	PEPFAR Global Fund GoT	535	3
	St. Elizabeth	Private/ RC	2005	PEPFAR Global Fund GoT	299	3
	Arumeru	Public	2004	Global Fund GoT	87	5
	Mt. Meru	Public	2004	Global Fund GoT	344	1
DAR ES SALAAM	M/nyamala	Public	2004	Global Fund GoT MDH	1791	5
	PASADA	Private/ RC	2003	PEPFAR Global Fund GoT	508	5 clinics organized on the basis of age
	Hindu Mandal	Private	2002	Global Fund GoT	178	6

GoT: Government of Tanzania



Patients waiting for services at Mwananyamala Hospital, Dar es Salaam, one of the public health care facilities in the study.

Chapter 4: Quantitative results

Quantitative data were collected from exit interviews, semi-structured interviews and adherence tools.

4.1 Demographic characteristics of ARV users

Age and sex distribution

See Table 3 for the average ages of patients by sex and type of instrument used for data collection.

Table 3: Age and sex distribution of ARV users (N = 207)

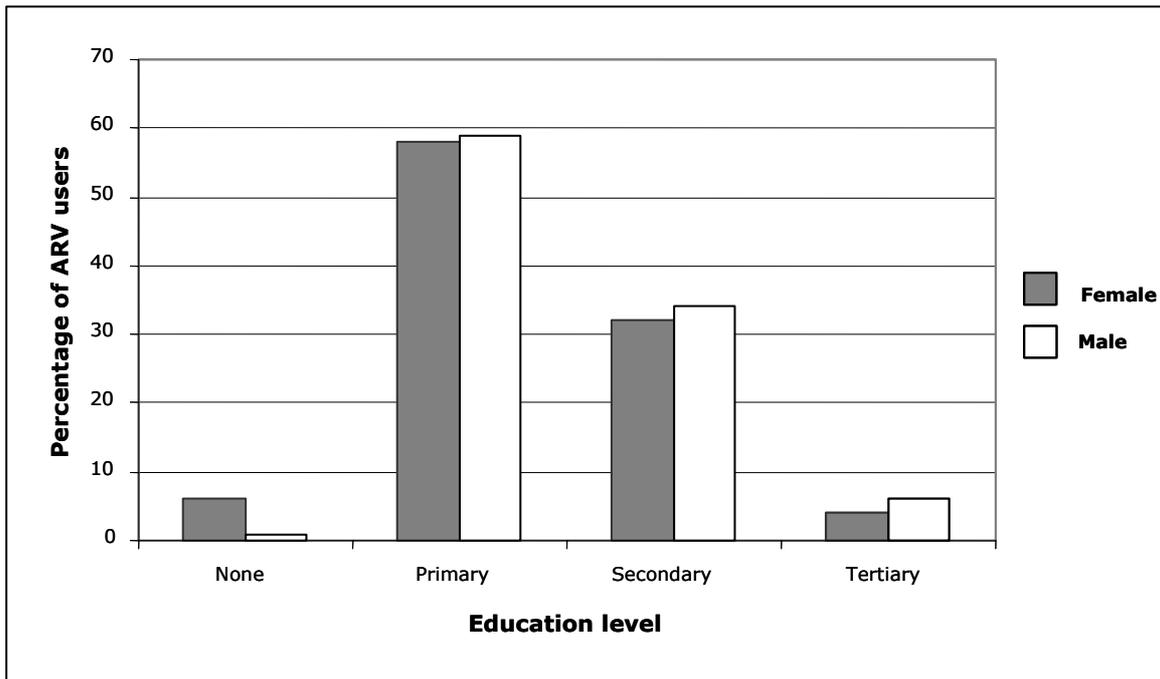
Sex	Age	Tool			Total/Mean
		SSI	Exit interview	Adherence tool	
		N=30	N=70	N=107	207
Male N=68	Mean age	45.4	43.5	39.6	42.8
	Range	24-57	18-60	27-51	18-60
Female N=139	Mean age	36.4	35.2	38.3	36.6
	Range	18-50	18-56	18-64	18-64

Combining all the three tools for ARV users, the mean age of male ARV users surveyed was 43 years and for females it was 37. Three interview tools were used but each ARV user was subjected to only one of these. Females featured most in all types of tools of data collection (67%).

Levels of education

Most of the ARV users participating in this study (almost 60%) had completed primary education and just over 30% had completed secondary education (see Figure 3 below).

Figure 3: Sex distribution of the ARV users by level of education



Occupation

ARV users: out of 65 females interviewed (exit interview or semi-structured interview), the largest group (37%) were not employed, followed by 35% who were working in a business. Among the 35 males interviewed, the most prominent occupations were private employee and business owner (each accounting for 29%).

Health care staff: a total of 29 staff were interviewed, including:

- ◆ 5 medical doctors, 3 of them managers
- ◆ 9 nurses
- ◆ 5 counsellors, one of whom was also a social worker
- ◆ 6 pharmacists
- ◆ 1 dietician
- ◆ 1 laboratory technician
- ◆ 1 receptionist.

4.2 Adherence rates

The following is a summary table showing the level of adherence of ARV users by facility.

Table 4: Adherence of ARV users by facility (N=107)

Hospital		Two-day recall (sun and moon chart)	Visual analogue (glass of beads)	Pill count (pharmacy slips)	Composite adherence (one-month visual analogue and pill count)
ARUSHA	Arumeru (Government) N=4	100%	83%	100%	91%
	Mt. Meru (Government) N=23	100%	83%	97%	90%
	St Elizabeth (Private) N=8	100%	82%	98%	90%
	Selian (Private) N=16	100%	79%	100%	89%
Weighted means*		100%	82%	98%	90%
DAR ES SALAAM	Mwananyamala (Government) N=19	100%	83%	98%	90%
	PASADA (Private) N=24	100%	83%	97%	90%
	Hindu Mandal (Private) N=13	100%	82%	99%	91%
Weighted means *		100%	83%	98%	90%

* Weighted by number of patients at each facility.

The composite adherence for one month (for the seven health facilities involved) was 90%. In the public health facilities, the mean composite level of adherence for one month was 90.1%, while in the private facilities it was 89.9%. The weighted mean adherence rates for the ARVs users in Arusha and Dar es Salaam were similar (90%). The majority of clients seemed to be observant of their routine daily schedule for taking ARVs and used watches, radios and alarm clocks to remind themselves of medication times. However, a few people did not take their medication at the correct times. FGD participants observed that it was difficult to adhere to the exact schedule for taking ARVs.

"There is problem of adhering strictly to time and if you forget it is a problem."
(Female FGD, Selian Hospital, Arusha)

From the health workers' perspective (using the semi-structured questionnaire), the mean percentage of adherence was estimated to be 87.8% (range 60%-100%). According to health staff, adherence was interpreted to mean using medicines as prescribed, at the right time and at the correct dosage, and attending the facilities as scheduled for follow-up checks.

Table 5: Number and percentage of ARV users according to adherence rate in the health facilities studied (N=107)

28 day mean composite adherence rate	Arusha		Dar es Salaam		Total
	Private No. (%)	Government No. (%)	Private No. (%)	Government No. (%)	
Moderate adherence (85%-95%)	19 (79)	18(67)	29 (78)	19 (100)	85 (79)
High adherence (>95%)	5 (21)	9 (33)	8 (22)	0(0)	22 (21)
Total	24 (100)	27 (100)	37 (100)	19 (0)	107 (100)

Table 5 shows that only 21% of ARV users achieved optimal adherence (as measured by a combination of monthly visual analogue and pill count) while 79% achieved only moderate adherence.

Table 6: Number and percentage of ARV users according to adherence rate and sex in health facilities studied (N=107)

28 day mean composite adherence rate	Male	Female	Total
	No. (%)	No. (%)	No. (%)
Moderate adherence (85%-95%)	28 (85)	57 (77)	85 (79)
High adherence (>95%)	5 (15)	17 (23)	22 (21)
Total	33 (100)	74 (100)	107 (100)

Table 6 above shows that a slightly higher proportion of females achieved optimal adherence (23%) compared to males (15%) among the ARV users studied. However, overall there was no significant difference between males and females in adherence ($\chi^2 = 0.4, p=0.51$).

Table 7 below shows the comparison of the adherence rates according to the education level of ARV users. There appears to be no association between education and adherence rates.

Table 7: Comparison of composite adherence rates among ARV users according to education level (N=107)

Level of education	Adherence rates		Odds ratio (95% confidence interval)
	Moderate adherence (85%-95%)	High adherence (>95%)	
No education/primary not completed	5	2	1
Primary completed	53	10	2.12 (0.24-15.46)
Secondary	27	8	1.35 (0.15-10.67)
Tertiary	0	2	0.0 (0.0-3.59)

Chapter 5: Qualitative results

The qualitative information reported below was collected from FGDs, key informant interviews and from semi-structured interviews with ARV users.

