THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

RESEARCH PROPOSAL

A STUDY ON ADHERENCE TO ANTIRETROVIRAL THERAPY IN TANZANIA - A PRE-INTERVENTION STUDY

Submitted by: Irunde H., Ngemera M.
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ABBREVIATIONS

AIDS	= Acquired Immune Deficiency Syndrome
AMREF	= African Medical and Research Foundation
ART	= Antiretroviral Therapy
ARV	= Antiretroviral
GFATM	= Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	= Human Immunodeficiency Virus
IEC	= Information Education Communication
INRUD	= International Network of Rational Use of Drugs
NGO	= Non-Governmental Organization
NIMR	= National Institute of Medical Research
MUCHS	=Muhimbili University College of Health Sciences
MNH	=Muhimbili National Hospital
PLWHA	=People Living with HIV/AIDS
TFDA	= Tanzania Food and Drugs Authority
WHO	= World Health Organization

PROJECT SUMMARY:

Investigators: Henry Irunde; Mwemezi Ngemera; Florence Temu; Stephen Nsimba; Christopher Comoro; Janneth Maridadi; Sikubwabo Ngendabanka.

Project title: A study on adherence to antiretroviral therapy in Tanzania – a pre-intervention study.

Background: In Tanzania, HIV/AIDS remains a serious health problem, second only to malaria, and is marked by a prevalence rate of more than 7.4%. About 1,894,160 individuals aged 15 years and above were estimated to be living with HIV in Tanzania during the year 2002. HIV/AIDS is a public health problem and major development crisis that affects all sectors. It has drastically affected health, economic and social progress – reducing life expectancy, deepening poverty, and contributing to and exacerbating food shortages.

Problem statement: There is a lack of proper documentation on ARV treatment adherence and possible factors contributing to ARV non-adherence in Tanzania. Studies in other countries have described a range of factors affecting ARV treatment adherence at various levels, i.e. at individual, community and health facility levels.

Study objective: The purpose of this study is to identify possible factors and operational barriers contributing to non-adherence for ARV treatment among HIV/AIDS patients and possible ways for improving the adherence in Tanzania.

Specific objectives:

- To determine the proportion of patients who adhere and do not adhere to ARVs treatment in selected health facilities in Tanzania.
- To identify factors (structural, socio-economic, cultural and disease-related) contributing to non-adherence
- To assess the quality of the operating structures for provision of ARVs in the selected health facilities
- To assess the quality of the processes involved for ARVs consumption among patients in the selected sites
- To document suggestions and proposals for improving ARVs treatment adherence from users, healthcare providers and support groups.

Study setting and Population: The study will be conducted in six health facilities offering ARV treatment in Dar es Salaam, Tanga and Mbeya regions. In addition, home visits will be done to conduct semi-structured interview to ARV users and separate focus group discussions will be conducted to both community leaders and ARV users.

Methodology and Sampling: Rapid appraisal methodological techniques using both qualitative and quantitative data collection methods will be used. Patients on ARVs, community leaders and healthcare personnel will be studied.

Data Analysis: Qualitative data will be categorized and summarized into matrices, figures and tables based on the kind of tools used. Quantitative data will be analyzed using computer software for data analysis such as EpiInfo Version 6.04 or STATA.

Timeline: The study will be conducted for 12 months of the year 2005.

Budget: A total of USD 12,440 will be spent.

1. INTRODUCTION

1.1 Country Situation

The United Republic of Tanzania, situated in the East Africa, has an area of 945,087 sq km, divided into 26 regions and a total population of 36,588,225 (July 2004 est)[1]. The birth rate is 39 births/1,000 population (2004 est.)[1], the death rate 17.45 deaths/1,000 population (2004 est.)[1], and life expectancy at birth 44.39 years (2004 est.)[1]. It is one of the poorest countries in the world with a gross domestic product (GDP) per capita of $600[1]. The literacy rate is 85.9% (male) and 70.7% (female)[1].

1.2 Background Information and Rationale

In Tanzania, HIV/AIDS remains a serious health problem, second only to malaria, and is marked by a prevalence rate of more than 7.4%. About 1,894,160 individuals aged 15 years and above were estimated to be living with HIV in Tanzania during the year 2002[1,2]. HIV/AIDS is a public health problem and major development crisis that affects all sectors. It has drastically affected health, economic and social progress – reducing life expectancy, deepening poverty, and contributing to and exacerbating food shortages[3].

The advent of potent antiretroviral therapy (ART) in 1996 has changed the way people in the world's richest countries view HIV/AIDS[3]. Although these treatments do not provide cure and present new challenges of their own with respect to side effects and drug resistance, they have dramatically improved rates of mortality and morbidity, improved quality of life, revitalized communities and transformed perception of HIV/AIDS from a plague to a manageable, chronic illness[3].

Various initiatives are being carried out in Tanzania to increase availability of ARVs and other drugs for management of opportunistic infections. Potential and available sources of funding additional to Government budget include the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) whose 3rd round grant amounted to USD 87 millions, the US President's Emergency Plan for AIDS Relief (PEPFAR), Tanzania Multi-country HIV/AIDS Program funds, Clinton Foundation, CIDA as well as funds from other individual partners[4]. The Tanzania Food and Drugs Authority has registered more than 50 antiretroviral formulations enabling private pharmaceutical companies and hospitals to stock and sell ARVs[5]. Increasing numbers of Non-Governmental Organizations and private companies are promoting or/and establishing HIV/AIDS policies and treatment programmes for their employees – for example, AMREF and Tanzania Cigarette Company.

The prices of ARVs have fallen dramatically. In 2000, the price of a first-line WHO-recommended combination antiretroviral regimen to treat one patient for one year was between US$ 10 000 and US$ 12 000 on world markets.

