Need for improving quality of operating structures and processes for better ARV adherence for patients with HIV/AIDS in Tanzania and other African countries: an experience from Tanzania

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Abstract

Objective: The study was carried out in order to determine the following objectives: (1) To determine the proportion of patients who state achieving or not achieving optimal adherence to antiretroviral therapy (ART) in selected Care and Treatment Sites in Arusha and Dares Salaam regions in Tanzania. (2) To identify factors such as structural, cultural or disease related contributing to sub-optimal adherence to antiretroviral (ARVs). (3) To assess quality of operating structures and processes for provision of antiretroviral (ARVs) in the selected healthcare facilities. (4) To document suggestions and proposals for improving ART adherence among ARV users. **Methods**: Data from 7 studied facilities (3 public and 4 private/or faith based) includes 207 interviews from ARV users, 28 staff interview staff, 26 observations during consultations, 8 focus group discussions, 10 key informant interviews, and stock checks in 6 facilities. The study design was a cross-sectional using both qualitative and quantitative data collection techniques. Quantitative data were collected by using an adherence tool check list, while qualitative data were obtained using a consultation observation checklist, semi-structured interviews, focus group discussions (FGDs) and key informant interviews. **Results**: There were slight variations in the quality of operating structures and processes in the two studied regions. However results indicate that ARV adherence in Arusha region was comparatively similar to that of Dares Salaam. The composite adherence for one month in seven facilities was 90% and only 21% of ARV users achieved optimal adherence. **Conclusion**: The overall mean composite adherence rate of 90% in the two areas surveyed is encouraging. More efforts to improve the quality and processes of operating structures in our study facilities and others in Tanzania are needed to ensure optimal adherence among the larger group (79%) of ARV users who are currently taking less than the critical 95% of their medications.

Keywords: Antiretrovirals (ARVs); HIV/AIDS; Antiretroviral therapy (ART); Adherence; Tanzania

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INTRODUCTION

HIV is a serious public health problem in Tanzania, with an estimated prevalence of 7% among adults[1]. HIV is a major development crisis that im-

pacts health, economic, and social progress - reducing life expectancy, deepening poverty, and exacerbating food shortages [National AIDS Control Programme (NACP)].

The advent of ARVs in 1996 changed the HIV experience for people in the world´s richest countries[2]. 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[2].

Over the past few years, the price of ARVs has fallen dramatically, thus making them more available in the developing world where they were previously unaffordable for millions of people. The Government of Tanzania (GoT) has ambitious plans to put more than 400 000 people on ARVs within a five-year period (October 2004-September 2009). As ART enrolment is scaled up in Tanzania, there is a need for community mobilization and empowerment in order to address social factors that constrain adherence. An understanding of these factors is crucial in order to plan for the increase in ART access. 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[3].

Adherence is described as the engagement and accurate participation of an informed patient in a plan of care[4]. 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 care plan, as well as keeping appointments and tests as scheduled[4]. Studies have shown no significant difference in adherence between resource-limited and resource-rich countries, suggesting that patients in all environments have trouble adhering to medicines 100 % of the time.

To maintain viral suppression of HIV requires maximum adherence (at least 95%) to ART[5,6]. It is therefore recommended that all ARV programmes worldwide should have a concurrent plan for adherence assessment and support[4,7].

The role of socio-demographic characteristics, such as gender, race, age, exposure category and educational level as predictors of adherence has produced largely inconsistent results[8]. Low adherence is not restricted to certain social classes, but is widespread and unpredictable. It varies not just between individuals, but also for the same individual over time[9,10] 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[8].

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[11-14]. 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[15,16].

MATERIALS AND METHODS

This study was a cross-sectional study survey using both qualitative and quantitative techniques[17]. Quantitative data were collected using an adherence tool, exit interviews and semi-structured interviews. The adherence tool measured ARV adherence by using three different methods: a two day recall period, pill count, and visual analogue where glass and beads were used. This was done before the patients collected medication from the pharmacy. The exit interview was conducted after the patient had been attended to.

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

Study sites and population

The study was conducted in Arusha and Dares Salaam regions of the United Republic of Tanzania. Arusha is situated in the northern highlands and has a population of almost 1.3 million, while Dares Salaam lies in the coastal region with almost 2.5 million inhabitants[18]. These two cities were chosen

because they had already been providing ARVs for at least three months at the time of the study.

The study population included ARV users (adult) from seven health care facilities who met the criterion of being on ART for at least three months, clinical staff at the seven health care facilities, pharmacists, and key informants from the communities where the ARV users live (eg., AIDS activists from NGOs, coordinators of HIV programmes and representatives of the local government).

Data collection
Data were collected using semi-structured interviews, FGDs, key informant interviews, an adherence measurement tool, and observation of consultations. Members of the research team met each evening to review the daily experiences, and the Principal Investigator checked the completeness of the collected data daily. In order to maintain consistency, the same team collected data in both Arusha and Dares Salaam.