5.1 Factors that influence adherence to ARVs from the users' perspective

Information about HIV, AIDS and ART

While the majority of patients seemed to be knowledgeable about ART, a few patients were not well-informed about how ARVs work and were not aware of the consequences of sub-optimal adherence to ARVs. Perceptions about ARVs were not uniform among the users. Some described ARVs as having significant side-effects, while others perceived ARVs to be very helpful medicines which were decreasing the "fierceness" of the disease in the body. Several men said that if they stopped taking the ARVs the virus would increase and body resistance would decline, while most of the women indicated that taking ARVs makes the virus "sleep" and lengthens the patient's life. In FGDs, some of the participants observed that it was difficult to keep taking the medicines at the correct time.

Both male and female ARV users who had learned about the use of ARVs had positive opinions. One female client from Arumeru indicated that:

"ARVs have improved my quality of life. If I stop using them I will die."

Similarly, a male client from the same area noted that:

"ARVs have helped to increase my body immunity, my health is improving. If I stop using ARVs, the disease will come back."

A female ARV user attending an FGD in Dar es Salaam said:

"Drugs bring our energy back and we are getting hope of living."

A male participant in an FGD in Dar es Salaam was also positive about the impact of ARVs:

"My CD4 cell counts were down but after using ARVs now they have gone up. I'm not getting opportunistic infections."

Despite widespread information about the AIDS pandemic, the idea of bewitchment as a source of HIV was still reflected in the perception of some patients. A few of them thought that AIDS was therefore inevitable and that everyone was at risk of infection. From their perspective, someone with AIDS was presumed to be already a dead person. Three options for AIDS treatment were advanced: traditional healers, faith healing and the use of ARVs.

Although there was a difference between the study settings, in general there was no difference in perceptions about HIV and AIDS between the different groups of informants. Most key informants interviewed who worked in HIV-related fields commented that at the community level there was a lack of knowledge about ARVs and this was a threat to treatment adherence. Key informants stressed the importance of adherence counselling to ensure that patients do not drop out. They said that although medication was considered to be very effective, good counselling could help motivate patients to be more adherent. Although some key informants noted that belief in links between witchcraft and HIV infection still prevails in some population groups and reliance on traditional healing persists, many people increasingly put their trust in ARV medicines. Many more patients are now attending HIV treatment clinics and, as a result, these are becoming more congested.

Counselling in ARV administration is now increasingly included in information sessions for patients on ART. One male patient from Mt. Meru hospital who had received some counselling said he remembered to take his medication "*due to fearsome instructions from doctors.*" However, a female patient from a faith-based facility in Arusha reported that she was not told what would happen if she stopped taking the medication. In Arusha, FGD participants expressed similar concerns about the quality of counselling. Participants at one male FGD reported that:

"You find 25 patients and only one person attending all these patients and he just tells you to go and collect your medication." (Male FGD participant, Selian, Arusha)

Similarly, a participant in a female FGD said:

"I did my HIV test (in AMREF Dareda) and was told that I am infected, (but) without proper preparation," meaning that she was not adequately counselled. (Female FGD, Selian, Arusha)

In contrast, patients in Dar es Salaam, commented on their appreciation of the quality of the counselling they received. According to male participants in different FGDs, the majority believed that counsellors were providing a good service, including providing information on nutrition. A participant in a female FGD in Dar es Salaam reported that:

"We are advised to bring our husbands here so that we are both counselled on how to live in harmony. Voluntary counselling and testing staff are very helpful to direct people where to go for ARVs."

According to interviewees, the main modes of channelling health-based information in the surveyed health facilities included leaflets, seminars, adherence counselling, television and video. Meanwhile, conversation between patients provided an additional source of information.

Disclosure and social support system

Out of 100 ARV users interviewed (70 exit interviews and 30 semi-structured interviews), only eight were living alone in a household. It was found that 93.5% of the 30 semi-structured interviewees who were on ARVs had disclosed their HIV status, with 82.7% of them receiving some form of treatment support, such as transport support, food assistance and reminders to take medicines.

However, interviews with key informants and FGD participants revealed that stigma is still prevalent in society. PLWHIV were said to be affected by stigma both at home and in the workplace. This could affect both disclosure and adherence. According to a participant in a female FGD (Selian, Arusha):

“My utensils were put separate, including my spoon. All your belongings are not touched and you feel bad.”

The situation was worst for those employed in the private sector:

“I was a driver. I lost my job when my relative went to tell my boss that I was HIV-positive.” (Male FGD, Mwananyamala, Dar es Salaam)

“I lost my job after my boss noticed that I was HIV-positive.” (Female FGD, Selian, Arusha)

“I work in a drug store. I am told not to touch medicine because my hands have black spots and have been told that if customers notice, they will stop buying medicine from our store.” (Female FGD, Mwananyamala, Dar es Salaam)

“If I disclose I will be stigmatized. They look at us as if we are prostitutes. We are treated like leprosy patients.” (Male FGD, Mwananyamala, Dar es Salaam)

“Disclosure brings problems. You can lose business. Sometimes I am not invited to attend ceremonies because I have disclosed.” (Female FGD, Sinza, Dar es Salaam).

On the other hand, some respondents indicated that they had received some support as a result of disclosing their HIV status:

“I have told my family and if the time of taking medication comes they remind me.” (Male FGD, Selian, Arusha)

“My husband knows my status and we are helping each other. We cannot disclose in a workplace.” (Female FGD, Mwananyamala, Dar es Salaam)

Reminders to take medicines

A substantial percentage (44%) of respondents (42 out of 95) who were on ARVs reported that without any help they were able to remember the routine schedule for taking their medicines. Some of them commented that, as a result of strong counselling they had received they did not miss taking the ARVs. Meanwhile, 33 respondents (34%) reported having family carers, including a spouse and children, who used to remind them to take their medicines and 19 others (20%) said they used reminders such as clock alarms and calls to prayer at the mosque (*adhana*). Twenty respondents (21%) reported having forgotten to take their ARVs at some time since they started treatment.

Adherence to ARVs was also affected by other circumstances, such as forgetting to take medicines when travelling or very busy. One female FGD participant observed that failure to disclose and the need to ensure confidentiality can also inhibit people from taking medicine.

Food

Lack of food was cited as a problem for most ARV users. According to FGD participants, lack of food disrupted the daily schedule for taking medicines and affected adherence. Both male and female ARV users complained that the medicines were increasing their appetite and that they did not have enough food. A male ARV user at St Elizabeth Hospital explained:

“The problem I have with ARVs is related to food. I have no money and ARVs increases appetite. I am not capable of buying food.”

However, none of the ARV users interviewed for the study said they had stopped taking ARVs despite a lack of food. The persistence of ARV users in continuing treatment even when they went hungry was also corroborated by staff interviewed in the health facilities. A male doctor in Arumeru hospital observed that:

“Food is a big problem, patients are getting appetite when they use drugs, but have not stopped using medication.”

Other interviewees remained concerned at the potential impact of hunger on adherence to ART. For example, a female FGD participant observed that some patients take their medication only once a day, in the evening, because that is the time when they have food, and a key informant in Sinza, Dar es Salaam, noted that some patients were selling ARVs in order to buy food. This implies that food scarcity can be a drawback to adherence.

Complexity of treatment regimen

It was also observed that the complexity of the treatment regimens is a problem for some ARV users. Patients on ART are required to take their prescribed medicines at the same times of day on a regular basis. However, ARV users had different perceptions of

the treatment regimen and the correct time for taking the medicines. A female client from Arumeru commented that:

“It is a problem to take the medicines at the right time every day.”

This particular client indicated that she was taking her first dose of the day at 0700 hours and the second one at 2100 hours, thereby exceeding the recommended time of 12 hours between doses. Another popular misconception was revealed by a male FGD participant in Dar es Salaam:

“It is true you can forget taking drugs according to schedule but it is not good to exceed the recommended time interval by more than five hours.”

Most ARV users interviewed in Dar es Salaam indicated that they were taking their ARVs according to the required schedule, compared with a smaller proportion of those in Arusha.

According to the health staff interviewed in both Dar es Salaam and Arusha, most ARV users were following the required treatment schedule. A female nurse from Arumeru in Arusha said:

“Most patients follow the instructions given them on proper use of ARVs.”

Similarly, a nurse from a facility in Dar es Salaam stated that:

“A few patients do not follow their appointments but the majority are using ARVs properly.”

Meanwhile, a pharmacist in Dar es Salaam noted that:

“A few patients have difficulties in following the correct drug regimen.”