Now the price for some generic combinations is approximately US$ 300 per person per year[6].

The increased accessibility to ARVs, need to be supported by initiatives to maximize adherence to treatment. Maintenance of viral suppression require maximum patient adherence to ART[7] and irrational use may result in spread of virus resistant to medicines, decreased quality of life, progression to AIDS, death, and will require regimen change and may increase treatment costs[8,9].

It has been observed that where there has been irrational use of drugs, increased bacterial and parasite resistance have occurred. Studies have reported that many species of bacteria have developed resistance in developing countries where antibiotics are often freely available without prescription and often with uncertain or incorrect diagnosis[10],[11]. For instance, on the malaria parasite, because of resistance developing, the Tanzania Ministry of Health did change the first line drug for treatment of uncomplicated malaria from Chloroquine to Sulfadoxine-Pyrimethamine (SP)[12]. The same can happen to ARVs if treatment implementation is not done carefully.

Tanzania has an ambitious plan of putting more than 400,000 people living with HIV/AIDS on ARVs within a five year period, 65,150 will be treated by 2005. Without proper community mobilization and empowerment addressing salient social contextual factors and targeting HIV affected populations' support. This plan may result in irrational usage and non-adherence. It is therefore important to study factors which can hinder or decrease ARV treatment adherence in Tanzania during the early days of ARVs roll out and thereafter plan for proper interventions.

Adherence is described as engagement and accurate participation of informed patient in a plan of care[13]. It has a broader meaning than compliance which encompasses the extent which a patient follows instructions implying understanding, consent and partnership. But adherence includes entering into and continuing in a programme, care plan, such as meeting appointments and tests as scheduled. Adherence to treatment encompasses more than adherence to medications like ARVs[13]. However it is the intention of this study to look at the adherence to ARV treatments among the eligible HIV/AIDS patients.

In an ideal situation, a 100% level of adherence is required for ARV treatment success. Though adherence is a problem in poor countries due to multifaceted factors, studies show that there is no significant difference in adherence between resource-limited and resource-rich countries, suggesting that patients have trouble in taking 100% of their pills. It is therefore recommended worldwide that for any ARV programme there should be a

concurrent plan for adherence assessment and support[13,18]. A 'near perfect adherence' should be where there is 95% and above adherence.

It is therefore justifiable to have this study of the factors which contribute to adherence are identified and proper structures for support or improving adherence are developed.

1.3 Statement of the Problem

While the Government and other players are determined to increase accessibility to ARVs, specific initiatives towards adherence to ARVs need to be in place to ensure rational ARV use at all levels including the community level.

Currently there are ongoing training activities for healthcare workers on prescribing and dispensing ARVs. Previous studies in Tanzania with other diseases have indicated that some patients do not have enough knowledge and/or do not remember how to use various prescribed and dispensed drugs contributing to irrational usage[14,15,16,17]. This has also observed in settings where ARVs are used and so favours emergence of resistant HIV strains, treatment failure and increased treatment cost.

A study conducted in Botswana indicated that 54% of patient were adherent by self-report while 56% were adherent by provider assessment[18]. The study showed that patients had to overcome great odds to adhere to treatment: they lacked adequate funds, often had to travel great distances to the clinics providing ARVs. If cost were eliminated as a barrier, then adherence rate is predicted to improve to 74%[18]. The Botswana government has taken several initiatives for improving adherence such as; increasing access to ARVs in the public sector, improvements in the distribution of ARVs, increased availability of clinical and laboratory monitoring, and strengthened health infrastructures for delivering care.

There is a lack of proper documentation on ARV treatment adherence and possible factors contributing to ARV non-adherence in Tanzania. Studies in other countries have described a range of factors affecting ARV treatment adherence at various levels, i.e. at individual, community and health facility levels. Such factors can be grouped into:

- Structural factors e.g. poor support services, low accessibility to service etc. For example, it may be important to review how easy or difficult it is for a patient to come to clinic. Does he need to pay for transportation? Who will mind the children when she comes for an appointment? Do the clinic hours make care and treatment inaccessible? Are providers very friendly and caring?
- Disease and treatment factors e.g. seriousness of the disease and adverse drug reactions and side effects etc. Side-effects, even if mild, can influence the patient's willingness to take specific medication. By educating the patients in advance about what to expect, discussing

techniques such as masking a bad taste with food, and reviewing pill-taking behaviour regularly, providers can minimize these medication-specific barriers. If the patient is seriously sick support by a family member can be useful.

- Social economical and cultural factors e.g. poor patient knowledge and information, lack of social support, poverty and stigma etc. Poverty, fear of stigma, misconceptions about HIV/AIDS care and treatment, the need for secrecy, inability to communicate with providers due to language barriers, illiteracy – all can play role in non-adherence.

(See Figure 1- Problem Analysis Diagram attached)

1.4 Expected Outputs

The study will address the following:

- The magnitude of ARV treatment adherence and non-adherence in Tanzania.
- Possible factors (structural, socio-economic, cultural and disease-related) contributing to ARV treatment
- Possible operational barriers towards ARV treatment adherence
- Possible interventions to be undertaken to address ARV adherence.

The study will also recommend measures for improving ARVs treatment adherence among eligible HIV/AIDS patients in Tanzania.

1.5 Significance of the study

Taking ARV medicines is not an easy task since it is a life treatment. It is hoped that the findings generated from this study will make several contributions to both knowledge and understandings of what is one the worst calamities to hit the world, Sub-Saharan countries such as Tanzania affected most. The qualitative and quantitative data collected in this study will be made available to health planners such as Ministry of Health and is hoped that this will lead to better designed, better directed and more culturally sensitive intervention programmes to deal with Socio-cultural problems associated with non-adherence. In addition findings will assist the Ministry of Health in efforts to develop a scheme for rational use of ARVs, and also serve as a resource for research teams developing new protocols.

