KENYA PROPOSAL THIRD DRAFT

Project Title:

Study to Assess Adherence to Anti Retroviral therapy and Underlying Factors in Patients on Anti-Tuberculosis Treatment during the Continuation Phase.

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Project Summary

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Project title: Study to Assess Adherence to Anti Retroviral therapy and Underlying Factors in Patients on Anti-Tuberculosis Treatment during the Continuation Phase**.**

Background:

Majority of HIV infected patients are also co-infected with Tuberculosis (TB) (50%-60% in Kenya), and TB is the leading cause of morbidity and mortality in HIV infected patients (40%). Anti Retroviral (ARV) therapy has been shown to reduce the incidence of TB in HIV infected patients by more than 80% according to a study conducted in South Africa. In Kenya, the gains observed in the decline of TB cases in the middle of 1980's has been reversed by the effect of the dual epidemic. The TB treatment in this country has been the 8 month SCC and patients access free drugs and services in all public health institutions and majority of faith based health institutions.

Before the end of 2003, the access to ARV's was beyond reach to many Kenyan due to prohibitive cost , inability for the health workers to comfortably prescribe the ARV's, cost of the lab services and general lack of commitment to AIDS treatment. After the launching of the 3 by 5 WHO and UNAIDS initiative, the commitment to AIDS treatment has increased with the current number of people on ARV's in the country standing at 25,000 compared to about 9,000 at the end of 2003 (*WHO/MOH ARV update report sept 2004).* This has been made possible by the declining costs of drugs and establishment of initial 30 ART centres in the country by end of Sept 2004.

There is need to strictly follow the patients on ARV treatment and at the same time taking anti-TB therapy due to anticipated possible drug reactions, side effects and opting out of treatment due to cost of drugs and lab costs and drug resistance. We need to document all the scenarios and hence share the experiences hence the need for such operational research.

Problem Statement: HIV co-infection is driving the TB epidemic in many countries and TB in high HIV prevalence areas is a leading cause of morbidity and mortality among the HIV-infected patients. The

magnitude of adherence to ARV treatment for patients who are on the continuation phase of anti-TB treatment is not known. Factors ranging from lack of knowledge on the importance of adherence, fear of stigmatization, clear policy, pill burden associated with the treatment regimens of both infections, lack of integration of the two programmes at the facility level, poverty and other social economic problems contribute to the possible adherence problems with the co-treatment for these conditions.

Study Objective: To identify the level of adherence among patients on ARV treatment while on anti TB treatment in the continuation phase and to investigate the underlying factors.

Specific Objectives:

- To determine the level of ARV adherence among patients on the continuation phase of anti TB treatment.
- To determine the level of knowledge of health workers regarding co-administration of ARVs and anti TB drugs.
- To determine the level of awareness of patients regarding treatment for the co-infection.

Study Setting and Population: The study will be conducted in three health care facilities, which treat HIV/TB co-infected patients. These will include public, faith based and a primary health care facility.

Methodology and Sampling: Rapid appraisal using both qualitative and quantitative data collection methods will be used. The population will include all the patients on treatment for co-infection management who attend the study sites. The patients who will be included in the study will be those that are on co-therapy and have been treatment for two months.

Data Analysis: For qualitative data triangulation of the findings of the different methods will be used. The statistical analysis will be by SPSS as well as manual analysis. The study outcomes will be measured as a % attendance, % drop out rate, % patient recording missed doses, average waiting time per visit, patients knowledge of correct dosage, health worker knowledge on side effects of both ARV and TB treatment, % of patients given information on side effects, %of patients using traditional medicines together with ARV and anti TB treatment, % patients recording improvement in health status. The data will also be categorized by gender and age where data is available.

Timeline: The study will be conducted for 12 months during 2005.

Budget: 12471.40 USD

Background Information

Many HIV infected patients are also co-infected with Tuberculosis (TB) (50%-60% in Kenya) (*Tuberculosis and Leprosy Control Guidelines 2003)* and TB is the leading cause of morbidity and mortality in HIV infected patients. Anti Retrovirals (ARV) therapy has been shown to reduce the incidence of TB in HIV infected patients by more than 80% according to a study conducted in South Africa. Substantial number of patients still present with active TB while on ARV therapy. (*The Southern African Journal of HIV Medicine May 2004 pg. 9).*

Of the estimated 1.5 million people infected with HIV in Kenya, about 200,00 are in urgent need of Antiretroviral Therapy (ART). Currently, there are only 12,000 people on ARV in Kenya majority of whom are managed within the private sector. In order to avoid early treatment failure for the individual and the development of resistant strains in the community, which would have dire public health implications there is a need for extremely strict adherence to treatment. The importance of strict adherence to treatment with ARV cannot be overemphasized. Near perfect adherence (>95% - Patterson et al. 2000) is required to achieve maximal viral suppression – anything less than this leads rapidly to the development of viral resistance and hence, to much earlier treatment failure. Missing even one treatment in a week translates to only 92.8% adherence. Approximately 3000 patients are on both ARV and anti TB treatment in Kenya. (*Ministry of Health, National AIDS and STD Control Programme, 2004. "Kenyan National Clinical Manual for ARV Providers", 1st Edition NASCOP, Nairobi)*

ARV providers that do not seriously address the complex issue of adherence will fail in their objective of helping their patients, and on a public health level they will cause the development of multi-drug resistant stains within the population they serve. General measures and methods of assessing adherence have been issued for the healthcare providers, and these can help to increase adherence. They are included in the Kenya National Clinical Manual for ARV Providers, which are to be used during the treatment encounters with patients.

Tuberculosis is a major cause of morbidity and mortality in Kenya. It affects all age groups although the majority of cases are reported between age group 15-45 years with more males

affected than females. The HIV epidemic has contributed to the rapid increase of TB cases in this country. Other factors associated in the increase are social economic trends such as the mushrooming of periurban slums, overcrowding in prison, poor nutrition and the limited access to general health care.

