BARRIERS TO ANTIRETROVIRAL ADHERENCE FOR PATIENTS LIVING WITH HIV INFECTION AND AIDS IN UGANDA

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**List of Acronyms**

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>ART</td>
<td>Anti retroviral Therapy</td>
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<tr>
<td>HAART</td>
<td>Highly Active Antiretroviral Therapy</td>
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<td>HIV</td>
<td>Human Immune deficiency Virus</td>
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<td>JCRC</td>
<td>Joint Clinical Research Centre</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>MTCT</td>
<td>Mother To Child Transmission.</td>
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<td>NACP</td>
<td>National AIDS Control Programme</td>
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<td>PLWHA</td>
<td>People Living with HIV/AIDS</td>
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<td>UNAIDS</td>
<td>Joint United Nations Program on HIV/AIDS</td>
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<td>TASO</td>
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PROJECT SUMMARY

According to several studies carried out in Uganda, the overall prevalence of HIV infection in 2002 was estimated to be almost 6.2%. The private sector roll out programme for Anti-retroviral treatment started at JCRC and the number of the PLWHA getting access to these drugs through JCRC has been slowly but steadily growing. This was because initially few Ugandans could afford the charges for the treatment and monitoring. Currently 4000 PLWHA access ART through JCRC and a number of patients also access their ART through MILDMAY international Centre. It is known that these two centres are well resourced in terms of equipment, experience and human resources. Thus they have good follow up programmes and earlier studies in Uganda on adherence to ART have shown it to be at a reasonably high level of about 90%. (WHO report 2003)

In 2003, the Ministry of Health of Uganda government published a free Anti Retroviral [ARV] treatment plan and roll out of the treatment started in June 2004 at 25 accredited centres. Currently, 2700 PLWHA have access to ART through the government free programme. Because of decentralisation, many of the rural poor now also have access to ARV treatment. (National Strategic framework for expansion of HIV/AIDS care and support 2001/2-2006/7)

In the process of implementation of this programme, all the government centres/facilities seem to have faced the following problems: insufficient training of staff, poor infrastructure, long waiting time, lack of trust, stigma, poor supply system and poor motivation of staff. Stigma, cultural beliefs, pill burden, poor patient information and knowledge, the use of traditional medicine and poverty also seem to negatively affect the way patients adhere to ARV. At least 95% adherence is required for these ARV regimens to be fully effective and to avoid the emergence of resistant strains of the virus. Attaining this high level of adherence is a serious concern today in Uganda.

In this study, the research team will be interested in the adherence of PLWHA to ARV. The study will include the two major private centres in the country providing ART (JCRC & Mildmay) and 8 government facilities.
The study will use a triangulation of methods in which both qualitative and quantitative methods will be used to study factors affecting non-adherence to ARV treatment in Uganda.

It is expected that the findings generated from this study will contribute to knowledge and understanding of non-adherence to ARVs and be useful in developing interventions that will be undertaken to address ARV adherence. Data collected in this study will help health planners like Uganda Ministry of health come up with better designed, better directed and more culturally sensitive intervention programmes to deal with socio-cultural problems associated with non-adherence.

1.1 BACKGROUND TO THE STUDY

HIV is a pandemic infection which affects every part of the globe. According to the International AIDS Vaccine Initiative report, there are a total of 40 million HIV infected persons in the world and of these 28.5 million are found in Sub Saharan Africa. (IAVI 2002)

Sub Saharan Africa has the largest number of HIV infected people and the situation remains bleak as the region remains home to 28.5 million adults and children living with HIV/AIDS. Current estimates are that 20-26% of people aged between 15-49 years are living with HIV or AIDS (Africa Health 2001). The catastrophic impact of HIV/AIDS in sub-Saharan Africa is threatening development in all sectors of society. The loss of productive workers and increases in health care and social service spending require difficult decisions about resource allocations across all government sectors (UNAIDS 2002).

In the early 1990s, Uganda had the highest prevalence of AIDS in the world, but the Government implemented strong preventive measures through a policy of openness, public information, communication and education and national and international collaboration through partnership of private and public sectors to bring down HIV/AIDS rate from high level of over 30% in some sentinel\(^1\) sites to the current level of 6.2%. These rates remain unacceptably and appallingly high, yet this is one of the most hopeful scenarios in Africa and an example to emulate (Mugyenyi 2002).