2. OBJECTIVES

2.1 Broad Objectives

The purpose of this study is to identify possible factors and operational barriers contributing to non-adherence for ARV treatment among HIV/AIDS patients and possible ways for improving the adherence in Tanzania.

2.2 Specific Objective

By the end of 2005:

(i) To determine the proportion of patients who adhere and do not adhere to ARVs treatment in selected health facilities in Tanzania.

(ii) To identify factors (structural, socio-economic, cultural and disease-related) contributing to non-adherence

(iii) To assess the quality of the operating structures for provision of ARVs in the selected health facilities

(iv) To assess the quality of the processes involved for ARVs consumption among patients in the selected sites

(v) To document suggestions and proposals for improving ARVs treatment adherence from users, healthcare providers and support groups.

3. METHODOLOGY

3.1 Study design

This will be a cross-sectional analytical study whereby both qualitative and quantitative methods of data collection will be used. It will be done between January and December 2005(Gantt chart annexed).

3.2 Study Area

Due to limited resources, the study will be conducted in Dar es Salaam, Tanga and Mbeya regions. Dar es Salaam is the largest commercial city in Tanzania with more than 3 millions population and lies along the coast of Indian ocean. Mbeya is a region at the southern part of the country about 700 kilometres from Dar es Salaam and Tanga region at the north-east about 300 kilometres from Dar es Salaam. These three sites represent a range of sites where ARV treatment is being provided. According to National Aids Control programmes report, these regions also constitute high prevalence of HIV/AIDS patients[2].

Map of Tanzania with arrows indicating study sites.

3.4 Sampling strategies and sample size

Convenience sampling method will be used to select 6 facilities, that is four healthcare facilities not offering home care support and two health facilities offering ARVs with home care follow up. However the criteria of urban/semi-urban/rural consideration will be made when choosing the facilities to enable comparison of findings between health facilities.

A total of 180 patients will be studied in all 6 facilities including their catchments areas, that is an average of 30 patients per each facility and its catchment's area. This is based on WHO manual on investigation drug use in the facility[19]. It is expected that 20 patients will be studied in each facility (5 in-depth and 15 exit interviews) while 10 patients will be studied at home for a period of 3 weeks (they will be interviewed at the first week followed by pill counts at the second and third week to determine adherence). Hence, a total of 60 patients will be interviewed at home using a modified weekly illness recall method[20]. Interviews conducted at home will complement results obtained from interviews at the facility as well as information obtained from focus group discussions with PLWHA. All records of the interviewed patients will be assessed.

Seven health workers will be chosen purposively to complement information on operating structures, processes and suggestions for improving adherence to ART.

In addition, selected community leaders and PLWHA from within the catchments areas of health facilities will participate in the study to complement objective five.

3.5 Study population

The study population includes patients attending HIV/AIDS care and treatment units from the identified hospitals; as well as staff working in these units and community leaders from the respective localities.

Inclusion criteria for interviewees

Patients

- adult (by Tanzanian definition- 18 years and above)
- been on ARV treatment for 3 months or more
- patients ARV treatment records for the last 3 months available

Health workers

- routine staff at the ARV clinic
- well informed about patients e.g. home based nurse attached to ARV clinic

Exclusion criteria

Patients

- ARV treatment initiated from a different clinic from the study centre
- Below the age of 18
- On ARV treatment for less than 3 months

Heath workers

- working at the care and treatment unit for less than a month
- not in direct interactions with patients

3.6 Working definition for adherence

- perfect adherence : 100% consumption of ARVs without skip doses in the last 3 months

- near perfect adherence: =95% consumption of ARVs in the last 3 months (with minimum of 1 skip dose a week)