In order to address the new challenges posed by the TB epidemic, the ministry of health through the National Leprosy and Tuberculosis Programme (NLTP) has identified the following areas for maximum emphasis: strengthening of the NLTP central unit, decentralization of diagnostic/treatment centers to increase access to TB services, TB/HIV collaboration, collaboration with the private health sector and increased awareness of TB control in both health workers and the communities. (*Tuberculosis and Leprosy Control Guidelines 2003)*

Burden of TB

TB disease has reemerged as major public health problem in the world. It is estimated that a third of the world population is infected with tubercle bacillus. Eight million people progress to active TB disease with 1.8 million deaths each year. Kenya is among the 22 high TB burden countries in the world. In 2003 the NLTP reported 95,158 of all cases of TB among whom 38,158 were smear positive Pulmonary TB (42%). The case notification rate is 118 for all forms of TB per 100,000 populations. The WHO estimates that the current case detection rate (CDR) of TB is 47% (which means that only 47% of all the new cases are being registered and only by the NLTP). (*Tuberculosis and Leprosy Control Guidelines 2003)* The treatment success rate is at 80% and average annual increase over the past 5 year period is 14%. (*NLTP Annual Report 2003)*

Impact of HIV on Transmission of TB

Infection by HIV destroys the immune defense mechanism of the body by targeting the T lymphocytes. This is an important risk factor for the development of TB. In normal circumstances the lifetime risk of development of TB from latent to disease is about 10% while this risk increase to 10 times more in HIV infected persons. The mechanisms relevant for the development of TB in immuno-compromised patients are reactivation of existing dormant bacilli, progression from recent infection to disease and re-infection. There is transmission of

tubercle bacillus to the general population from the TB patients who developed TB because of HIV infection. TB can occur in all stages of HIV infection. Infectious TB often occurs before other opportunistic infections in HIV positive patients. This depends on the pool of infectious cases in the community. In a late stage of HIV infection, TB more often presents as sputum smear negative pulmonary or extra pulmonary TB. (*Tuberculosis and Leprosy Control Guidelines 2003)*

Justification of the Study

So far little is known about adherence to ARVs and the factors affecting adherence. The magnitude of non-adherence to ARV treatment for patients who are on the continuation phase of anti-TB treatment is not known and it is important to build up some evidence to determine how to maximize adherence and successful treatment

Not all TB patients are tested for the HIV status although HIV is the most important factor determining progression to clinical disease in patients with dormant TB. Among people infected with TB, their lifetime risk of developing clinical TB is between 30-50% if they are infected with HIV. Additionally HIV positive people initially not infected with TB have an approximately 50% chance to develop TB following primary infection with tubercle bacilli. (*Tuberculosis and Leprosy Control Guidelines 2003)*

Even when patients comprehend the consequences of non-adherence to medication, adherence rates are sub optimal. Good adherence is a decisive factor in treatment success. Unlike other chronic diseases, the rapid replication and mutation rate of HIV means that very high levels of adherence are required to achieve durable suppression of viral load. The potent and effective new combinations of antiretroviral agents have proven efficacious in reducing viral load and improving clinical outcomes. However, pill burden, the complicated dosing requirement, and the suboptimal tolerability make adherence difficult. Because of the great importance to successful treatment of AIDS patients with ARV's, effective strategies for maximizing adherence are essential.

The therapeutic regimens recommended by WHO have been shown to be highly effective for TB treatment, but poor adherence to medication is a major barrier to its global control *(Sabate E. Adherence to long-term therapies: Evidence for action Geneva, Switzerland: WHO, 2003)* Poor adherence to prescribed treatment for TB, which is a communicable disease, increases the risks of morbidity, mortality and drug resistance at both the individual and community levels. The Kenya NLTP follows the principles of the DOTS strategy for the treatment of tuberculosis as promoted by WHO.TB patients are treated free of charge in the public health facilities.

Factors that Affect Adherence to Treatment

At the national and facility level there is lack of integration of both HIV/AIDS and TB programmes. There is limited collaboration and communication between the two programmes and therefore patients have to attend different departments for the services. There is inadequate manpower and trained personnel to handle these patients. Effective use of treatment guidelines, inadequate supply of ARVs and insufficient infrastructure might contribute to the issue of non-adherence.

At the facility level possible factors that may affect adherence include ill prepared health care institutions which leads to long waiting times and stretched support system for monitoring and follow up of patients, record keeping and data management, staff with inadequate knowledge on side effects and adverse drug reactions, pill burden, heavy work load for staff leading to lack of motivation.

At the community level, factors include are beliefs and fear of stigmatization, lack of knowledge on treatment for the co-infections and importance of adherence, poverty and economic burden.

Factors affecting adherence at the individual level include a lack of support through buddy system, fear, stigma, lack of knowledge on treatment, pill burden, long distance to and long waiting time at the facility, side effects, dosage identification, poverty and economic burden.

NB: Please refer to Problem Analysis Diagram in Annex 111

Objective of the study

To determine the level of adherence to ARV treatment amongst patients on anti-TB treatment in the continuation phase and to investigate the contributing factors for adherence.

Specific Objectives

- To determine the attendance rates of patients on ARV treatment while on anti TB treatment in the continuation phase.
- To determine the level of knowledge of health workers regarding co-administration of ARVs and anti TB drugs.
- To determine percentage drop out rates of patients on treatment for co-infections.
- To determine the level of awareness of patients regarding treatment for co-infection.
- To identify practice of health workers and patients regarding the adherence of ARVs during anti-TB treatment.
- To assess the level of collaboration/communication between the NASCOP/NLTP activities both at the facility and the national level.
- To provide recommendations that will improve adherence to treatment in patients.