Side-effects

Although ARVs are known to cause some side-effects in the initial stages of treatment, these usually subside over time. However, this important information is not common knowledge among patients on ARVs. For example, patients in Arusha said:

“I was not informed of side-effects and what will happen to me if I stop taking medication.” (Male ARV user, Arumeru)

“I don’t know, I have not been told of impending side-effects.” (Female ARV user, Selian)

In one of the male FGDs, side-effects were cited as one of the reasons for missing a dose of ARVs. One male FGD participant from Dar es Salaam offered the following information on side-effects:

“When I started using medication I was feeling very cold. I went to ask at the hospital and they asked me, “Do you want to stop medication? Did we not tell you that the medicine had some side-effects?” Three days later I was fine.” (Male FGD, Sinza)

However, in Arusha, a male FGD member reported that side-effects had affected his treatment schedule:

“I had side-effects and decided to take medication only once per day.” (Male FGD, Arumeru)

Most ARV users reported experiencing some side-effects in the initial stages of treatment but these had largely subsided over time. However, in some cases, the treatment regimen had to be changed. Some of the common side-effects mentioned were body rash, swollen legs, nausea, headache, increased heart rate, diarrhoea and vomiting.

It was suggested by one respondent that adequate counselling and education about the appearance and disappearance (over time) of side-effects would help to better prepare ARV users for possible side-effects and make them more bearable.

“If side-effects are very severe patients may stop medication, but due to continuous counselling and education we give them we advise to continue and most follow.” (Female receptionist, Selian Hospital, Arusha)

5.2 Quality of operating structures

The information below was derived mainly from structured observations and from notes taken by researchers who visited the facilities.

Structural issues

Both health care providers and ARV users highlighted a number of structural problems in the health facilities which had a potential impact on adherence to ART. At Mount Meru in Arusha, for example, there was no separate room for consultation and thus no possibility of confidentiality for patients. At the time of this survey, three doctors were sharing a single room and consulting with three different ARV users at the same time. However, ARV users frequently mentioned that they were accorded respect. Elsewhere, at St Elizabeth, the waiting area was limited. In Arusha, the faith-based facilities generally had better operating structures than those in the public sector, where confidentiality was compromised by lack of space and the number of consultation rooms that were shared.

In contrast, consultations in Dar es Salaam took place in more appropriate consultation rooms. Although the quality of the infrastructure varied between the different facilities, it provided for adequate confidentiality, good counselling and adequate laboratory services.

The public health facilities in Dar es Salaam are well-endowed due to their involvement in the MDH project and operate on a daily basis unlike most of the facilities in the Arusha region. For instance, of the two public sector hospitals studied in Arusha, Mt. Meru had only one ART clinic per week, while Arumeru was running ART clinics daily (Monday to Friday), and the faith-based facilities were operating ART clinics three days per week.

Other structural problems highlighted included: the lack of prescribing capacity at Arumeru Hospital, where ARV users went home without medication on days when the hospital's only prescriber was not on duty; limited waiting space at the Hindu Mandal private facility in Dar es Salaam, which was difficult for both ARV users and care providers; lack of transport for the staff involved in home-based care services; and lack of medicines at ART clinics for the treatment of HIV-related opportunistic infections.

In addition, a female FGD participant in Arusha complained about the rigid bureaucratic procedures involved in transferring to another ART clinic closer to home:

"I was registered to start ART clinic in Kilimanjaro Christian Medical Centre (KCMC) in Moshi a year ago. At that time there was no ART clinic near my village. Now there is a clinic near my home but I am denied transfer from KCMC to my home clinic. KCMC is very far from here, about 170 km away. Sometimes I do not have the fare to travel to KCMC, hence missing my doses."

Key informants also maintained that there were not enough health care facilities providing ART. Meanwhile, ARV users complained that services in the few existing facilities were deteriorating due to the increasing number of patients. One key informant from Kinondoni, Dar es Salaam, suggested that:

"ART clinics should be increased and more private hospitals should also be included in the programme."

There were reports of wide variations in the length of time ARV users had to wait at the clinics. According to ARV users, waiting times varied from less than one hour to 10 hours (see Table 8 below).

Table 8: Average time spent by ARV users in health facilities studied

Number of ARV users interviewed		Hours spent before being attended to	Hours spent while being attended to at the clinic
Exit interview (N=70)	Mean time spent	2.5	4.8
	Range	1-8	1-10
	Waiting time most frequently experienced (mode)	1 (48.6%)	6 (21.4%)
SSI patients (N=30)	Mean time spent	3.8	5.1
	Range	1-8	1-9
	Waiting time most frequently experienced (mode)	1 (25.8%)	6 (22.6%)

SSI: Semi-structured interview

Staff qualifications and working conditions

A total of 28 staff were interviewed (including 16 from the four nongovernmental facilities). They included a dietician, laboratory technicians, counsellors, medical doctors, pharmacists and social workers. Only one of them had primary school education only and five had studied up to secondary education level only. The remaining 22 (78%) had undergone various tertiary education, including college education.

On the day of the exit interview, 97% of all patients saw the doctor and 77% saw a pharmacist while only 21% saw a counsellor, as presented in Table 9.

Table 9: Categories of health staff seen by patients on day of exit interview (N=70)

Cadre of staff	No. of patients who consulted with this category of health worker	Percentage
Counsellor	15	21%
General nurse	20	29%
Pharmacist	54	77%
Doctor	68	97%

The staff interviewed had worked in ART clinics for a period ranging from 3 to 36 months, with an average of approximately 15 months. Some staff (21.4%) had 12 months' experience of working in ART clinics. However, only three (10.7%) of the respondents reported that the training they had received for ARV management was adequate. Twenty respondents (70.7%) said that the training they received was too short and that they needed additional training.

A major complaint was the pressure of work. A nurse in one facility in Dar es Salaam said:

"There is a lot of work in this ART clinic and we are overworked."

As a result, many of the ART staff had multi-functional roles. For instance, one counsellor was responsible for routine nursing duties as well as administrative and supervisory duties. Out of 28 respondents, 11 (39.3%) were involved in adherence counselling in addition to other routine duties. In addition, nine nurse-counsellors were also dispensing drugs.

All the health facilities surveyed indicated that they were receiving an increasing number of ARV users, thereby adding to their workload. A female participant of an FGD in Mwananyamala said:

“If the situation remains like this, doctors will be tired and the last patient will not be attended properly.”

Meanwhile, a staff member from a hospital in Arusha suggested that doctors should start the clinic earlier.

In Dar es Salaam (but not in Arusha), the staff in public facilities are provided with some topping-up allowances. However, the majority of health care workers (93%) expressed low motivation. Other challenges are shown in Table 10 below.

Table 10: Challenges most frequently mentioned by health staff (N= 28)

Challenges	Number of respondents	Percentage
Low motivation	26	92.9
Heavy workload	23	82.1
Inadequate training	20	71.0
Long waiting hours for patients	12	42.9
Too few staff	11	39.3
Work fatigue	5	17.9
Being faced with difficult or non-compliant ARV users	3	10.7

In summary, staff complained of the increased workload involved in treating ARV patients, for which they were not adequately trained. In contrast, patients largely expressed appreciation for the quality of care provided, despite complaints about long waiting times.

Availability of guidelines and diagnostic equipment

A number of facilities lacked the necessary laboratory and diagnostic equipment. This led to delays for patients as they had to return again in order to get the results of tests (see Table 11).

Table 11: Status of diagnostic facilities in health facilities studied

Type of facility (N=7)	ELISA machine for HIV testing	CD4 machine	Biochemistry tests	Adequate laboratory space
Government (N=3)	1	1	1	2
Non-Government (N= 4)	4	2	2	4
TOTAL	5	3	3	6

The table shows that of the seven health facilities, only three had both CD4 and biochemical testing machines. According to both ARV users and staff, the services of the laboratory and testing were inadequate in some of the surveyed facilities. Problems cited included the unavailability of CD4 reagents and of CD4 cell count machines. As a result, test results were delayed because they had to be carried out in other facilities elsewhere.

All the facilities had NACP guidelines for ART. In addition, one nongovernmental facility in Dar es Salaam had WHO guidelines as well. The MDH project had also provided guidelines to its sites in Dar es Salaam. However, none of the facilities visited had their own policy guidelines.

Staff from all seven facilities reported that they had adequate HIV testing facilities and reagents and had no problem with processing results. However, two facilities in Dar es Salaam were concerned about delays in obtaining results.

Availability of medicines

The prescribed ARV drugs were usually available in all seven facilities. Of the interviewed staff, only five (including four from government facilities) reported periodic shortages of prescribed medicines, requiring them to borrow medicines from nearby facilities. However, it was learned retrospectively during the course of this study that ARV drugs were out of stock for a whole month in Arumeru Hospital, causing an interruption in treatment for ARV users. The unavailability of ARVs was linked to a delay in supplies from the Medical Stores Department. However, this situation has now been rectified. About 36 patients were on ARVs at that time and were asked to get their supply from the nearby Mt. Meru Regional Hospital.