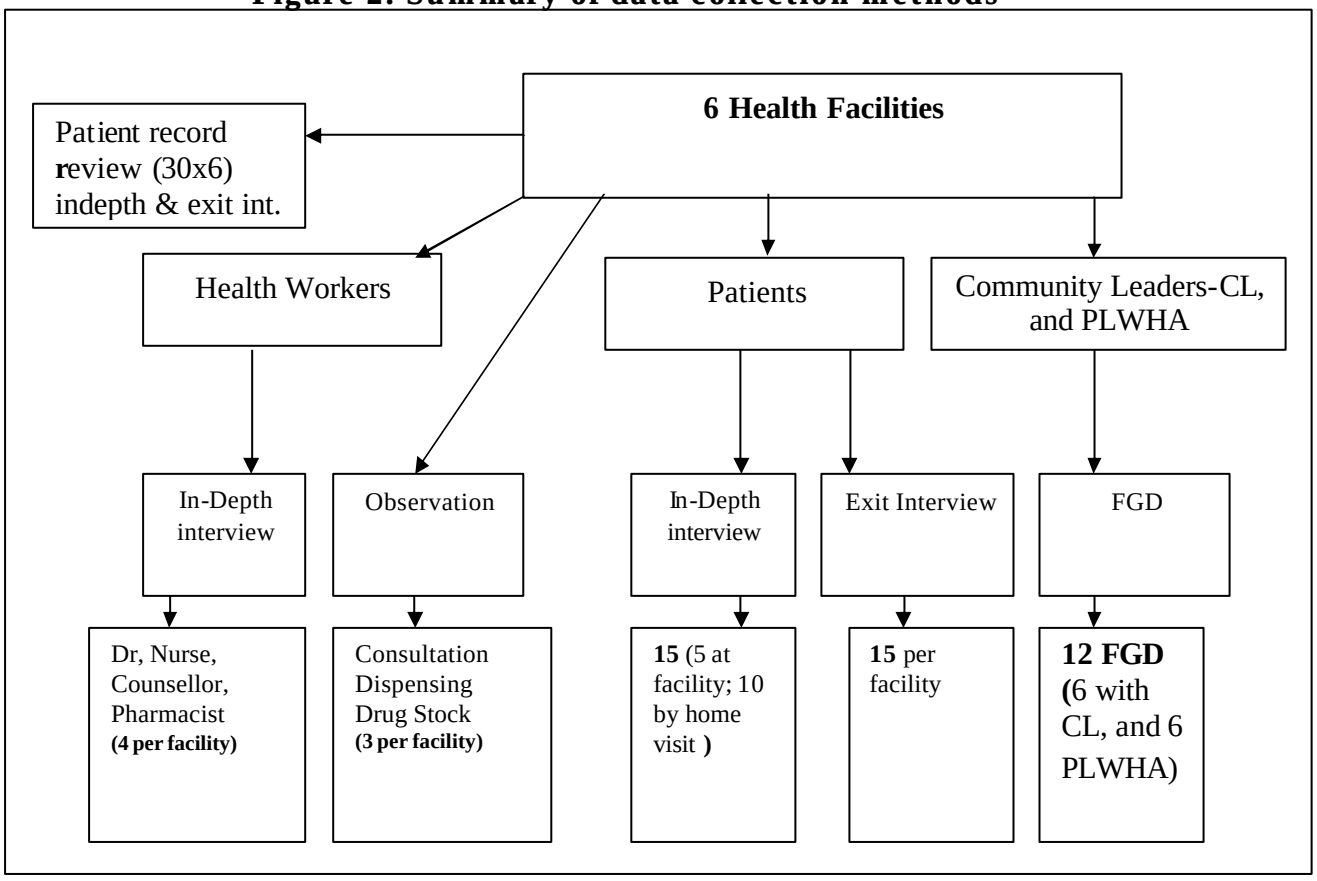
- modest adherence: 94.9% - 90% consumption of ARVs in the last 3 months (with minimum of 2 skip doses a week)
- low-adherence: <90% consumption of ARVs in the last 3 months with (more than 2 skip doses a week)

3.7 Data collection method

Various methods will be used for this study. These will include:

- **Semi-structured interviews** (for both patients on ART and health workers) will gather data on background information, the aspect of knowledge, attitude, perception and practice on the use of ARVs. The interview will also solicit demographic and socio-economic and cultural information, general assessment of adherence, report of adherence in the previous three months, reason for (non)adherence or abandonment of treatment, motivation aspect of treatment, opinion on the quality of care provided and how to improve adherence.
- **Review of patients' records** to determine level of adherence and gather clinical data of the patients. Records for all patients interviewed shall be retrieved to substantiate information regarding demographic data and disease state information, ARV use and adherence. A data capture sheet will be used by research assistants to collect information from patients records.
- **Observation** during consultation to collect information on the nature and services provided to the patients on ARVs. Also to gather information on the operating structures. Checklists will be used to collect this information.
- **Exit interviews** to general patients not necessarily on ARVs, attending care and treatment units so as to assess the quality of care received.
- **Focus group discussions** (FGD) with community leaders and PLWHA separately, to explore community knowledge, beliefs, attitude and behaviour on the use of ARVs, social support to PLWHA and to obtain suggestions/opinions on improving adherence to ARVs.

Figure 2: Summary of data collection methods



3.8 Ethical Consideration

Ethical clearance will be sought from the Ethical Committee in the Ministry of Health. Permission will be sought from in-charges of the health facilities and individual interviewees. Confidentiality will be observed and unauthorized persons will not have access to the data collected. Each subject will be assigned a study identification number, and these subject identifiers will not be released outside the research group. Codes will be used and no identification will be made for the responders. Data will only be accessed by the research group. Respondents will be informed that their data will be used anonymously and that the aim of the study is to understand better the problems and how ARVs user can better be supported.

3.9 Pre-Testing

Research assistants will be selected looking at their education level, gender balance and preferably non-medical staff. Training of research assistants will be done for 4 days and will be followed by pre-testing of the research tools/instruments with a selected sample of the target population not from the actual targeted study facilities. The pre-testing will be done prior conducting the actual main study and necessary adjustments/corrections of the research tools will be made accordingly. For home interview, one local interviewer will be trained to conduct semi-structured interview at the first week and do pill counts weekly for a period of 3 weeks.

4.0 Plan for Data Collection, Processing and Analysis

Data will be collected by research assistants under supervision of the principal investigator (PI) and co-investigator. Interviews will be administered to the study subjects by trained research assistants. Observations and record auditing will be done by the PI and the first 3 co-investigators. Focus group discussions (FGDs) will be conducted by an experienced social scientist Dr Comoro from the Dept of Sociology, University of Dar-es-Salaam-Tanzania and will be assisted by Dr Stephen Nsimba from MUCHS/INRUD-Tanzania. Completeness of the data will be checked every day by the principal investigator. Data collection is expected to last for about 3 months.

4.1 Data analysis

Data coding, checking and cleaning will be done before entry into the computer statistical programme [Epi-Info Version 6.04 or STATA) by a statistician. Each questionnaire/data collected from each study sample will be coded. Data collected from interviews will be categorized and summarized into matrices, figures and tables based on the kind of the tool used. Quantitative data will be analyzed using computer software for data analysis such as EpiInfo Version 6.04 or STATA. For qualitative data obtained from FGDs, these will be analyzed by all investigators after translation and transcription has been done by social scientist using various qualitative

methods/approaches available with inductive and deductive coding to structure the data into categories or using a NUDIST software programme.