Study Design and Methodology

The study is an operational research, which will apply rapid appraisal technique using both qualitative and quantitative data collection methods. Data collection instruments will be developed with technical input by a social scientist, a statistician, the WHO Kenya Country Office Technical Advisor on HIV/TB and staff from the University of Amsterdam. The investigators assisted by research assistants who will be students or paramedical staff will do data collection. The research assistants will be recruited from the Kenya Medical Training Center and will be trained Clinical Officers on postgraduate studies. These will trained on the data collection process by the social scientist and the investigators. The investigators and the social scientist will supervise data collection and also conduct focus group discussions. Prior to the data collection a pretesting of the tools will be conducted by the investigators together with the research assistants.

Design:

The proposed research will be a descriptive study that will use a survey research design involving both quantitative and qualitative methods.

- The quantitative methods will involve a review of patient records of attendance at the outpatient and pharmacy at the three (3) health facilities.
- The qualitative methods will consist of survey of three (3) categories of people to assess practices related to adherence. These will involve: interviews of patients and health workers, Exit interviews of patients, structured practice observations, and focus group discussions of patients, caregivers and communities members.

Record Review:

Both TB and ARV patients' registers will be reviewed to determine attendance and drop-out rates of patients on treatment. The following information will be collected:

1. Percentage of patients registered in the clinic.
2. Percentage of patients attending the clinic on the appointment day.
3. Percentage of patients expected to attend the clinic on the appointment day
4. Percentage patients with prescriptions filled

This data will be categorized by gender and age groups where possible.

Interviews:
Patients and health care workers will be interviewed to assess their knowledge on the importance of adherence.

Exit interviews: will be conducted to determine the practices and behaviour of the patients regarding the treatment and advice they have received. Patient's knowledge and practices on adherence will also be assessed. To ensure privacy and confidentiality, the health facility will be requested to provide a separate area for the interview near the exit.

Structured interviews: will be administered to healthcare providers to assess knowledge and practices regarding adherence to treatment.

Structured Observations: will be used to assess the practices of health care providers during treatment encounters. Observation will be done on how the providers monitor adherence and whether the adherence monitoring form is available and in use, whether pills are counted and what measures are taken to promote adherence to treatment. Observations will also be undertaken of patients while on treatment. Provider will tend to behave because they know they are being watched. Better do simulated case study or simply ask the providers about their practices

Focus Group Discussions (FGDs): will be held with caregivers and community members to assess their behaviour and practices toward the management of patients on co-treatment. The setting for the FGDs will be both at the community level and the health facility level. At the community level care givers and stakeholders will be interviewed on their perception and behavior towards adherence to treatment of patients with co-infections. At the facility level the patients will be interviewed through their support groups to establish their practices and factors that affect their adherence to treatment. The recording will be done manually as well as using a tape recorder.

Study setting

The study will take place at the community level in Kenya and three (3) health facilities where services are provided to patients with HIV and TB. The three health facilities will comprise of a faith based hospital, a public hospital, and a primary health care facility or a private health facility.

Study population and sample size,

The study population will involve patients, health workers, administrators, and patients affiliated (connected) at the participating study hospitals. Participants of the focus group discussions will also involve people living in communities surrounding the study hospitals.

Convenient sampling process will be used for the survey of health care workers and exit interviews.

Eligibility Criteria:

- Patients: those that will be included in the study will be those who are registered in the health facility and have been on treatment for a period of at least two months. Patients' recruitment will be carried out over a period of time in order to increase the likelihood of achieving adequate sample size. We will aim at interviewing a minimum of 30 patients per facility

- Health workers and administrators will be recruited into the study as they exist or are available at the facilities. The health workers will include the health facility in charge, a clinician, a pharmacist/dispenser, a counselor, a nurse, a home base care worker or community health worker, and a nutritionist where available.

- Focus Group Discussions will involve approximately 10 community members in each catchment area.

Data sources or collection process

At the hospitals, data will be collected by:

- For the study of attendance and compliance, we will review patient records, and looking for patients identification, age, sex, whether on appointment or other visit. Other records to be reviewed will be pharmacy records on availability of drugs, types of drugs stocked, whether prescriptions are filled fully, This data will be collected in a pre- designed form and a structured observation form.
- Patient follow up will be for a period of six months, which is the period of the continuation phase of TB treatment.
- For the interviews of health workers and administrators, we will use a structured interview questionnaire inquiring about, caliber of staff, whether trained on ARV therapy or TB management, their role in the management of the patients, knowledge of importance of adherence and how they are involved in promoting adherence. We will also inquire about their difficulties in conducting their duties as well as factors they think affect adherence.
- For the patient exit interviews: We will use a questionnaire which will ask about the patients views and practices regarding the treatment they receive. We shall also inquire about the issues and difficulties that they face in adhering to treatment. Their feeling about the treatment encounter and their well-being will also be discussed.

Focus group discussions of community members will involve..care givers, members of the community, opinion leaders, members of the civil society and HIV/AIDS support groups. We will use a FGD guide and a tape recorder to record the responses. A rapportuer will also take notes manually. 1 FGD will be held at the community level within reach of the health facility. 1 other session will be held at the health facility level with the patient support groups. The FGDs will be conducted in the local language. At the end of each FGD the moderator and observers will meet to summarize the key findings and observations.

Data Analysis:

Data analysis will be done by triangulation of the different methods for the qualitative data.

The quantitative data will be analyzed by using SPSS on computers at the ava ilable in our offices and with assistance from the statistician. The following quantitative study outcomes will be measured % attendance, % drop out rate, % patient recording missed doses, average waiting time per visit, patients knowledge of correct dosage, health worker knowledge on side effects on both ARV and TB treatment, percentage of patients given information on side effects, percentage of patients using traditional medicines together with ARV and anti TB treatment, % patients recording improvement in health status.