During the survey period, there was also a shortage of supplies of Triomune 40 at the Mt. Meru Hospital. When needed for dispensing during the clinic day, the hospital had to borrow supplies from Arumeru Hospital.

Although medicines for opportunistic infections were reported to be available in some of the facilities, these were not provided free of charge in faith-based and private facilities with the exception of anti-tuberculosis medicines. In Arumeru Hospital in Arusha, medicines such as fluconazole and other antifungal medicines were not available, and there was no substitute drug for clients who had experienced an adverse drug reaction after using cotrimoxazole.

Since all facilities providing ART were getting medicine supplies from the Medical Stores Department, there were no significant variations in the available stock of ARVs. However, Hindu Mandal and Selian, both faith-based facilities, showed some slight variations in stocked medicines. For example, Hindu Mandal stocked indinavir and didanosine and Selian stocked abacavir and didanosine, medicines that were not available in other surveyed facilities. In addition, there were no fixed-dose combinations for syrup preparations, which poses a problem for paediatric treatment. In some of the facilities surveyed, there was inadequate space for drug storage and for counselling during the dispensing of ARVs.

Provider-patient interaction regarding use of ARVs

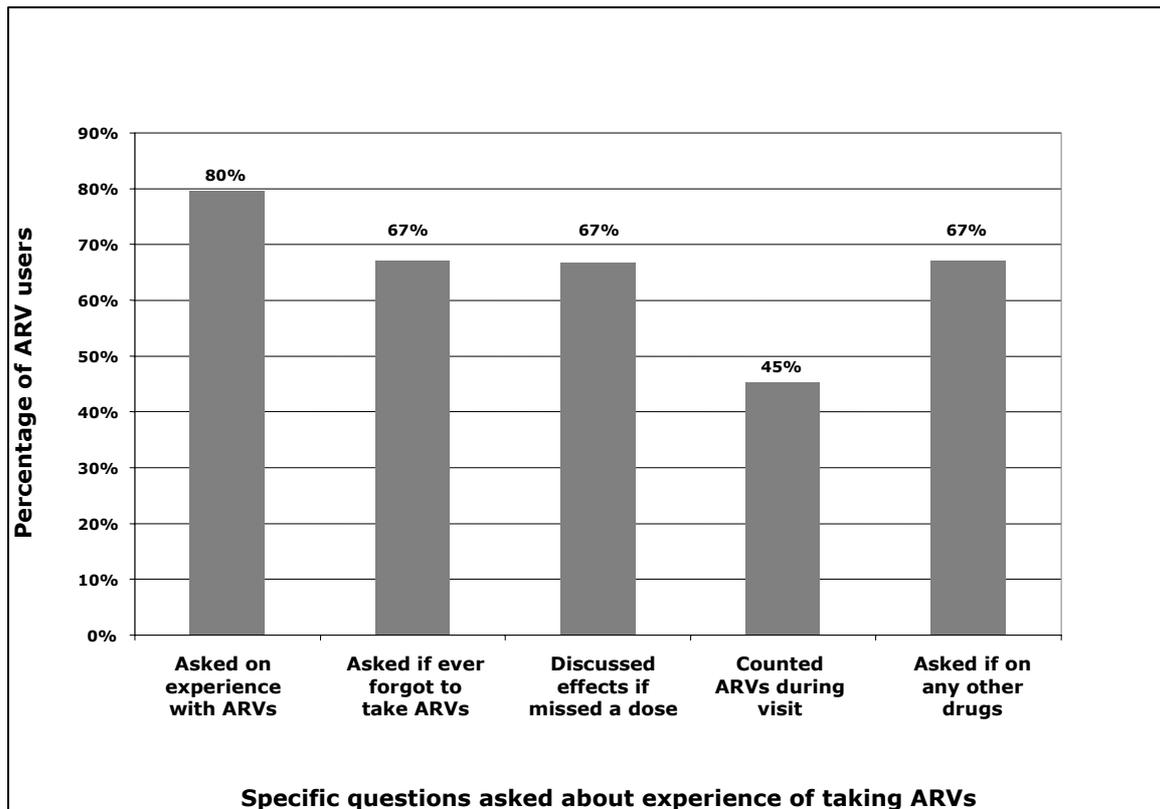
In all the ART facilities studied (both public and private) respondents stated that providers showed respect for ARV users. This may be the result of initial training, which was conducted by NACP under the MoH. One male FGD participant said:

“Providers show a warm relationship to clients and provide good services.” (Male FGD, Mwananyamala, Dar es Salaam)

However, hospital support staff who had not received any training on how to deal with AIDS patients were reported to be stigmatizing ARV users and behaving in an unethical manner towards them. For example, it was reported that a hospital cleaner in one of the public facilities in Dar es Salaam had shouted loudly to indicate the place where ARV users were seated, waiting to be attended to. This had been a major source of embarrassment for all involved.

As part of the follow-up on treatment adherence, health staff were expected to ask specific questions on the use of ARVs. Figure 4 below summarizes the questions most frequently put to ARV users. These data were obtained during the observation of consultation phase of the study.

Figure 4: Questions most frequently asked by health workers during follow-up in ART clinics (N=64)



During observation of consultations, seven new ARV users who came to start treatment were told about the possible side-effects, six were told about the importance of continuing with treatment, five discussed how to use ARVs, and four were informed about what to do if they forgot to take a dose. However, there was no discussion about other reproductive health needs, such as contraception and safer sex, in any of the observed consultations.

Costs

The cost of travel to the health facility for ARV users ranged between Tshs 200 to Tshs 30 000 (approximately 20 US cents to US\$30.00), while the distance travelled ranged from 1 km to 246 km. Most patients had started ART less than one year ago (mean 8.7 months, range 3-36 months). Costs were described as a constraint to adherence. Some ARV users said they were unable to keep their appointments because they could not afford the cost of travel. Patients also cited other costs, including registration and consultation fees. A registration fee of Tshs 1500 (US\$ 1.50) was levied at all facilities in Arusha except Mount Meru, where the registration fee was Tshs 3000 (US\$ 3.00). Elsewhere at Selian Hospital in Arusha, in addition to the registration fee, patients were also charged a consultation fee of Tshs 3000 (US\$ 3.00) per visit and Tshs 15 000 (US\$ 15.00) for each laboratory investigation to monitor the CD4 cell count. With the exception of the private Hindu Mandal Hospital, which charged a monthly consultation fee of Tshs 1000 (US\$ 1.00), the facilities surveyed in Dar es Salaam were not charging any fees.

5.3 Opinions and suggestions given by respondents to improve provision of ARVs

Most of the clients interviewed were very thankful that they were on ART and commended the Government's efforts to roll out the ARV programme. They described the ART programme as a "life-saving" one which had given them new hope:

"Drugs bring our energy back and we are getting hope of living."

Both ARV users and staff in the facilities involved offered a number of suggestions on ways of improving the provision of ARV services. Some of the ARV users suggested that separate rooms for consultation should be made available in the facilities and that ARV medicines should be dispensed in consultation rooms to enhance client confidentiality. There were frequent requests from patients for an increase in the number of staff in order to help reduce waiting times. It was also suggested that frequent seminars should be held to remind ARV users of the importance of the appropriate use of ARVs. Other suggestions included ensuring the availability of laboratory services (including reagents) at health facilities and ensuring that medications to treat opportunistic infections were provided free of charge. In addition, some staff at Arumeru Hospital suggested that the working environment at that hospital should be improved, particularly the waiting rooms and consultation rooms.

There was a request that the Government should provide financial support to facilitate sustainable income-generating projects and food assistance for ARV users who are poor. Meanwhile, the local government was encouraged to raise awareness of HIV-related issues at community level in order to help reduce stigma. Some patients also proposed that researchers should visit them once a year to ask about the kind of problems they are facing.

Staff in the various facilities had a range of different opinions on employment-related issues, such as staffing and conditions of service, education and training, and working conditions. The most common request was that more staff should be employed in order to cope with the increasing number of ARV users. Staff working with ARV users also called for the payment of a topping-up allowance. Even those currently receiving some allowances indicated dissatisfaction at the meagre amount they receive and argued that they should be paid adequate salaries. Staff also suggested that transport should be made available for staff who provide home-based care for ARV users (monitoring treatment progress and counselling both ARV users and family members on treatment adherence). Another suggestion was that nurses on ARV programmes should be exempted from routine ward work. Meanwhile, a pharmacist working in a private health care facility in Dar es Salaam recommended that at each treatment facility a pharmacist should be responsible for dispensing ARVs.