Health facilities and patients will then be categorized into those with high adherent percentage and poor adherent percentage. Chi square test will be used for comparison of proportions and a p value of < 0.05 will determine the significance. This will be useful in exploring and comparing factors associated with (non-) adherence among these two categories of facilities. Stratified analysis and multivariate modeling methods will be used for analysis of the confounders and identify factors associated with adherence to treatment.

A scoring mechanism will be used to rate quality of structure and processes of service delivery associated with provision of ARVs and in each health facility adherence support mechanism will be described in depth

Suggestion and proposals on improving ART adherence will be compiled into 3 categories, that is, those obtained from patients, health workers and community leaders.

4.2 Limitations of the study

- Authorization from various authorities such as managers of health facilities might delay data collection
- Logistic problem if health facilities do not operate on daily basis
- The data from the records reviews might be incomplete or missing, misplaced or not recorded leading to bias.
- Sample size especially in weekly illness recall method where it is recommended to interview 100 family. But information obtained by interviewing 60 patient will be complemented by other methods (triangulation)
- Patients who will refuse to be interviewed might be having important information for this study.
- Observer or interviewer's bias which can be minimized by good training before data collection
- Budget.

5.0 Involving stakeholders

Research proposal (draft) is being circulated to stakeholders for comments before the final draft is submitted. Stakeholders such as National Aids Control Programme in Tanzania, Tanzania Commission for Aids, Tanzania-INRUD group, WHO-Country office, Association of Tanzanian Journalists, Policy makers in the Ministry of Health and Society of People Living with HIV/AIDS will be contacted for their comments. It has been not possible to convene a meeting with stakeholders due to lack of finance, however an electronic copy of this proposal has been sent to each stakeholder for

comment. Some stakeholders have already sent their comments and these been incorporated.

6.0 Dissemination of results

Results of this study will be compiled into a booklet with title "A study of Antiretroviral adherence in Tanzania". The booklet will bear various chapters such as; Executive summary, Introduction, Factors contributing to ARVs adherence and non-adherence in Tanzania, Suggestions and proposals for improving ARVs treatment in Tanzania, Proposed interventions etc. A meeting with stakeholders will be convened to discuss results and determine modalities of dissemination. It is expected that journalist will play a role to disseminate result of these findings. The report will be provided to the Institute of Health & Continuing Education-Ministry of Health, Dar-es-Salaam – Tanzania and to the many donors supporting ARV programs in Tanzania. Finally results will be published in international journal for dissemination worldwide.

7.0 Beneficiaries/ targets

Because the Tanzanian government has just started rolling out free ARVs programme, definitely there are areas which need improvement. Results obtained from this study will be used by the government, development partners and private sector engaged in ARVs programme to formulate and implement initiatives to improve adherence to ART in the community, including improvements in distribution of drugs and strengthening health infrastructure for delivering care. Generally beneficiaries of this initiatives will be all Tanzanians especially people living with HIV/AIDS, communities, healthcare professionals, policy and decision makers.

8.0 Requested technical assistance.

The University of Amsterdam, Medical Anthropology Unit is expected to provide free technical support for this study. Technical inputs and assistance is requested during developing and refining of data collection tools, training of research assistants, pre-testing the tools, data analysis and report writing. Training of research assistants will be conducted by key participants in presence of technical person for possible technical inputs. Presence of a technical person during pre-testing the tools of data collection is essential. Technical inputs during report writing is important for generating a high quality information to be published in international journals.

9.0 Monitoring

Since this is a rapid appraisal, monitoring will be done by the principal investigator starting during early stages of proposal development. Monitoring will include: checking for timeliness of activities and identify any delays in implementing work-plans, reviewing costs in relation to the initial budget, supervising research assistants and other personnel carrying out

their assigned duties and assessing cooperation of other stakeholders including obtaining ethical clearance from the Ministry of Health.

10.0 Budget

It is expected that a total of $ 12,440 will be spent in this study (break down attached). Training of research assistants, pilot studies will cost and field work allowances will cost $7,000; Hiring specialist (social scientist and statistician) will cost $1,000; Transport will cost $2000; Report writing $800; Secretarial services $300; Refreshment during focus group discussion $480; stationary and communications $ 200.

Budget for the study of ARVs Adherence in Tanzania 2004/2005

Category		**Unit**	**Rate ($)**	**Number of Person**	**Number of days**	**Total (USD)**
Allowances						
Research assistants	Training of research assistants, during pilot study, and field work	day	30	4	25	3,000
Investigators	Training & field work during pilot study	day	40 each	4	25	4,000
Hiring specialists	Social Scientist & Statistician	day	50 each	2	10	1,000
Secretary	Typing report and secretarial duties	day	30	1	10	300
Home visits	Train home visitors and data collection	day	10	6	6	360
FGDs	Refreshments	day	5	8	12	480
Sub-total						**9,140**
Supplies	A4 size papers, writing pads, pens, photocoping costs	Reams, pcs				100
Report writting	Investigators	day	40	4	5	800
Communication	Email, Fax, Phone calls etc	PC				100
Transport	Hiring a vehicle					2,000
contigency						300
Grand Total						**12,440**

Total amount of funds requesting for carrying this study is 12,440 USD .

Budget Justification

Personnel: About 4 investigators and 4 research assistants are required for the completion of the baseline data collection. They will take part also in other miscellaneous activities and as such their inclusion is necessary. Sixty to ninety (60-90) days of field activities/work will be required. While working these people will need to get per diem allowances during the whole period of data collection and this will be part of their motivation, hence the requested amount in the budget. It is reckoned that all investigators will spend about 60% their time on the proposed study, while the Principal investigator will spend 80-90% of his time.