Study Population:

The study will be conducted in three health facilities, which will include a mission hospital, a public hospital, and a primary health care within the city of Nairobi. The inclusion criteria for the health facilities will be that the facility offers both ARV and TB treatment and that there is evidence of good records.

Due to the nature of the study a census of all patients registered during 2005 at any stage of their TB continuation phase therapy (from the 3rd month of treatment onwards) will be used since there is likelihood that the number of patients on co-treatment may not be large.

Collaboration

The study will be carried out with the involvement of key actors and stakeholders..

Meetings will be held with Ministry of Health officials who will include the Director of Medical Services, Chief Pharmacist and both NASCOP and NLTP programme officials to seek clearance for the study. The local chapter of International Network on Rational Use of Drugs (INRUD) and WHO Kenya Country Office will be involved for technical support. Clearance for the study will also be sought from the health facilities and the Ministry of Health prior to the commencement of the study. Meetings will be held with patients, members of the community and the civil society. The results of the study will be disseminated through meetings, reports, media and continuing medical education for health care. Ethical clearance will be sort from the relevant authorities prior to the dissemination.

Stakeholders Involvement

The following stakeholders will be involved:

National level: HIV/AIDS and NLTP programmes, Ministry of Health staff

Health facility level: The officers in charge of the institution, heads of other departments including social workers, counselors and nutritionists.

Community level: patients, local administration, faith based groups, community based organization involved in HIV/AIDS, education officers and traditional healers.

Other stakeholders: INRUD Kenya, Health Action International - Africa, professional organizations

These stakeholders will be involved in meetings at the planning, implementation and report writing stages of the project. Prior to publication of the results stakeholders will be provided with the results and asked to comment.

Expected Results and Potential Contribution of the project

The expected outcome of the results will establish the rate of adherence to ARV treatment in patients on TB treatment in the continuation phase. The results will be the basis for the development of strategies to improve adherence to treatment by patients with co-infection. The results will contribute to a policy change to improve collaboration and the integration of the services between the NLTP and HIV/AIDs programmes both at the national and the facility

level. Health care providers, community and patients will be more aware of the importance of adherence to treatment. The result will also assist in identifying priority areas for intervention.

Intervention

As a result of the study the following interventions could be implemented.

1. An educational intervention through the training of health workers, creating awareness amongst patients and community members and distribution of information.
2. Managerial intervention through policy changes to integration of services for patients on both ARV and TB treatment increase multi-sectoral collaboration and follow up and monitoring.
3. Regulatory intervention by developing guidelines on treatment regimens for co-infection

Planning for these interventions will be undertaken once the results of this initial study are known. Depending on which are the key factors reducing adherence interventions will be designed to address these factors.

How Ethical Issues will be addressed

Request for informed consent from the MoH officials as well as the patients will be made. A letter for request of clearance will be sent to the Director of Medical Services and the Heads of NASCOP and NLTP, as well as administrators of the health facilities. Confidentiality will be observed for all patients and health facilities involved in the study. Data security will be ensured through using coded information, which will be available only to the investigators and the statistician.

Technical Support Requested

Technical support is being requested from the University of Amsterdam for the following activities.

1. Revision and editing of data collection instruments. The investigators and the social scientist will design the instruments. These will then be submitted electronically for review and revisions made during the first month.
2. Data analysis including transcribing, coding and triangulation of results.
3. Report writing and preparing articles for publication. Advice will be sought on the report structure and scientific publication of the report.

These two activities would need to occur during a field visits during 2005.

4. Dissemination of results to local and international forum. Suggestions and recommendations can be made via email dialogue and a field visit.
5. Designing intervention, which will include the appropriate type of intervention and the strategies to implement the intervention.

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Activity	Duration	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
1. Finalizing research proposal	1 week	x															
2. Seeking permission from Ministry of Health				x													
3. Meeting with stakeholders	1day			x				x	x	x							
4. Develop Research tools			x	x													
5. Submission of first draft			x														
6. Incorporation of experts' comments	1 week			x													
7. Submission of second draft				x													
8. Incorporation of second comments					x												
9. Submission of final draft					x												
10. Train Data Collectors							x										
11. Pre-test and review the tools							x										
12. Collect Data	6 months							xx	xx	xx	xx	xx	xx				
13. Analyse Data and write report									xx	xx	xx						
14. Submit first draft of report												x					
15. Incorporation of feedback or comments													x				
16. Submission of final report														x			
17. Convene Stakeholders meeting															x		
18. Disseminate and publicise findings															xx	xx	
19. Monitoring and evaluation	14 mths	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	

References:

1. WHO/MOH ARV update report September 2004
2. Tuberculosis and Leprosy Control Guidelines 2003
3. The Southern African Journal of HIV Medicine May 2004 pg. 9.
4. Ministry of Health, National AIDS and STD Control Programme, 2004. "Kenyan National Clinical Manual for ARV Providers", 1st Edition NASCOP, Nairobi
5. NLTP Annual Report 2003
6. Sabate E. Adherence to long-term therapies: Evidence for action Geneva, Switzerland: WHO, 2003

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Annex 1

Dummy Tables of results

Table 1

Indicators	Facility			Standard
	A	B	C	
Percentage attendance				100%
Percentage drop out rates				0
Percentage patients recording missed doses				0
Average waiting time per visit				30min
Patient knowledge on correct				100%
Health workers knowledge on side effects on both ARVs and TB treatment				100%
No. of patients given information on side effects No. of patients using traditional medicine together with ARV plus anti TB treatment				100% 0
Percentage of patients recording improvement				100%

Table 2

Results of Male Population in the Three Health Facilities

Indicators	Facility			Standard
	A	B	C	
Percentage attendance				100%
Percentage drop out rates				0
Percentage patients recording missed doses				0
Patient knowledge on correct				100%
No. of patients given information on side effects				100%
No. of patients using traditional medicine together with ARV plus anti TB treatment				0
Percentage of patients recording improvement				100%