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\(^1\) HIV Sentinel sites are those where blood samples of STD and antenatal clients are collected using unlinked anonymous methods. The blood samples are collected on a quarterly basis for testing at the Uganda virus Institute. Results from these sites are generalized for National HIV prevalence.
In 1986, Uganda established the National AIDS Control Program (NACP) in the Ministry of Health (MOH); and Uganda AIDS Commission was established in 1992 to coordinate multi-sectoral approaches to HIV/AIDS of which one of the major interventions was the introduction of the UNAIDS access initiative and the MTCT for HIV prevention (Kiwuwa 2002).

Uganda pioneered the use of Highly Active Antiretroviral Therapy (HAART) in an organized manner in Sub Saharan Africa since 1996. The antiretrovirals (ARVs) were imported and distributed to patients who could afford to buy the drugs. International organisations like UNAIDS which has been operational in Uganda since 1998, have increased access to ARVs although it has not necessarily decreased the costs. Recent importation of cheap generic drugs into the country by JCRC has caused pharmaceutical companies to markedly reduce prices of ARVs. Only about 2% (4000 individuals) of infected individuals in Uganda currently have access to ARVs. Since the price reductions, these numbers have risen and are likely to continue increasing. Considering that current recommendations are to give life long ARV therapy, these costs are still ways above what the majority of patients can afford (Mugyenyi 2001).

In Kampala, Joint Clinical Research centre is the biggest source of antiretrovirals and sees not even half of the users of antiretrovirals. Mugyenyi (2002) reiterates that this is a warning to pharmaceutical companies and international aid organizations that black-market antiretrovirals are becoming the biggest source of antiretrovirals and these drugs are going to be increasingly used by the community outside the medical institutions. This is worrying as small studies of antiretroviral therapy in developing countries show that there is already resistance circulating among patients who are starting their first “official” course of therapy. Therefore the best way forward is not to try to prevent people from using these drugs but to make the drugs affordable, widely available and demystified so that they can be dispensed to patients under medical supervision. To address this problem JCRC implemented a program to open up satellite sites to enable more people to access the drugs regionally.
1.2 JUSTIFICATION OF THE STUDY;

Emerging data suggest that among segments of the Ugandan society, there has been important behaviour changes with people reporting reducing the numbers of their sexual contracts based on government’s advice that people ‘love carefully’, “love faithfully” or stick to one sexual partner (Asiimwe-Okiror, 1995, Opio, 1996). However this does not mean that Ugandans are no longer vulnerable to HIV infection. On the contrary, the World Bank estimates that if current rates of infection in Uganda are maintained, then, by the year 2020, 2.8 million adults in Uganda will be infected with HIV. (World Bank 1995)

Antiretrovirals can increase the length and quality of life and productivity of patients. At JCRC for example, antiretroviral regimens have improved survival and decreased the incidence of opportunistic infections in people with HIV to a certain extent. Strict adherence to HAART regimens is crucial in order to maintain a low viral load and prevent the development of drug resistant virus. However, some clients at JCRC do not return for follow up on schedule and are likely to be non-adherent to prescribed HAART regimens. There is growing concern about loss to follow-up and non-adherence to antiretroviral therapy as significant barriers to care in Uganda as stated by Kityo et al in a presentation to XIV International AIDS Conference in July 2002 (Kityo et al 2002).

Although JCRC has been described in most literature as the largest provider of ART in Uganda, with funds from the Presidential emergency fund for Aids and Global fund for HIV/AIDS, the government of Uganda has implemented the programme in one national Referral Hospital [Mulago], in all the eleven Referral hospitals and eleven district Hospitals. This programme was implemented in 2004 and provides ARVs to 2700 patients. The government of Uganda has plans of doubling the number of patients accessing ARVs through its facilities in 2005. Already all these government Hospitals are reporting many cases of patient failure to turn up for re-supply. This is one of the indicators of the obvious problem of adherence as we already know there are so many problems related to these facilities which have existed and continue to exist as indicated in the problem analysis diagram.
This study will focus on patients who are accessing ART through these government facilities where monitoring and follow up may not be as adequate as in other organisations which are known to have experience and better facilities such as JCRC.