Training and pre-testing of research instruments:

Four (4) days training of 4 research assistants and pre-testing of research instruments (questionnaires) needs to be thoroughly tested and familiarized by our research assistants. This is very important for the success of the study and to obtain more reliable consistent (required data) information. Thus, the number of days for training research assistants including the field testing of the actual research instruments and different methods or approaches needed for this study are essential and mandatory and therefore these people need to be well trained before the take off of the actual study.

Transport: Transportation or lack of it is the greatest limitation to the execution of the proposed research project. As we do not have any vehicle, we will need to hire a vehicle in order to run the work smoothly once it takes off and this will simplify and make easier our movements in visiting the study sites/facilities. It should be noted that Public Transport is not reliable in Tanzania as it does not belong to the State, therefore it will not be a good idea to rely on this because of several reasons. However, visiting facilities outside Dar-es-Salaam, the research team will normally use private transport such as buses going to the regions where the study will take place.

Supplies: Stationery's and photocopying of questionnaires are needed. Thus, the availability of A4-size papers, other stationery materials to be used for fieldwork are essential in this aspect. In addition, budget for communication, fax, phone calls and dissemination of results are important and hence they have been included in the requested amount in the budget proposal.

Data analysis: Any meaningful research project can not be concluded without data entry, processing, analysis and the use of statistics. Our team has included all these costs plus use of expertise of the statistician in the budget and secretarial costs.

11.0 Key participants:

Key participants have been drawn from Tanzania Food and Drugs Authority especially those who participated in a course on Promotion Rational Use of Drugs in the community, Pretoria, South Africa; Muhimbili National Hospital; INRUD - Tanzania group, University of Dar es Salaam and National Institute of Medical Research in Tanzania.

11.1 Principal investigator (PI)

Mr. Henry Irunde (BPharm, MPH)
Pharmacist and Public Health Specialist
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11.2 Other Investigotrs

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Drug Information and Public Education Pharmacist
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UNAIDS PETRA/MITRA Project at Muhimbili National Hospital
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CURRICULUM VITAE

NAME	Henry Fillemon Irunde.
AGE	39 years.
ADDRESS	P.O.Box 77150 Dar es Salaam, Tanzania Tel: 0744 310 696, E-mail: irunde@yahoo.com
PROFESSION	Pharmacist and Public Health Specialist.
MARITAL	Married with children

KNOWLEDGE AND EXPERIENCES

- Health promotion and Education to the public and healthcare providers such as: educating healthcare professionals and the general public on disease prevention and rational use of medicines such as antiretrovirals through radio, TV, Seminars, News papers etc
- Hospital and community pharmacy experiences
- Writing research proposals for conducting operational researches
- Technical report writing and preparing Ministry of Health publications such as Drug Information Bulletin and Tanzania National Formulary.
- Pharmacovigilance and Drug Regulatory activities
- Managing Effective Drug Supply to the public

ACADEMIC INFORMATION

2000 – Awarded Master of Public Health [MPH] of University of Dar es Salaam, Tanzania.
1991 – Awarded Bachelor of Pharmacy [BPharm] of University of Dar es Salaam, Tanzania.

SHORT COURSES ATTENDED

2002- Attended a global course on promoting better use of medicines, Manila, Phillipine.
2004- Attended a ACP regional course of promoting rational use of medicines in the community, Pretoria, Republic of South Africa.

RESEARCH EXPERIENCES

1. Irunde, H; Screening of plants with oxytocic effects; 1991; unpublished but available at dept of clinical pharmacology, Muhimbili University College of Health Sciences.
2. Irunde, H: Factors influencing availability of essential drugs in Kisarawe district in Tanzania; 2000; Unpublished but available in medical library Muhimbili University College of Health Scieces.
3. Irunde *et al*: A survey on pharmaceutical sector in Tanzania; 2002; available in the Ministry of Health, Tanzania and WHO-Country office in Dar es Salaam.

CURRICULUM VITAE

Personal History:

Name: Stephen Elias Damson Nsimba.

Date of Birth: 27th March, 1958.

Nationality: Tanzanian.

Marital Status: Married with 4 children.

Position: Senior Lecturer-MUCHS.

Permanent Address:

Muhimbili University College of Health Sciences (MUCHS), School of Medicine, Department of Clinical Pharmacology, P.O. 65010, Dar-es-Salaam, Tanzania. Office Tel: 255-22-2150302/6 Ext 214; Fax: 2150465 or 2152489; Mobile: 0741-318113). Email: snsimba@muchs.ac.tz

Professional/Academic Qualifications:

1. University of Dar es Salaam, Faculty of Medicine: July, 1982-May, 1987: Awarded Doctor of Dental Surgery Degree (D.D.S).
2. Muhimbili Medical Centre: June,1987–May 1988 (One year internship). Awarded an Internship Certificate.
3. University College Galway: A Constituent College of the National University of Ireland (NUI): February, 1993 – March, 1995. Awarded Master of Science (M.Sc) in Pharmacology.
4. Karolinska Institutet-Stockholm, Sweden: March 1998-Nov, 2003. Awarded Doctor of Philosophy (PhD).

Professional Associations:

1. Member of the University of Dar-es-Salaam Academic Assembly (UDASA)
2. Member of the Medical Association of Tanzania (MAT).
3. Member of the Tanzania Dental Association (TDA).
4. Member of the Society of Pharmacologists in Eastern, Central and Southern Africa Preferential Trade Areas (SOCEPTA).
5. Member of the International Network for Rational Use of Drugs (INRUD).