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On the issue of education and training needs, the staff recommended that community-based education and training should be made available for both ARV users and carers to help ensure that patients follow prescription instructions properly. In addition, the staff said there was a need to train staff members in HIV-related health issues, such as minimizing the risk of tuberculosis infection when caring for patients who are co-infected with tuberculosis and HIV.

Chapter 6: Discussion, conclusion and recommendations

6.1 Discussion

A comprehensive study of ARV adherence in Tanzania has not yet been attempted. This study has been conducted in order to identify factors which constrain or facilitate adherence to ART and to suggest possible ways to improve adherence. Reports from other countries have emphasized that sub-optimal adherence is the main cause for the failure of ARV therapy. The unforgiving nature of HIV requires that levels of adherence be higher (>95%) and more sustained than in most other areas of medicine (Garcia et al., 2003; (Paterson, 2000).

The present study examined a range of factors that can have a negative impact on adherence, including: stigma, poor social support, mistaken beliefs, lack of food, side-effects, inadequate counselling, long waiting times at treatment facilities, transport-related and other costs, and long distances to the health facility. Factors which can help facilitate adherence which were investigated included: adherence counselling, disclosure of HIV status to family members, social support, a reliable medicine supply chain, information and education.

Adherence measurement

Three different adherence measurements were used in this study. Two-day recall was found not to be discriminatory. Use of tablet counts and 28-day recall using a visual device (beads) were combined to produce a composite adherence measure. However, there were substantial differences between the results of these two measures. As there is no gold standard for adherence measures, further studies are needed to validate these different measures by comparing the different results with viral load counts, as has recently been undertaken by Carrieri et al. in Malawi.

The results of this survey indicate a composite one-month average adherence rate of 90% for ARV users at the seven facilities involved. This meant that 90% of all the pills that should have been taken over the previous month by those interviewed were taken. However, only 21% of ARV users interviewed reported achieving the optimal level of adherence (over 95%) as measured by the composite adherence rate. The remaining 79% self-reported to achieve only moderate adherence (85%-95% adherence rate) and are therefore at risk of treatment failure and the development of drug-resistant forms of the virus.

There was little difference in the composite adherence rate among ARV users interviewed in Arusha and Dar es Salaam, and there was no difference in adherence rates between males and females. In addition, there was no significant difference in

adherence rates among ARV users with different levels of education. These findings were similar to the observation by DiMatteo in 2004 that adherence was generally unrelated to variables such as gender, education or socioeconomic status.

In a study conducted in Cameroon, Akam et al. (2004) found an overall adherence rate of 68%. In that study, the constraining factors were found to be the cost of medication and some side-effects. Elsewhere, a study conducted in Botswana by Weiser et al. (2003), reported that between 54% and 56% of patients were achieving the optimal adherence rate of at least 95%. In the Weiser study, financial constraints were identified as one of the principal barriers to adherence. However, it was estimated that if cost was eliminated as a barrier, then the adherence rate would increase to 74%.

Our study would appear to confirm Weiser's findings, which suggest that at population level there are many patients who do not achieve optimal (95%) adherence and who are therefore at risk of treatment failure and the development of drug-resistant virus. We remain interested in investigating further the differences in our various measurements of adherence – ideally comparing these with viral loads, as was recently undertaken in Malawi (Carrieri et al., 2001).

Structural issues

Administering an effective ARV programme is a daunting task. In the present study, there was no uniformity among the treatment facilities in terms of follow-up monitoring and checking of drugs. Some facilities, especially the private ones, did not have procedures for asking patients to come with their medicines for pill count monitoring and to check on patients' adherence to medication. Some health care facilities did not have proper medicine storage facilities, which may compromise the quality of the medicines.

Some of the health care facilities studied did not ensure adequate confidentiality for patients. The worst example of this was a situation in which three doctors were sharing one consultation room and consulting with three different patients at the same time. This can inhibit some patients from attending consultations or from communicating openly, and so impair adherence.

In this study, a major issue for patients was the lengthy waiting times. ARV users spent an average of five hours waiting and being attended to at a facility. Lengthy waiting times could have a negative impact on both attendance at clinics and adherence. Patients complained that staff working at ART clinics were overworked, and in some health care facilities they started the clinic late. Some patients had to travel long distances, and then had to wait for a long time at the facility, sometimes for 10 hours. In addition to the impact of this on adherence, the long waiting times were said to strain the relationship between staff and patients. Food was also a related issue since patients had to buy food while waiting for treatment, thereby incurring additional costs.

In administering ARVs, efforts should be made to minimize waiting times. In many settings it may be possible to provide patients with appointment times, so they do not

have to wait all day. Another improvement that could be considered is an increase in the provision of laboratory services at the treatment facilities. At present, many ARV users continue taking medicines without regular checks to monitor their CD4 counts and liver and kidney function. The availability of laboratory services could also help motivate adherence since patients would know through the laboratory results that they were improving. This is an area that needs to be strengthened.

Counselling

Although counselling is a key requirement for successful adherence to ART, the importance of the need for regular ongoing counselling is not always recognized. This was confirmed in our study by the fact that only 21% of patients saw a counsellor on the day of their exit interview. Patients are counselled intensively prior to treatment and at the time they start treatment. However, once on treatment there is very little counselling unless they have a particular problem. Yet it is well recognized by Horne and others that adherence rates decline over time (Horne et al., 2001). Patients need to be counselled whenever they come for refills and if they are achieving at least 95% adherence, they should be congratulated and encouraged. If they are not, the counsellor should be able to spend time with patients and suggest adherence strategies. If a patient forgets, possible solutions are the use of alarm clocks or reminders from a treatment "buddy." ARV users also mentioned using calls to prayer at the mosque as well as reminders from family members. If the patient has not disclosed that they are on treatment, the counsellor could suggest approaches to disclosing or finding a treatment supporter.

Costs

Poverty is a serious problem in Tanzania, which can have a negative impact on adherence. Both key informants and ARV users said that many patients complained that these medicines increase the appetite and cause hunger. Since lack of food has been described as a problem for most people on ARVs, food shortages among the general population in Tanzania are a serious concern. It was reported that some patients were taking their ARVs only once a day, in the evening, because that was the time when they had food, and that some patients were selling their ARVs in order to buy food. This implies that food scarcity can be a drawback to adherence.

Although ARV users received medicines free of charge, the additional costs incurred were cited as an important reason for not visiting the health facility for follow-up and medicine refill. These costs included travel costs, registration or consultation fees at health facilities, and money spent on food while attending the treatment facilities. In addition, some patients had to travel long distances to the facilities and, in some cases, had to stay overnight near the clinic, thereby incurring additional accommodation expenses. Costs were seen as a constraint to adherence. Some ARV users suggested that they should be given loans to run small-scale businesses to help them cope with the additional costs incurred through being on ART.

Knowledge and beliefs

To be successful, an ART programme depends on a certain level of knowledge and awareness among ARV users. However, this study found wide variation in the level of

knowledge among ARV users about HIV, AIDS and ART. While knowledge about HIV and AIDS is generally good, beliefs that people have been bewitched, had a spell cast on them or been afflicted by an AIDS devil/spirit (a '*jini*') are commonplace and inhibit adherence to ART. Greater efforts are needed to educate both the community and ARV users about HIV in an effort to dispel beliefs about witchcraft.

Stigma

According to the testimonies of some ARV users, stigma remains a major problem. Moreover, disclosure and stigma seem to be different sides of the same coin. On the one hand, disclosure may cost the individual their job, social support and their family. On the other hand, a substantial number of ARV users who had disclosed were receiving support from family members. This support included financial assistance for travel costs and food, as well as reminders to ensure that they take their medicines on time. Although disclosure can have both negative and positive effects on adherence, it was more generally linked to better adherence, since 82% of those who had disclosed received various forms of help on the use of medicines. Efforts to ensure that the community is better educated about HIV and treatment would go a long way towards reducing stigma and encouraging disclosure.

Side-effects

A study conducted by Weiser et al. (2003) in Botswana indicated that side-effects did not pose a major barrier to adherence. The study found that while 51% of respondents experienced some side-effects, less than 10% of them reported side-effects as a significant barrier to treatment adherence. This was also noted by Akam et al. (2003) who found that very few side-effects were noted or cited as a cause of poor adherence (5%). In the present study, very few ARV users cited side-effects as a constraint to adherence. While some ARV users who participated in FGDs mentioned side-effects as a cause for skipping doses or taking medication only once per day, in most cases the side-effects were reported to disappear over time. However, this important information was not always communicated to ARV users in advance. In order to promote adherence, ARV users should have access to adequate education about potential side-effects and their likely duration.