Table 3

Results of Female Population in the Three Health Facilities

Indicators	Facility			Standard
	A	B	C	
Percentage attendance				100%
Percentage drop out rates Percentage patients recording missed doses				0 0
Patient knowledge on correct				100%
No. of patients given information on side effects				100%
No. of patients using traditional medicine together with ARV plus anti TB treatment				0
Percentage of patients recording improvement				100%

Annex 11

Research questions for the development of questionnaires:

Research Questions	Suggested Methods
Health facility assessment 1. Which ARVs are in stock in the health facility? Did any stock-out of ARVs occur in the past 3 months? 2. Which combinations of ARVs are prescribed to patients as first-line therapies? 3. Which selection criteria / conditions are used to select ARV users? Do these criteria / conditions include the consideration of factors which are likely to determine adherence (such as disclosure of HIV status, partner notification, bringing a buddy, and/or adherence to prophylactic treatment to prevent opportunistic infections) 4. What is the cost of the first line treatment to users, (including transport and related costs for diagnostics etc)? Are the costs a barrier to consumers? 5. Are there any other barriers to use of ARVs? 6. How are patients with on co-treatment managed treatment? Is there integration of the care? 7. Is privacy and confidentiality ensured? 8. How are records kept? 9. How is adherence monitored? 10. Is there an organized appointment records? 11. Is readiness assessment done with all patients? Readiness form available and in use? 12. Group sessions are used for educating and counseling patients? Is there a buddy system in place?	➢ Interview with health staff involved in ARV and TB prescribing, counseling and dispensing ➢ Observations ➢ Review of records
On Information and communication 1. Do patients receive information on the following • How ARVs and Anti TB 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 2. When and where to get re-supply 3. Do clients receive written information about these points? 4. Are health workers:	➢ Interview with health staff involved ➢ Exit Interview with patients ➢ Structured observations

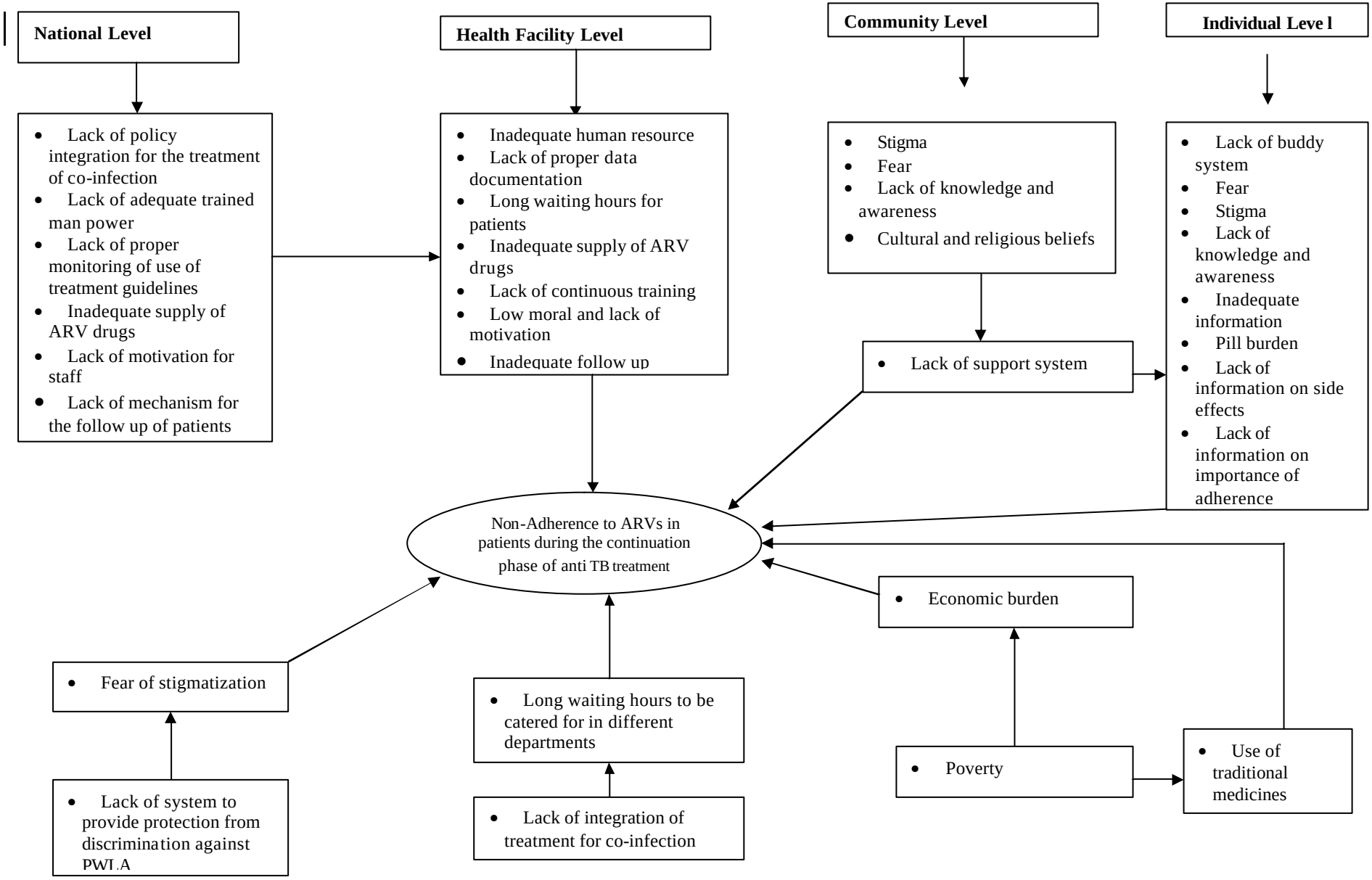
Research Questions	Suggested Methods
• treating ARV users with respect, and in privacy? • listening to ARV users and let them ask questions about the treatments and the effects on their bodies and their lives? • ask the ARV users about their experiences with ARVs in their everyday life when they come for follow-up visits, and to take problems with the drugs serious? • Give the same adherence messages 5. Do health workers fear acquiring AIDS? Specifically, do they think they can get AIDS: • by shaking hands with an AIDS patient • by using the same toilet • if an patient coughs in their vicinity. 6. Do health workers liase with family and community members to enhance adherence to ARVs? In what ways do they do so? How effective are these adherence support measures in their view? How could they be improved? 7. Does the health facility have a system to follow-up ARV users? 8. What are the levels of non-adherence to ARV regimes according to the health workers? What are the reasons for non-adherence according to them? Who adheres best and worst? What are main factors?	
On technical competence, human resource issues and available facilities: 1. Are health workers working in the ARV treatment programs trained in comprehensive AIDS Care, including both technical and psycho-social skills? 2. Are guidelines on care for PLWA available? 3. Is prescription in accordance with the guidelines? Specifically which CD4 count cut-off points are used for treatment initiation? 4. For new users, is the history of ARVs used previously checked? 5. Are diagnostic facilities (CD4 counts, viral loads) available? Which? Are they used appropriately? IF not, are clinical markers used to initiate and monitor treatment outcomes?	