Publications:

1. Massele, A.Y., Sayi, J., Nsimba, SED., Adjei-Ofori, D and Laing, RO. (1993). Knowledge and managament of malaria in Dar es Salaam, Tanzania. East African Medical Journal. 70,639-642.
2. Nsimba, SED., Kelly, JP and Leonard, BE, (1994). Dose dependent behavioural effects of phencylidine (PCP). Medical Science research Journal. 22,207-209.
3. Nsimba, SED., Kelly, JP and Leonard, BE, (1994). Effects of phencyclidine (PCP) on different routes of administration on behavioural parameters in the rats. Medical Science Journal. 22,399-401.
4. Nsimba, SED., Kelly, JP and Leonard, BE, (1994). Effects of olfactory bulbectomy on phencyclidine (PCP) induced behavioural changes. Indian Journal of Pharmacology. 26,136-140.
5. Nsimba, SED., Kelly, JP and Leonard, BE. (1997). Effects of acute and chronic haloperidoal administration and apomorphine challenge on the behavioural parameters in the rat. Indian Journal of Pharmacology. 29,15-19.
6. Nsimba, SED., Kelly, JP and Leonard, BE. (1997). The interaction between chlorpromozine and apomorphine on temperature response in the rat. Journal of Serotonin Research. 3,161-168.

7. Massele, A.Y and Nsimba, SED. (1997). Comparison of drug utilisation in public and private primary health care clinics in Tanzania. East African Medical Journal, 74,420-422.
8. Nsimba, SED., Kelly, JP and Leonard, BE. (1997). The effects of chronic rafoxanide administration on behavioural and physiological parameters in the rat. Indian Journal of Pharmacology. 29,289-295.
9. Nsimba, SED., Massele. A.Y., Warsame, MY and Tomson, G. (1999). Prescribing patterns of antimalarial drugs in urban health facilities in Dar es Salaam, Tanzania: with special emphasis on sulfa-based drugs. East and Central African Journal of Pharmaceutical Sciences. 2,12-15.
10. Nsimba, SED., Massele, AY., Mabatiya, ZA., Warsame, MT., and Tomson, G. (1999). A household survey on sources availability and use of antimalarial drugs in rural area of Tanzania, Drug Information Journal, 33,1025-1032.
11. Nsimba, SED., Abdi-Aden, Y., Massele AY., Rimoy, GH., Ericksson, O and Gustafsson, L (2001). The pharmacokinetics of a sugar-coated chloroquine (Dawaquine) marketed in Tanzania: a comparative study Journal of Clinical Pharmacy and Therapeutics. 33: 132-136.
12. Nsimba, SED., Massele, AY., Ericksen, J., Gustaffson. L., Tomson, G and Warsame. MY (2002). Case management of malaria in undefives at primary health care facilities in a Tanzanian district. Tropical Medicine and International Health. 7: 201-209.
13. Comoro, C., Nsimba, SED., Massele, AY., Warsame, MY and Tomson, G (2003). Local understanding, perception and reported practices of mothers/care takers and health care providers about childhood malaria in Kibaha district, Coast region, Tanzania. Acta Tropica 87, 305-313.

14. Nsimba, SED., Massele, AY and Makonomalonja, E (2003). Assessing prescribing in church owned primary health care (PHC) institutions in Tanzania. A pilot study. Tropical Doctor 33, 1-2.
15. Nsimba SED. (2003). Exploring malaria case management of underfive children in households and public primary health care facilities in the Kibaha district, Tanzania. PhD thesis submitted to Karolinska Institutet-Stockholm, Sweden.
16. Nsimba, SED and Sayi, GJ. (2004). Drug prescribing and dispensing practices by health care providers to mothers/guardians with sick under-five in primary health care facilities in Kibaha district – Tanzania: an observational and interview study (Submitted).
17. Ericksen, J., Nsimba, SED., Minzi, OS., Sanga, AJ., Gustaffson. L., Warsame, M and Tomson, G (2004). Household adoption of the new antimalarial drug policy in Tanzania-major changes in treatment practices (submitted).
18. Nsimba, SED and Rimoy, GH. (2004). Self-medication with chloroquine in a rural district of Tanzania: a therapeutic challenge for any future malaria treatment policy change in the country (submitted).
19. Nsimba, SED and Jande, MB. (2004). Household storage of pharmaceuticals, sources and dispensing practices in drug stores and ordinary retail shops in rural areas of Kibaha district-Tanzania (submitted).

CURRICULUM VITAE

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PERSONAL PARTICULARS
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EDUCATION BACKGROUND

Ph.D Sociology & Anthropology Carleton University, Ottawa, Canada, 1988
M.A. Sociology & Anthropology, Carleton University, Ottawa, Canada 1984.
M.A. Sociology, University of Dar es Salaam 1981
B.A. (Hons.) Sociology, University of Dar es Salaam 1980