Study limitations

There were some limitations to this study. First, the very few clients who refused to be interviewed or to turn up for FGDs may have significant information which has not been captured by this study. Second, the budget and time for this study were limited. Third, the method of determining adherence rates included self-assessment by ARV users and the literature suggests that patients tend to overestimate adherence (Chesney, 2000). Fourth, we were unable to relate the obtained adherence rate to viral loads and CD4 cell responses since this was not in our original plan, due to financial and logistical barriers to frequent laboratory monitoring in this setting. However, the combination of different approaches and respondents permitted extensive triangulation and gave us a comprehensive set of results in spite of the various problems faced.

6.2 Conclusion

Despite obstacles to ARV adherence, the overall mean composite adherence rate of 90% in the two areas surveyed is encouraging. However, more efforts are needed to ensure optimal adherence among the large group (79%) of ARV users who are currently taking less than the critical 95% of their dosage. The large variation in the results between pill counts and visual analogue demands an explanation. Therefore the two measures need to be validated against viral load, as was done by Carrieri et al. in Malawi.

Key challenges to optimal ARV adherence identified in this study include: the inadequate number of ART clinics; lengthy waiting times; travel costs and other treatment-related costs; an unreliable supply of ARVs in some facilities; stigma; lack of confidentiality; staff shortages; and a lack of incentives for staff. Such problems need to be tackled in order to ensure the smooth running of the ART programme and sustain optimal levels of adherence. Consideration should be given to providing support to ARV users to help alleviate poverty (including food support and loans to help people run their own business) and community education to help reduce stigma. In addition, more training is needed for staff in ART clinics to enable them to update their knowledge more frequently.

The GoT has established ambitious targets for ART and made a good start in rolling out ARVs. Many patients now have access to treatment and there is widespread appreciation of the Government and of the health workers involved in the programme. However, unless due attention is paid to the critical issue of adherence, the emergence of drug-resistance will be accelerated and the early treatment achievements could be reversed.

6.3 Recommendations

The following are presented as suggestions for interventions that we believe may promote ARV adherence rates among patients in Tanzania. They have not yet been evaluated and we would welcome the opportunity to undertake such intervention studies.

- ◆ **Institute pill counting.** Pill counting is an important monitoring and adherence promotion tool for both providers and users. However, in many facilities this system is not used. Although public facilities in Dar es Salaam have started pill counting, the system is weak and many patients do not bring their drugs for counting on clinic days. Pill counting will also help clear up suspicions that some patients are selling their ARVs.
- ◆ **Employ adequate numbers of well-trained staff.** More trained staff are needed to cope with increasing workloads in ART clinics. This will also help clients by reducing waiting times.

- ◆ **Increase access to ART clinics, as well as improving facility infrastructures and laboratory services.** This can be done both by increasing the opening hours of existing clinics and by opening new clinics closer to where people live. Such clinics might be used to review patients who have initiated treatment at a larger hospital facility.
- ◆ **Establish reliable drug supply.** There was some concern that the medicine supply chain is not yet reliable. A reliable supply of medicines needs to be instituted and efforts made to assure clients and providers that the supply chain is reliable.
- ◆ **Create proper referral networks of ARV users between facilities.** Such a referral and transfer network should allow patients to be treated as close to their homes as possible with minimum waiting times and travel costs.
- ◆ **Train staff in adherence counselling and continuously update their knowledge about HIV and AIDS.** This implies that not only pharmacists and dispensers have a responsibility for adherence counselling. Everyone from clerk to nurse to doctor to counsellor has a responsibility to encourage full adherence, recognizing how difficult it is for patients to maintain full adherence.
- ◆ **Train and support community counsellors who operate from their home (as seen in Arusha).** The use of community counsellors has been shown to be effective in other countries as well as in Tanzania. Creating training opportunities for such counsellors and involving them in follow-up and support of ARV patients should occur at every ART facility.
- ◆ **Prepare IEC material focusing on adherence to ARVs, stigma and disclosure.** These materials should emphasize that patients on ARVs need support to achieve optimal adherence and that patients on treatment can be healthy and fully able to work.
- ◆ **Waive registration and consultation fees.** Registration and consultation fees should be waived for AIDS patients.
- ◆ **Conduct intervention studies.** Intervention studies are recommended in order to sustain and promote adherence to ARVs. It is the wish of this research group to continue with intervention studies if funds are made available.
- ◆ **Loans and food support.** Due to the prevailing poverty in the country, loans and food support to ARV users should be considered by the Government and NGOs.

6.4 Proposed interventions

The following are the proposed interventions from this study.

INTERVENTION	SPECIFIC TARGET	METHOD OF EVALUATION	EXPECTED IMPACT
Managerial	Institute pill counting.	No. of clients bringing pills for counting.	Improve adherence rate.
	Employ adequate numbers of staff.	No. of new staff employed.	Reduce waiting time and improve counselling.
	Ensure reliable supply of medicines.	Availability of reliable medicine supply chain.	Improve adherence rate.
	Increase the no. of ART clinics.	No. of new ART clinics.	Reduce workload in ART clinics.
	Facilitate the transfer of ARV users to ART clinics closer to home.	No. of users transferred to ART clinics closer to home.	Improve adherence rate.
	Open clinics early and minimize waiting time.	No. of clinics open on time.	Reduce waiting times.
	Provide rooms for consultation that offer greater patient confidentiality.	No. of clinics with consultation rooms that offer patient confidentiality.	Improve attendance and adherence rate.
Educational: Training of provider	Update knowledge of staff.	System to update staff knowledge in place.	Improve adherence rate.
	Train staff in adherence counselling (emphasize initial side-effects).	No. of staff trained in adherence counselling.	Improve adherence rate.
	Train staff to be supportive, in an effort to minimize stigma.	No. of supportive staff trained.	Reduce stigma.
Educational: Training of the public	Train community counsellors who operate from home (as seen in Arusha).	No. of community counsellors trained.	Improve adherence rate.
	Prepare IEC materials focusing on promoting disclosure and reducing stigma.	No. and types of IEC materials prepared.	Increase disclosure rate and reduce stigma.
	HIV-related education for the public through radio, TV and newspapers.	No. of programmes produced.	Increase disclosure rate and reduce stigma.

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ANNEX 1: Exit interview with ARV users

Name of the interviewer: _____
 Interview number: _____
 Name of health facility: _____
 Date: _____

- Greeting
- Assurance of confidentiality

1. Sociodemographic information on informant

- a) Sex
- b) Age
- c) Educational level (no education, primary, secondary, tertiary)
- d) Who do you live with (spouse, children, house girl etc)?
- e) Employment status (unemployed, self, government, NGO)
- f) Distance from facility (in time or distance)

2. Whom did you consult/visit today? (can include more than one)

- Counsellor
- Nurse
- Medical doctor
- Pharmacist
- Other

3. What was the reason for your visit today?

- To start using AIDS medicines
- Routine follow-up, if yes: when did you start using the AIDS medicines?
- Other reason

4. What was the result of the visit?

- I got AIDS medicines for the first time
- They gave me a refill of my medicines
- They gave me a different kind of medicine. If yes, why did the doctor prescribe different medicines?
- Other (describe)

5. If you were given AIDS medicines for the first time today, or were given a new kind of AIDS medicine today, what did the health worker tell you? (Open-ended, then probe on following topics)

- How ARVs work
- How to use them
- The need to continue treatment
- What to do if a pill is forgotten
- Possible interactions with other drugs
- Which side-effects can occur and what to do if they occur
- (Breast) feeding requirements
- When and where to get re-supply

6. (If client was given a repeat prescription, ask him/her the following; if not applicable, proceed to 8)

- a) Did you talk with the health worker about your experience of using your medicines?
- b) Did the health worker ask you if you have missed a dose? If yes, did the health worker explain what the effects are of missing a dose?
- c) Did your health worker count your pills before giving you a new supply?
- d) Did the health worker ask you if you were taking any other medicines?

7. Assessment of adherence and non-adherence

- a) Do you have your medicines with you? May I see them? Please can you tell me when you take each of the medicines? (Refer to table with sun and moon, or other checklist)
- b) Are there any other medications you are taking (e.g. septrin, herbs etc)
- c) Over the last two days, when did you take your pills? (Not including today - from yesterday evening and back.)
- d) Did you perhaps miss any? (Confirming (c), sympathetic manner. Details if yes.)
- e) What do you use to remind yourself to take your pills?

8. Cost consideration

- a) How much do you have to pay to cover your travel expenses when you visit the clinic?
- b) What is the cost of registering at the clinic (if any)?
- c) What is the cost of the ARV medicines that you take (if any)?
- d) Do you lose any income as a result of your coming to the clinic?
- e) Do you incur any other costs as a result of your taking ART?
- f) Do you and your family have to give anything up in order to be able to pay for your ART?

9. Quality of care in the centre

I would like to ask you some more questions about the way you were treated in the centre today.