Research Questions	Suggested Methods
6. In what way does the ARV treatment program affect the workload and job-satisfaction of health workers? 7. What do health workers consider as major problems regarding treatment of and care for ARV users?	

Research Questions	Suggested Methods
Patients on co-treatment 1. What is the view of patients on the quality of ARV care? What is considered good and what is considered problematic in the care provided available to them? 2. Do ARV users feel listened to and treated with respect at the health facilities, specifically do they get a chance to ask questions about the treatments and the effects on their bodies and their lives? 3. Do ARV users trust the health workers? 4. Do they feel dependent on the health workers, and do they fear this dependence on them as source of life-prolonging treatment? 5. What are the views of ARV users on efficacy and safety of the ARVs that they are taking? 6. What are their experiences with the drugs for co-treatment? What is it like to take drugs? How do they fit in everyday life routines, like going to town, working, going to school? 7. How should the drugs be used according to them? Are they aware of the correct treatment schedule? Do they know why they need to adhere to the schedule? 8. Have there been times when they could not take medicines according to the prescription? If so, why not? What were the consequences of missing a dose? Was it perceived to be a problem? If yes, what is done to avoid missing a dose? Specifically in the past week, were doses missed? When and why? 9. What is the cost of the treatment to the users, including transportation, food, diagnostic tests and other related costs? 10. Are appointments with the ART facility kept? If not, why not? (delay, waiting time, waiting space) 11. Do the users experience side-effects? Which? What have they done to diminish these side-effects? Did they or do they want to switch drugs? 12. Do family friends and members know that ARVs are taken by the user? If yes, do they support the ARV users in his/her treatment? How? If not, why has the user not disclosed their HIV status and/or use of medicines? Do they have a designated buddy system? 13. What do they perceive as most problematic	➢ In-depth interview at a location of choice with patients using ARVs for more than one month ➢ Focus group discussion with men and women ARV users

Research Questions	Suggested Methods
regarding adherence to ARV treatment? What could be done to improve this?	
Community 1. What local terms are used to refer to HIV/AIDS and TB infection? 2. Is HIV/AIDS a stigmatizing condition? Are patients on co-treatment subject to discrimination at health facilities, work, and school or in the community. What types of stigmatization occur. Has the availability of ARVs in the health facilities diminished stigma? If not, why not? 3. Do people generally disclose their HIV status? Do they disclose that they are taking medicines? If not, why not? 4. Do people know how HIV and TB are transmitted? And how it is not transmitted? 5. Are people aware of voluntary testing and counseling facilities? To what extent do they use them? If not, why not? 6. Are people aware of the availability of AIDS medicines in health facilities? What is their view of the quality of care of the different facilities providing ARVs? What are the advantages and disadvantages of the different facilities providing ARV care in the area? 7. Have community organizations, church organizations, and/or organizations of people living with HIV and AIDS living in the community been involved in preparing for the introduction of ARVs in the facilities? Are these organizations involved in treatment literacy and adherence support programs? 8. What are the costs and benefits of taking ARVs according to patients on co-therapy, and their family members and relatives? 9. Do community members want an AIDS treatment facility to be established in their community? If yes, what would the community be willing to contribute? 10. Are the members of the community aware of the importance of adherence? 11. What kind of support do they give to the patients? 12. Is there a buddy system in the community?	➢ Semi-structured interviews with community leaders (teachers, community health workers, community support groups. Organizations of PLWA, church groups, social workers etc) ➢ Focus groups with community members.

Annex 111
Problem Analysis Diagram of Possible Factors Contributing to Adherence to ARVs



Annex 1V

Curriculum Vitaes and Commitment Letters

DR. JENNIFER AKINYI ORWA

GENDER: Female
PROFESSION: Pharmacist
DESIGNATION: Principal Research Officer, Kenya Medical Research Institute, Center for Traditional Medicine and Drug Research, P.O. Box 54840 – 00200, Nairobi, Kenya.
E-mail: jorwa@nairobi.mimcom.net

Education, Relevant Workshops and Training:

- Doctor in Pharmaceutical Sciences (Pharmaceutical analysis), Katholieke Universiteit Leuven, Belgium, 2000
- Master of Science (Pharmacology), Chelsea College, University of London, 1984
- Bachelor of Pharmacy, University of Nairobi, 1979
- Stakeholders' workshop on Promoting Rational Medicines Use in the Community, organized by INRUD-Kenya and HAI Africa, December 9, 2004, Nairobi, Kenya.
- PRDU Training and Training of Trainers (TOT) International Workshop on Promoting Rational Drug Use (PRDU). February 1 – 14, 2004, Nairobi, Kenya.
- WHO/MOH/HAI Training on baseline survey of health facilities, 31st March – 4th April 2003, Nairobi, Kenya