PUBLICATIONS

1. Ebola, Fear of the Unknown, (Co-authored with J. Sivalon) Tanzania Health Research Bulletin, Vol 3.2 June 2001.
2. "Health Sector Reform: Hope in the Horizon" Tanzania Health Research Bulletin, Vol 3.1 January 2001.
3. Urban Sociology - A Chapter in a book entitled Introductory Sociology - A Reader and Lecture Notes, (ed.) John Sivalon, DUP, 2000.
4. "Election 2000 - A Case Study of the Temeke Constituency", an article in a forthcoming Book by the IDS and PCB.
5. Local Understanding, perception and practices of Mothers and Health care providers on childhood malaria in Tanzania: Its implication for Malaria Control (Submitted to ACTA Tropika).
6. "The Role of Social Sciences" A Paper to be read at the 4th National Seminar in AIDS Research in Tanzania, Tanzania Medical Association, Held at BoT College Mwanza 13 -15 December 1999.
7. Co-authored with KARP Investigators "The Social Transmission route of HIV-1 Infection - The role of high-risk environments in a rural area of Kagera Region Tanzania, in Journal of Health Risk and Society (Forthcoming).
8. Co-authored with KARP Investigators "The Social and Cultural Contexts of HIV/AIDS Transmission in the Kagera Region, Tanzania", Journal of Asian and African Studies.
9. Co-authored with Killewo, Kwesigabo, Mhalu, Lugalla, Biberfeld, Wall & Sandstrom, "Acceptability of Voluntary HIV testing with counselling in a rural village in Kagera, Tanzania", in AIDS CARE (1998) Vol. 10, No. 4.
10. Some Cultural Aspects On HIV/AIDS Transmission in Kagera, Tanzania. Proceedings of the 15th Annual Scientific Conference of the Tanzania Public Health Association (TPHA) on Population, Environment and Health in Tanzania: Towards the Twenty-first Century. Held at The Sokoine University of Agriculture, Morogoro, Tanzania November 1-15, 1996, TPHA Publication, 1997.
11. Co-authored with Lugalla, Mutembei, Dahlgren Emmelin, Killewo, Kwesigabo and Sandstrom, "The Availability and Acceptability of Intervention Strategies Against HIV/AIDS Internationales Afrikaforum Weltforum Verlag 4/1997 33. Jahrgang 4. Quartal.
12. "A Socio-Cultural and Institutional Background Influencing the Acceptability of Intervention Strategies Against AIDS and HIV in Kagera Region, Tanzania", National Institute For Medical Research (NIMRI), Proceedings of the 12th Annual Joint Scientific Conference with a Seminar on Research and Control of AIDS and other Sexually

Transmitted Diseases in Eastern, Central and Southern Africa, 21-23 February 1994, Arusha, Tanzania (December, 1995).

13. Co-authored with Killewo "AIDS as a Disaster in Africa -9 Associated Myths and Responses", Proceedings of the Joint TPHA 12th Annual and ESCAPHA 2nd Biennial Scientific Conference, 25th - 29th, Arusha International Conference Centre, Tanzania (October 1995)
14. Availability and Acceptability of Intervention Strategies Against AIDS/HIV-1 Infection in Kagera Region, Tanzania, Co-authored with Lugalla JLP, Mutembei AK and Dahlgren L, Published in the Abstract book as proceedings of the VIII International Conference on AIDS in Africa and VIIth African Conference on STD, Marrakech, Morocco, December 12th - 16th, 1993.
15. Gender Oppression, Sex, Changing Customs and the Spread of AIDS in Kagera, Tanzania, Co-authored with Lugalla JLP, Mutembei AK and Dahlgren L. Published in the Abstract book as proceedings of the VIII International Conference on AIDS in Africa and VIIth African Conference on STD, Marrakech, Morocco, December 12th - 16th, 1993.
16. Counselling and HIV testing as an intervention strategy in the control of HIV infection Co-authored with Killewo JZJ, Lugalla JLP and Kwesigabo G, In Systematic interventions and their evaluation against HIV/AIDS in Kagera region, Tanzania, Proceedings of a workshop held in Bukoba town, Kagera, Tanzania 10 - 11 May, 1993. Kagera AIDS Research Project, 1993:39-41.
17. Systematic interventions and their evaluation against HIV/AIDS in Kagera region, Tanzania, Co-authored with Killewo JZJ, Lugalla JLP and Kwesigabo G. Proceedings of a workshop held in Bukoba town, Kagera, Tanzania 10 - 11 May, 1993.
18. "Myths about HIV/AIDS", A paper presented at a Counselling Training Workshop held at the Muhimbili Medical Centre, Dar es Salaam, 16th - 20th August, 1993.
19. "Myths about HIV/AIDS" a paper presented at the Muhimbili University College of Health Sciences (MUCHS) Training Workshop, 16th-20th August 1993.

12.0 BANK DETAILS.

Recommended bank account for this activity is that of Tanzania Food and Drugs Authority in the City Bank [T] Ltd. Funds should be deposited in this account with details described below.

Name of the Bank: CITIBANK TANZANIA LIMITED
Beneficiary name: TANZANIA FOOD AND DRUGS AUTHORITY
Swift Code: CITITZTZ
Account No: 100380013
DAR ES SALAAM, TANZANIA.

GANTT CHART (2004/2005)

Activity	Duration	Sep	O	Nov	Dec 04	Jan	Feb	Ma	Apr	May	Jun	Jul	Aug	Sep	O	Nov	Dec 05
1. Finalising research proposal	1 week	x															
2. Clearance from Ministry of Health				x	x												
3. Circulate draft to stakeholders for comments	15 days		x	x													
4. Develop Research tools	30 days			x													
5. Submission of first draft	1 day		x														
6. Incorporation of experts' comments	1 week			x													
7. Submission of second draft	1 day			x													
8. Incorporation of second comments	15 days				x												
9. Submission of final draft	1 day				x												
10. Select and Train Data Collectors	10 days						x										
11. Pre-test and review the tools	2 days						x										
12. Collect Data	60 days							x	x								
13. Analyse Data and write report	60 days									x	x						
14. Submit first draft of report	3rdweek											x					
15. Incorporation of feedback or comments	30 days												x				
16. Submission of final report	4thweek													x			
17. Stakeholders meeting to discuss results	1 day														x		
18. Disseminate and publicise findings	60 days															x	x
19. Monitoring and evaluation	16mths	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

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Figure 1: Problem Analysis Diagram Of Factors Contributing To Non-Adherence To ARVs