- (a) What do you think of the service you receive at this clinic? (General, open-ended, and then prompt, as below: ask for details as necessary)
- Do you feel listened to?
 - Are you given the chance to state your problems and ask questions?
 - Are you treated with respect?
 - Do you feel you can trust the health workers?
 - Do you have privacy during consultation and counselling?
 - How do you find the environment of the clinic?
- (b) How long did you spend altogether at the clinic when you last came for review?
- (c) How long did you have to wait before being attended to?
- (d) Did you receive any written information?

10. Perceived problems and possible solutions

- a) What do you perceive as most problematic regarding taking the ARV treatment?
- b) What do you think could be done to improve this?

Have you any questions for me?

Thank you for your time and cooperation!

ANNEX: 2: Semi-structured interview with ARV users

Name of the interviewer: _____
 Interview number: _____
 Name of health facility: _____
 Date: _____

- Greeting (to create rapport with ARV user)
- Statement of confidentiality.

1. Sociodemographic information on informants

- a) Sex
- b) Age
- c) Educational level (no education, primary, secondary, tertiary)
- d) Who do you live with (spouse, children, house girl etc)?
- e) Employment status (unemployed, self, government, NGO)
- f) Distance from facility (in time or distance)

We would like to understand a bit about how it is for people taking ARVs. Could you tell me how you spend a normal day? How do you spend your spare time? What do you do to relax?

2. Medical history of patient

- a) When where you first diagnosed?
- b) What made you decide to go for testing?
- c) When did you start treatment for HIV (HAART)?
- d) How do you feel about your health since you started treatment? How would you describe your health since you started treatment?
 - Better
 - The same
 - Worse

3. Patient knowledge about HIV/AIDS

We would like to understand what people actually know about the illness that they have. Can you tell me what you know about HIV/AIDS? (Allow patient to say what they want, then probe on the following: cause of HIV infection, cause of AIDS, prevention, life-long infection). Apart from this, is there anything else you may have heard from your community that explains AIDS in a different way?

4. Patient knowledge about ARVs

We would like to understand what people know about their treatment. Could you help us with this by telling me what you know about ARVs? (Allow patient to say what they want, then probe on the following: Prolongs life, Improves quality of life, Life long treatment, Knowledge about side effects.)

5. Assessment of adherence and non-adherence

We are trying to find out how patients manage to take their medicines – for some people it's not a problem, but we also know that others don't always find it easy. Please feel free to be open about the problems you face with this. Everything you say here will remain confidential, and will not be shared with anyone at the clinic.

- a) Do you have your medicines with you? May I see them? Please can you tell me when you take each of the medicines? (Refer to table with sun and moon, or other checklist)
- b) Are there any other medications you are taking (e.g. cotrimoxazole, herbs etc)
- c) Over the last two days, when did you take your pills? (Not including today - from yesterday evening and back.)
- d) Did you perhaps miss any? (Confirming (c), sympathetic manner. Details if yes.)
- e) This is a very important question. We appreciate how difficult it can be to take pills on a daily basis. If you sometimes miss a dose, please can you tell me what causes this to happen? Can you give an example or two?
- f) On the other hand, what is it that helps you to take your pills regularly and on time? (e.g. organizations, individuals, clock etc)
- g) Have you disclosed your status to any one? If so, who? Do they help you to take your pills? [If not covered in (f)]
- h) Have you had your treatment changed at any moment since you started on ART. If yes, why? (e.g Treatment failure, Side effects)
- i) Have you ever missed an appointment at your ART clinic? (Reasons, and details on type of consultation: review/refill etc.)
- j) What do you think happens in your body if you skip your ARV medication?
- k) Have you ever thought about stopping ART? If yes, details.

6. Perception about HIV/AIDS, ARVs and stigma

Have you had any experience of being treated differently because of your HIV status?

7. Cost considerations

- a) How much do you have to pay to cover your travel expenses when you visit the clinic?
- b) What is the cost of registering at the clinic (if any)?
- c) What is the cost of the ARV medicines that you take (if any)?
- d) Do you lose any income as a result of your coming to the clinic?
- e) Do you incur any other costs as a result of your taking ART?
- f) Do you and your family have to give anything up in order to be able to pay for your ART?

8. Quality of care

- a) What do you think of the service you receive at this clinic? (General, open-ended, and then prompt, as below: ask for details as necessary)
 - Do you feel listened to?
 - Are you given the chance to state your problems and ask questions?
 - Are you treated with respect?
 - Do you feel you can trust the health workers?
 - Do you have privacy during consultation and counselling?
 - How do you find the environment of the clinic?
- b) How long did you spend altogether at the clinic when you last came for review?
- c) How long did you have to wait before being attended to?

9. Perceived problems and possible solutions

- a) What do you perceive as the biggest problem regarding taking ARV treatment?
- b) What do you think could be done to improve this?

Have you any questions for me?

Thank you for your time and cooperation!

ANNEX 3: ARV users, FGDs

- Name of ARV-providing health facility
- Participants per FGD (6-8)
- Adults (= or >18 years, men and women separately)
- One moderator, one note-taker (*and* use of tape recorder)
- Neutral venue outside the facility
- One FGD with men, and one with women per facility

Short introductory remarks

- Introduction of researchers and participants
- Thank participants for agreeing to participate, all share a common feature – they are on ARV treatment, are here to share thinking about ARVs and difficulties to take ARVs, want to learn from participants
- Explain purpose of study, purpose of this discussion, reassurance about confidentiality, agree on rules

Guide for discussion

1. What treatments do you know to be available for treating HIV? What is your opinion about these? (e.g. alternative treatments; traditional remedies; healing; spiritual; prayers; perceived benefit of treatment).
2. What is your experience of ART? (probe about adverse effects, pill burden, lack of food, lifestyle issues, adherence).
3. How do you think you are being treated (handled) by the health care workers (probe, *in relation to adherence*: privacy, confidentiality, respect, being listened to, time spent with patient, waiting time, integration with other services, under-the-counter payments)
4. What do you think about the counselling that you receive? (probe especially on importance of adherence)
5. What support is available for you in the community, in the family, in the workplace? (probe about discrimination, stigma)
6. What do you think could be done to help people to adhere more easily to their treatment?

Duration of discussion (1½ hours); provide refreshments

Conclusion, thank participant

ANNEX 4: Adherence measurement tools

Date: _____

Name of the interviewer: _____

Name of health facility
providing ARV: _____

- a) Interviewer introduces him/herself
- b) Explain purpose of exercise: “You have come here to get your ARV medication. We know that it is very difficult to take this medication, and we are doing some research to find out whether patients manage to take their medicines correctly – would you have a few minutes to answer some questions?”

1. Sociodemographic issues

- a) Sex
- b) Age
- c) Level of education completed
- d) How far did you have to travel today?

2. Cost considerations

- a) How much do you have to pay to cover your travel expenses when you visit the clinic?
- b) What is the cost of registering at the clinic (if any)?
- c) What is the cost of the ARV medicines that you take (if any)?
- d) Do you lose any income as a result of your coming to the clinic?
- e) Do you incur any other costs as a result of your taking ART?
- f) Do you and your family have to give anything up in order to be able to pay for your ART?

3. Treatment and adherence issues

- a) How long have you been on ART?
- b) Have you experienced any side-effects with your ARV medication? (If yes, has this been a reason for you to skip your medication at any time?)
- c) Has distance to the clinic ever been a reason for you to skip your medication at any time?

- d) Has cost ever been a reason for you to skip your medication at any time?
- e) What do you think happens in your body if you skip your ARV medication?
- f) Does a lack of food ever make you skip your medication?
- g) Do you have anyone to remind you to take your medication?
- h) Have you ever missed an appointment at your ART clinic?
- i) Have you ever had to skip a dose because you felt you had to hide your medication from others around you?

4. Adherence counts

“We would like you to get your best guess about how much of your ARV medication you have managed to take in the last month. We would be surprised if it is 100% for most people.”

We will take several approaches to measuring adherence:

I. Two-day recall diary

Three elements within this, as in sun and moon chart

Over the last two days, when did you take your pills? (Not including today - from yesterday evening and back.) Please mark with a cross when you took pills on the form below.

When did you take your medicine yesterday?																			
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Name of medicine																			
When did you eat yesterday?																			
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

II. Visual analogue approach

(a) Ask patient to pour one lot of beads (representing all the pills they would take in any given month, note separately for each medicine), A glass full of beads is marked with 0-10 cm line, after pouring beads to an empty glass, estimate pills not taken by looking at the mark of beads remaining in the first glass.

III. Pill count

Train the pharmacist to do pill count and fill the slip shown below.

Ask the client to take the slip to the pharmacy to be completed. Collect the slip from the pharmacy.

ANNEX 5: Key informant interview

- Participants are community leaders, coordinators of ART, or people who have had some direct experience with ART;
- Adults (= or >18 years)
- One moderator, one note-taker (*and* use of tape recorder)
- Neutral venue in the community

Short introductory remarks, explain purpose of study, define what we mean by 'adherence', purpose of this discussion, reassurance about confidentiality

Introduction of researchers and participant.