Relevant conference presentations:

- Orwa, JA. Development of Local and National Antibiotic Use Policy. 25th African Health Sciences Congress, Symposium on Antimicrobial Resistance, October 4, 2004, Nairobi, Kenya.
- Orwa, JA, Mukoko J and Mueni L. Monitoring and assessing the Pharmaceutical situation in Kenya. National Stakeholder Workshop on the Kenya Pharmaceutical Baseline Survey 2003 and Revised Kenya National Drug Policy Implementation Plan 22nd – 23rd June, 2004, Safari Park Hotel, Nairobi, Kenya.
- Orwa J, Ombogo J, Ojoo M, Oluka M, Ogaja E, Wanyanga W, Thuo M. Assessing Drug Use Practices in Free Medical Camps in Kenya–II. Second International Conference on Improving Use of Medicines, ICIUM 2004. March 30 to April 2, 2004, Chiang Mai Thailand.
- Orwa J, Ombogo J, Ojoo M, Oluka M, Ogaja E, Wanyanga W, Thuo M. Assessing Drug Use Practices in Free Medical Camps in Kenya–I. Strategies for Enhancing Access to Medicines (SEAM conference 2003), December 10 – 12, 2003, Dar es Salaam, Tanzania.
- J.A. Orwa, Improving traditional medicine use. Pharmaceutical Society of Kenya Annual Symposium, 30th May to 2nd June 2002, Mombasa, Kenya
- J.A. Orwa, Access to Essential Drugs: The Role of the Pharmacist. Pharmaceutical Society of Kenya Annual Symposium, 31st May to 2nd June 2001, Mombasa, Kenya

Relevant Publication:

- J. A. Orwa, L. K. Keter, S. P. A. Ouko, I. O. Kibwage and G. M. Rukunga. Influence of manufacturing practices on quality of pharmaceutical products manufactured in Kenya. *E. Afr. Med. J.* 81 (2004) 287-292.
- J.A. Aluoch-Orwa, C.O. Ondari, I.O. Kibwage, and J. Hoogmartens. Quality of intravenous infusion fluids manufactured in Kenya. *E. Afr. Med. J.* 72 (1995) 800 - 804.

16th December 2004

Statement of availability

INRUD - Kenya's main objective is to improve health care delivery through research, education, and advocacy through the promotion of rational use of medicines (RUM). And INRUD - Kenya members collectively and individually continue to collaborate with other health professionals in activities aimed at promoting rational drug use.

As a member of INRUD-Kenya executive, I am committed to making available my experience and expertise in medical research to support INRUD-Kenya collaborative research project proposal on assessing the adherence to ARV medicines by people taking TB medication. In view of this commitment, I am willing and able to be involved in the implementation of the project proposal as a PI for the proposed period.

Thank you

Sincerely,

Dr. Jennifer A Orwa
Treasurer, INRUD-KENYA

Name:	LILLIAN NYAMBURA GITAU
Gender:	Female
Qualifications:	Diploma in Community Health, Diploma in Pharmacy
Current Position:	Training Manager (2003 to date)
Previous Position:	Project Officer (Sustainable Healthcare Foundation) (2000 to 2003) Training Officer, Staff Pharmacist (Mission for Essential Drugs & Supplies) (October 1993 to 1999) Program Officer (Bamako Initiative Project, Primary Health Care Programme, Ministry of Health) (January to September 1993) Pharmaceutical Technologist (Ministry of Health) (1986 to 1992)

PROPOSALS AND RESEARCH WORK DONE

- Oral and poster presentation in the 2nd International Conference in the Improved Use of Medicines **(ICIUM)** in Thailand. Title of paper "Effect of an Educational Intervetion on Antibiotic Use in the Treatment of ARI and Malaria in Six Mission Hospitals in Kenya"

- Oral and poster presentation in the 1st International Conference in the Improved Use of Medicines **(ICIUM)** in Thailand. Title of paper " Drug use Studies and the Impact of Small group In-service Training on Improving the Use of Drugs in Three Mission Hospitals in Kenya"

- Developed a proposal titled " A study to assess the effect of an educational intervention to influence appropriate prescribing in the use of antibiotics in the treatment of ARI and malaria in mission hospitals in Kenya".

- Conducted a pre and post intervention study to assess the effect of an educational intervention to influence appropriate prescribing in the use of antibiotics in the treatment of ARI and malaria in mission hospitals in Kenya.

- Presented a paper entitled " Health Policy Implications of Community and the Use of Drugs" at the Infection Control Association of Kenya Annual General Meeting and Scientific Conference.

- Participated in a study to field test the WHO manual "How to Use Applied Qualitative Methods to Design Drug Use Intervention"

- Developed a proposal titled " A survey to assess the knowledge, attitudes and practices of health care workers in the treatment of opportunistic infections in HIV infected patients in a community health care programme in Nairobi slums, Kenya".

16 December 2004

Statement of Availability

I Lillian Gitau, as a participant of the PRDUC course 2004 and a participants in this proposal development, I wish to state my commitment and availability to participate in this project.. This project will enable to put into action what I learnt at the course. It will also be a great opportunity for me to be able to work in this area of promoting adherence to treatment with a view of extending this work in the use of other medications such as anti malarials, which are used irrationally within the community.