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. For the qualitative data, Nudist software was used to code and summarize the data using themes.

RESULTS

Social demographic characteristics of ARV users
The mean age of ARV users surveyed was 43 for males and 37 for females. Most (60%) had completed primary education and just over 30% had completed secondary education (Table 1).

Adherence measurements and rates
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 results with viral load counts, as has recently been undertaken by Carrieri *et al*[9], in Malawi. The results of this survey indicate a composite one-month average adherence rate of 90% (Table 2).

From the health workers' perspective (using the semi-structured questionnaire), the mean percentage of adherence was estimated to be 87.8% (range 60%-100%). 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. The number and percentage of ARV users according to adherence rate in health facilities studied and according to sex are presented in Tables 3a & b respectively.

A slightly higher proportion of females than males (23% vs 15%) achieved optimal adherence among the ARV users. However, overall there was no significant difference between males and females in adherence ($\chi^2 = 0.4$, $P = 0.51$).

Furthermore, a comparison of the adherence rates according to the education level among ARV users showed no association between education and adherence rates (Table 4).

Quality of operating structures and processes
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 ART adherence. 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. This can inhibit some patients from attending consultations or from communicating openly. However, ARV users frequently mentioned that they were accorded respect. In contrast, consultations in Dares Salaam took place in more appropriate consultation rooms.

Other structural problems included: (a) 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; (b) limited waiting space at the Hindu Mandal pri-

vate facility in Dares Salaam, which was difficult for both ARV users and care providers; (c) lack of transport for the staff involved in home-based care services; and (d) lack of medicines at ART clinics for the treatment of HIV-related opportunistic infections.

Key informants 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.

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. Furthermore, lack of diagnostic equipments and reagents were frequently mentioned during interviews and FGDs (Table 5).

Table 1 Age distribution of the ARV users in relation to sex ($N = 207$).

Sex	Age	Tool			Total/Mean ($N = 207$)
		SSI($N = 30$)	Exit Interview($N = 70$)	Adherence tool($N = 107$)	
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

Table 2 Adherence of ARV users by facility (%, $N = 107$).

Hospital		Two – day recall	Visual analogue	Pill count	Composite adherence
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
Dares 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

Table 3a Number and percentage of ARV users according to adherence rate in the health facilities studied (%, $N = 107$).

28 day mean composite adherence rate	Arusha		Dares 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 3b   Number and percentage of ARV users according to adherence rate and sex in health facilities studied （$N = 107$）.

28 day mean compositeadherence rate	Male No. （%）	Female No. （%）	Total 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 4   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	0.00（0.00 − 3.59）

Table 5   Status of diagnostic facilities.

Type of facility（$N = 7$）	Lack of ELISA machine	Lack of CD4 machine	Lack of biochemical tests	Inadequate laboratory space
Government （$N = 3$）	2	2	2	1
Non- Government（$N = 4$）	0	2	2	0
Total	2	4	4	1

Counselling

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/nurses." 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. 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. Although the quality of the infrastructure varied between the different facilities in Dares Salaam, it provided for adequate confidentiality, good counseling and adequate laboratory services. Faith-based facilities generally had better operating structures than those in the public sector.

Staff qualifications and working conditions

A total of 28 staff were interviewed. This included a dietician, laboratory technicians, counselors, medical doctors, pharmacists and social workers. One of them had only primary school education and five had studied up to secondary education level. The remaining 22 （78%） had undergone some tertiary education, including college. On the day of the exit interview, 97% of all patients saw the doctor, 77% saw a pharmacist, 29% saw a nurse, while only 21% saw a counselor.

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; however, only three （10.7%） 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. Many of the ART staff had multi-functional roles. Out of 28 respondents, 11 （39.3%） were involved in adherence counseling in addition to other duties. One

counselor was responsible for nursing tasks as well as administrative and supervisory duties; nine nurse-counselors 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.

Meanwhile, a staff member from a hospital in Arusha suggested that doctors should start the clinic earlier. The majority of health care workers interviewed (93%) expressed low motivation. Challenges included: heavy workloads (82%), inadequate training (71%), long waiting hours for patients (43%), too few staff (39%), work fatigue (18%), and being faced with difficult or non – complaint ARV users (11%). 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 lack of necessary laboratory and diagnostic equipment in some facilities caused delays. Of the seven health facilities, only three had both CD4 and biochemical testing machines. This necessitated that tests be conducted elsewhere and patients return for test results. According to both ARV users and staff, the testing services of the laboratory were inadequate. Specific problems cited included the unavailability of CD4 reagents and CD4 cell count machines.

All the facilities had guidelines for ART - these may have been from NACP, WHO or project-specific documents. However, none of the facilities visited had their own policy guidelines.