1. Do you know where people can obtain ARVs in this area? (Probe also perceptions on ART, availability of traditional healers in that area etc.)
2. How does your community view for people who are taking ART? (Probe on stigma, discrimination, logistical issues for reaching clinic etc.)
3. Do they face any problems with adherence to their medication? (Probe on poverty, hunger, access to ART etc.)
4. What activities take place at the moment in your community to help people adhere to their medication? (Probe on support, home based care, individual.)
5. What *should* be done to ensure that people on ARVs take their medications as instructed?

Duration of discussion (1 ½ hours)

Conclusion, thank participants

ANNEX 6: Semi-structured interviews (with staff)

Name of facility: _____
 Date: _____
 Interviewer: _____

- Questions 1,2,3,4,17,18,19,20 should be answered by all categories of persons
- Questions 10 should be answered by Doctors and Pharmacists only.
- Questions 7 should be answered by a Pharmacist only
- The rest of questions see asterisk guidance [*]

Number	Question	M	Dr	N	P	So/Co	Di	R
Tasks and training								
1	What is your job in this clinic?	*	*	*	*	*	*	*
2	How long have you been doing this job?	*	*	*	*	*	*	*
3	What specific training have you received for this job in relation to ART? Tell me about the training (Details)	*	*	*	*	*	*	*
4	Do you think this training has been sufficient? (Details)	*	*	*	*	*	*	*
Drugs, treatment and procedures								
5	Which treatment guidelines for ART do you use in this facility? (Give details if necessary, e.g. national guidelines etc.)	*	*	*	*	*	*	
6	Are the drugs you prescribe always available? (If not, give details – how often, reason, what do you do about it)	*	*	*	*	*	*	
7	Are the drugs in the guidelines you use to dispense always available? (Give details – how often, reason, what do you do about it?)				*			
8	How reliable are your lab and diagnostic support services? Do results come in on time? Details.	*	*	*	*	*	*	
9	What is your procedure when a patient is put on ART for the first time?	*	*	*	*	*	*	
10	What is your procedure when a patient switches regimens?		*		*			

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Number	Question	M	Dr	N	P	So/Co	Di	R
Adherence issues								
11	How do you think your patients do, generally speaking, in terms of adherence to ART?	*	*	*	*	*	*	
12	Generally speaking, do your patients keep their appointments?	*	*	*	*	*	*	
13	Could you estimate the percentage of your patients who you think are sufficiently adherent to ART? (Respondent gives their definition of 'sufficiently adherent'.)**	*	*	*	*	*	*	
14	We would like to get your views on the following (probe): a) How would you compare adherence between women and men? b) How would you compare adherence between older patients and younger patients? c) How does a patient's educational level affect adherence? d) How do you think that cost to patients influences adherence? e) How do you think the distance to the health facility affects adherence? f) In what way does having or not having a treatment-support partner affect adherence? g) Duration of treatment? h) Side effects? i) Lack of food? j) Knowledge about ART?		*	*	*	*		
15	Do you have a standard practice at this facility to support your patients to adhere to their treatment? If yes, is it documented? Can we see it? In what way is it used?	*	*	*	*	*	*	
16	What are the main challenges you face in supporting your patients to adhere to ART (especially for longer term users)?	*	*	*	*	*	*	
Challenges and staff support								
17	What are the main challenges you and your colleagues face more generally in your work? (if necessary, prompt re workload, stress, burnout)	*	*	*	*	*	*	*
18	Have these challenges changed in any way since you started here?	*	*	*	*	*	*	*
19	Is any special support made available to staff engaged in ART at this facility?	*	*	*	*	*	*	*
20	Is there anything you would like to see done differently in this facility? If yes, what?	*	*	*	*	*	*	*

Key

Managers – M
Doctor – Dr
Nurse – N
Pharmacist – P

Counsellor – Co
Social workers – So
Receptionist – R
Dieticians – Di

ANNEX 7: Observation (consultations)

Don't forget informal, unstructured observations!!!

Name of facility: _____
 Date: _____
 Observer: _____
 Time observation started: _____
 Time observation ended: _____

Person observed

2. Doctor – Dr
3. Dieticians – Di
4. Nurse – N
5. Pharmacist – P
6. Receptionist – R
7. Counsellor – Co
8. Social workers – So

Things to note for observation

- Questions 2,6,7,8,19,20,21 should be answered by all categories of persons
- Questions 1,3,4,5,9,10,11,12,13,15,16,18 should be answered by Doctors, Nurses, Pharmacists and Social workers
- Questions 14 and 17 should be answered by a Pharmacist only
- Suggest a 'one-in, one-out' approach for conducting observations – follow one patient in for observation; take time to write up notes while the next one goes in; then follow the next patient in.
- Response forms should include 'yes/no' boxes to be ticked where relevant, with space for writing down other details.

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Number	Topics for checklist	Yes	No	Not applicable	Details
1	What is the reason for the visit?				
2	Is patient well received? (If not, describe.)				
3	Does the consultation take place in privacy? (describe consultation room and environment)				
4	Does the health worker ask about any symptoms?				
5	Is the patient invited to ask questions? (If yes, what do they ask? If yes, was the question addressed? Details.)				
6	Is the patient told what to do next (within the health facility)?				
7	Is the patient told where to go for that?				
8	Is the patient told when to come back for refill and review?				
9	Is the sequence of events in relation to treatment protocols explained to <i>new</i> patients? (Requires training for observer)				
10	Do <i>new</i> patients receive comprehensive general information about ART? (How ARVs work, How to use them, The need to continue treatment, What to do if a pill is forgotten, Possible interactions with other drugs, Which side effects can occur & what to do if they occur, (Breast) feeding requirements, When and where to get re-supply) Are new patients asked if they were previously exposed ARVs through PMTCT, Or buying themselves from medical stores?				
11	Are <i>new</i> patients and those switching regimens given information about importance of adherence to ART: (i) dose, (ii) timing, (iii) what will happen if vomit up the pill, (iv) forgets timing, (v) misses dose, (vi) travelling?				
12	For follow-up users only: is there any discussion about the patient's experience of using their medicines? (specifically side effects)				
13	For follow-up users only: Does the health worker ask if the patient missed a dose? If yes, does the health worker explain what the effects are of missing a dose?				
14	For follow-up users only: Does the health worker count the patient's pills before giving him/her a new supply?				
15	Does the health worker ask the patient if they are taking any other medicines?				
16	Is the importance of adherence to ART reinforced?				

Number	Topics for checklist	Yes	No	Not applicable	Details
17	Does the patient receive specific tools to remind them to take their drugs? (eg pill calendar)				
18	Is the patient asked anything about their adherence strategies (include categories for adherence support partner/s, clock, mobile phone, other)?				
19	Is there any effort made to confirm whether or not the patient understands the information and instructions given?				
20	Does the clinician/nurse/counsellor <i>listen</i> ? (details?)				
21	Do the health workers ever act or speak in any negative way (impatient, judgemental etc) towards patients? (If yes, describe)				

ANNEX 8: Observation of antiretroviral (ARV) stock

Clinic:..... Name of interviewer:..... Date:..../...../ 2005

1.Availability of drugs in stock:

Active ingredient(s)	Brand name	Dosage form	Strength(s)	In stock? (Y/N)	Out of stock in the past days?
-d4T/3TC/NVP	Triomune 30	Tab	D4T30mg/3TC150mg / NVP 200mg		
"	Triomune 40	Tab	D4T40mg/3TC150mg / NVP 200mg		
Efavirenz	Stocrin®, Sustiva®	Tab	50, 200, 600mg		
"	"	Oral sol.	150mg/5ml		
Lamivudine	3TC®	Tab	150mg		
"	"	Oral sol.	50mg/5ml		
Lopinavir+ ritonavir	Kaletra®	Tab	133,3mg+33.3mg		
Nevirapine	Viramune®	Tab	200mg		
"	"	Oral susp.	50mg/ 5ml		
"	"	Oral sol.	400mg/5ml		
Stavudine	D4T, Zerit®	Tab	30, 40mg		
"	"	Oral sol.	5mg/5ml		
Zidovudine	Retrovir®	Tab	100, 250mg		
"	"	Syrup	50mg/ml		
"	"	Infusion	10mg/ml		
Zidov+ Lamiv.	Combivir®	Tab	300mg+150mg		

2. Are buffer stocks written in the stock record card? Yes No
3. Is there a written policy for emergency procurement of ARV?
Yes No
4. Is the storage condition satisfactory? Yes No
5. Is storage room / space / size satisfactory? Yes No
6. Are stock register/records with respect to prescription maintained? Yes No