Thank You,

Yours Sincerely

Lillian Gitau

Susan Murithi

Gender : Female
ACADEMIC QUALIFICATIONS

University of Dar-es-salaam (2001)
Advanced diploma in Dermato-Veneriology

Kenya Medical Training College (1995)
Higher diploma in Clinical Medicine
Specialized in Leprosy and Tuberculosis

Kenya Medical Training College (1989)
Diploma in Clinical Medicine and Surgery

KEY SKILLS & EXPERIENCES

- An experienced Dermato-Veneriologist, with extensive exposure in preventive, promotive and clinical management of lung diseases.
- Progressive involvement in providing training and technical assistance to community health programs, school health and in HIV/STI programs.
- Experience includes substantial clinical work at national and regional levels on HIV/AIDS and opportunistic infections.

EMPLOYMENT HISTORY

National leprosy and Tuberculosis Program (NLTP)
Position: Program Officer
Responsibilities:

- Coordinating community Based TB care services at the National level
- Running a specialist skin clinic with treatment of opportunistic infections associated with HIV/AIDS
- Participating and providing technical assistance to implementing partners in research methodologies and organizational development in Tuberculosis and HIV/AIDS
- Working with program coordinator in managing and delivery of financial aspects of project including project budgets and expenditures.
- Establishing and maintaining close working relationship with key implementing partners in TB and HIV/AIDS.
- Participation in collection of baseline information where programs are not in place.
- Providing information and organizing training resources for effective program developments.

TRAINING AND CONFERENCES ATTENDED

- **Training in Management (Nairobi)**
- International federation of dermatology conference(Tanzania)
- HIV/AIDS clinical management(Nairobi)
- Performance improvement Approach workshop(Uganda)
- Trainers of Trainers in TB control(Harare)

PROFESSIONAL MEMBERSHIP

- Kenya Clinical Officers Association
- Kenya Association of Dermatology Officers

OPERATIONALRESEARCH UNDERTAKEN

2000-Level of Knowledge Among Health Workers In Identifying Leprosy and Contributing Factors In Meru District-Kenya(chief investigator)

Name:	Dr. Joel Kangangi Karimi
Gender:	Male
Duty Station:	WHO Kenya
Responsibility:	Focal person foe HIV/AIDS, Tuberculosis, 3x5 Initiative, OPEC/WHO Funds initiative
Collaborators:	Works closely with the Ministry of Health to offer support matters related to HIV/AIDS and tuberculosis. Participates in the United Nations theme groups for HIV/AIDS.
Work Experience:	Worked in the Ministry of Health as District Medical Officer of Health, Provincial Coordinator for TB and Leprosy a KNCV sponsored NLTP project, National Professional Officer for TB and Leprosy at the Ministry of Health Headquarters among many appointments. Has participated in many research projects and initiatives.
Education:	MbchB, DTCE, DTM, MDerm, HMRI and numerous certificate courses Member of many task forces both local and international trained as TB consultant.

Name: Dr. Jacinta Ndambuki

Gender:	Female
Profession:	Social Scientist
Education:	PHD in Management Sciences and Research Methodology, University of New England, New South Wales, Australia
	Masters in Management Sciences and Research Methodology, Kenyatta University, Nairobi
	Bachelor of Education and Home Economics, Kenyatta University, Nairobi

Budget

1 US$ = Ksh. 80 [1]

	Budget Category	No.	Unit Cost	No of Days	Total Costs (US$)
	Personnel				
1	Principal Investigator [2]	1	50	15	750
	Research Associates [2]	2	50	30	3000
	Consultants				
	Statistician (data entry and analysis)	1	50	14	700
	Social Scientist	1	50	14	700
2	**Travel Costs**				
	Research team [3]	4	10	30	1200
3	**Field Allowances (Food, incidentals)**				
	Principal Investigator	1	10	15	150
	Research Associate(s)	2	7.5	30	450
	Consultants				
	FGD Moderators	3	12	2	72
	FGD Rapporteur/Recorder	3	12	2	72
	Research Assistants	2	10	30	600
	Follow up visits for patients at the community level [4]	2	5	30	300
4	**Other Direct Costs**				
	Stationary supplies(pens,paper,bags,note books)				50
	Photocopying	2000	0.05	1	100
	Focus Group Discussion	3			
	FGD meetings meetings costs (Refreshments)	30	3.5	3	315
	Tape recorder [5]	1	120		120
	Tapes and batteries	1	35		35
	Training Costs				
	Training of data collectors [6]	2	12.5	2	50
	Investigators	3	12.5	2	75
	Pretesting costs				
	Travel costs (Research team) [7]	5	10		0
	Materials (photocopying)	500	0.05	2	50
	Computing costs ([8])				
	Printing paper (reams)	6	6.25		37.5
	Catridges (Hp 840C Desk jet)	3	31.25		93.75
	Disks	1	17.5		17.5
	Data Analysis				
	Coding of questionnaires ([9])	3	10	7	210
	Data entry				0
	Data analysis				0

Report Writing	
Secretarial costs	175
Printing and binding of report	
Dissemination of results	
Meeting with stakeholders	200
Technical Support	
To be provided by University of Amsterdam)	
Questionnaire designing	
Data analysis	
Report Writing	
Dissemination of results	
Designing of Intervention	
Developing Intervention	
Implementation of Intervention	450
Training, meetings, community activities, communication strategies)	
Sub Totals	9972.75
5% Adminstration fees and bank charges [10]	498.6375
	10471.3875

Banking Details
Account Name: INRUD KENYA
Bank: Barclays Bank, Moi Avenue
Account Number: 7054867
Swift Code: BARCKENX

Note

1	Barclays Bank of Kenya Exchange Rate rate	1US$= 80	as at 15/12/04
2	Recommended rates for local researchers		
3	Cost of hire of private vehicle to research sites		
4	Possible costs for follow up of patients		
5	Market price for the recorder		
6	Hire of training venue, cost of training per person		
7	Cost of hire of private vehicle to pre-test sites		
8	Computer services will be local contribution to the project		
9	Cost of data coding assistants		
10	To cater for fluctuations in local currency		