Availability of medicines
The prescribed ARV drugs were usually available in all seven facilities. Of the interviewed staff, only five 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. About 36 patients were on ARVs at that time and were asked to get their supply from the nearby Mt. Meru Regional Hospital .

Medicines for opportunistic infections (OIs) were not always available. For example, in Arumeru Hospital in Arusha, fluconazole and other antifungal medicines were not available, and there was no substitute drug for clients who had experienced an ad-verse reaction to cotrimoxazole. Furthermore, medications available for OIs were not provided free of charge in faith-based and private facilities with the exception of anti-tuberculosis medicines. There were no fixed-dose combinations of syrup preparations, which poses a problem for paediatric treatment; and in some of the facilities surveyed, there was inadequate space for drug storage and medication counselling.

Provider-patient interaction regarding use of ARVs
In all the ART facilities studied, 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.

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.

DISCUSSION

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[6]. This study suggests that at a population level there are many patients who do not achieve optimal (95%) adherence and who are therefore at risk of treatment failure and to the development of a drug-resistant virus.

Thus, 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 of at least 95%[5,6]. Insufficient adherence to ARVs is likely to result in treatment failure and the emergence of drug resistant strains of HIV and if this happens it definitely requires changing to second line treatment regimens, and this greatly increases treatment costs[3]. So every effort should be made to prevent this from occurring especially in developing countries where there are meager resources and governments and its people can not afford buying very expensive medications for its people. Administering an effective ARV

programme is a daunting task and this study identified many structural issues which could seriously impact ARV adherence. These include overcrowded facilities with inadequate confidentiality for patients, lack of adequate monitoring and checking of drugs, lack of proper medicine storage facilities, and lengthy wait times. ARV users spent an average of five hours waiting and being attended to. The long wait times were said to strain relationships between staff and patients, who also complained that staff working at clinics were overworked. Food was also a related issue since patients who traveled long distances and then had to wait for several hours had to buy food while waiting for treatment, thereby incurring additional costs.

Inadequate equipment and supplies was also found to be a problem. This was further complicated by inconsistent availability of OI medications and pediatric formulas. Furthermore, laboratory services are needed for strengthening, improving or confirming diagnosis, monitoring disease prognosis and medications the patients are taking. However, most of the essential basic equipments were lacking in most facilities studied. The availability of laboratory services could also help motivate adherence since patients would know through the laboratory results that they were improving. At present, many ARV users continue taking medicines without regular checks to monitor their CD4 counts and liver and kidney function.

Although counseling is a key requirement for successful adherence to ART, the importance of the need for regular ongoing counseling is not always recognized. This was confirmed in our study by the fact that only 21 % of patients saw a counselor on the day of their exit interview. Patients are counseled intensively prior to treatment and at the time they start treatment. However, once on treatment there is very little counseling. It is well recognized that adherence rates decline over time[15,16], therefore patients should be counselled whenever they come for refills and the counselor should suggest adherence strategies. If patients are achieving at least 95% adherence, they should be congratulated and encouraged.

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 was not 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 patients tend to overestimate adherence[19]. Fourth, financial and logistical barriers prevented us from being able to relate the obtained adherence rate to viral loads and CD4 cell responses. However, the combination of different approaches used in this study permitted extensive triangulation and gave us a comprehensive view of our results including the accompanied adherence difficulties encountered.

CONCLUSION
Despite obstacles to ARV adherence, the overall mean composite adherence rate of 90% in the two areas surveyed is encouraging. There was little or no difference in the composite adherence rate between the two study sites, between males and females, or among ARV users with different levels of education. 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. Additionally, the large variation in the results between pill counts and visual analogue demands an explanation despite the fact there are reports showing that variations in patients adherence to medical recommendations are common[20]. Therefore the two measures need to be validated against both CD4 count and viral load, as was done in Malawi[9].

Key challenges to improving operating structures and processes so as to achieve optimal ARV adherence by patients include increasing number of ART/ARV clinics; decreasing or shortening waiting times; putting in place a reliable (improving ARV supply chain) as this will help avoid stockouts; increasing patients confidentiality by improving infrastructures; employ more trained staff training to curb shortages and provide frequent on job trainings for health staff; improve and provide adequate counselling and provide incentives to staff in ART clinics in order to motivate them. Such problems need to be tackled in order to ensure the smooth running of the ART programmes and the maintenance of optimal levels of adherence.

Recommendations
The following are presented as suggestions for interventions that we believe may promote ARV adherence rates among patients in Tanzania.

Employ adequate numbers of well-trained staff. This will decrease staff workload and reduce patient wait times.

Increase access to ART clinics. This might mean increasing a clinic´s hours or opening additional clinics closer to where people live.

Establish reliable drug supply. Adherence is reduced if the supply chain is unreliable or interrupted.

Train staff in adherence counselling and continuously update their knowledge about HIV and AIDS. 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.

Improve infrastructure to reduce overcrowded conditions. Confidentiality is essential during consultations.

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