Non-adherence to treatment regimens is not unique to people living with HIV/AIDS (PLWHA). From the literature it is clear that non-adherence is ubiquitous. Estimated rates of non-adherence for ARV users range from 10% - 92% with an average of 50% (Eraker, Kirsch & Becker, 1984; Epstein & Cluss, 1982). In people with HIV-infection, reports of adherence (usually defined as taking 80% or more of the prescribed regimen) range from 25% - 85% (Chesney, 1997; Muma, Ross, Parcel & Pollard, 1995; Samet, et al., 1992; Broers, Morabia & Hirschel, 1994; Singh, et al., 1996; Ford, Carson & Peperell, 1998; Bachiller, Arrando, Liceago, Iribarren & Olloquiegui, 1998). In HIV-infected patients on HAART, 80% - 90% adherence has been associated with failure to achieve complete viral suppression in 50% of patients (Paterson, et al., 1999). These are high percentages that require to be investigated with regard to non-adherence to HIV HAART regimens.
NON ADHERENCE TO ARVs

SERVICE FACTORS

Poor support services
- Long waiting time
- Inadequate trained health workers
- Treatment guidelines not available
- Poor drug supply
- Insufficient infrastructure

Poor quality of services provided
- Poor Staff motivation
- Inadequate counselling
- Inadequate follow-up of patients
- Lack of knowledge & info

PATIENT FACTORS
- Cost of care
- Patient income
- Side effects + ADRs
- Pill burden

SOCIO-ECONOMIC AND CULTURAL FACTORS

Beliefs and patient’s preference to traditional medicines and alternative therapy

Perception on the causes and transmission of HIV

Age, sex, literacy level of patient

Poor social support

Stigma

Lack of employer support

Mobility

Occupation

Low accessibility of services

Long distance to the health facility
1.3 OBJECTIVES OF THE STUDY

The main objective of this study is to study factors leading to non-adherence to ARVs in selected government and non-government sites in Uganda.

Specific objectives are to:

(a) Determine patient’s knowledge, attitudes, perceptions and on the use of ARVs
(b) Establish patient’s information sources and communication channels more acceptable to them
(c) Determine beliefs and practices that affect adherence to ARVs
(d) Establish the type of services delivered to patients receiving ARVs in selected sites in Uganda.
(e) Establish the kinds of social support given to patients taking on ARVs
(f) Gather information from ARV users and support groups on improving ARV adherence which can be useful for planning an intervention.

1.4 SIGNIFICANCY OF THE STUDY

Taking HAART regimens is not an easy task since it is a lifetime treatment. It is hoped that the findings generated from this study will make several contributions to both knowledge and understanding of what is one of the worst calamities to hit Uganda and the world in many years. It will also contribute to the Sociological /Anthropological understanding of non-adherence and be useful in developing interventions that will take into consideration the problems faced by people taking ARV treatment at Jinja hospital and Uganda as a whole. It is expected that the qualitative and quantitative data collected in this study will be made available to health planners such as Ministry of Health and it 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.

Some of the burning issues answered in this study may be incorporated immediately to address urgent problems that may not require scientific inquiry at Jinja Hospital.
Since 1996, an overwhelming amount of evidence from clinical trials has been published validating the use of HAART for the treatment of human immunodeficiency virus (HIV) infection. Suppression of HIV replication, immune reconstitution, a halt in disease progression, increased survival; reduced morbidity and a better quality of life have been defined as the biological and clinical goals of treatment. In countries where access to this standard of care is available, AIDS related mortality and morbidity have significantly declined (Pallela, et al., 1998; Detels, et al., 1998).

Maximum and durable suppression of HIV viral replication to below the level of detection is necessary to achieve these biological and clinical goals. To achieve success requires near-perfect adherence to combination regimens. Failure to suppress viral replication completely inevitably leads to the selection of drug resistant variants limiting the effectiveness of therapy (Condra, 1998; Perrin & Telenti, 1998). Non-adherence in patients on anti-HIV therapy is the strongest predictor of failure to achieve viral suppression below the level of detection (Deeks, 1997), and faulty adherence to anti-HIV drugs most often underlies treatment failure. It would appear that > 95% percent adherence may be necessary to adequately suppress viral replication, produce a durable response and halt disease progression (Paterson, Swindels & Mohr, 1999). This means that missing more than one dose of a regimen per week may be enough to cause treatment failure.

The challenge of adherence in the face of potential viral resistance, treatment failure and disease progression is worrying. Patients on long-term HAART with undetectable HIV in plasma still harbour replication-competent virus (Furtado, et al., 1999; Shrager & D'Souza, 1998). It would mean that with current medications HAART, at best, would be a life-long process. Conscientious treatment adherence is difficult under any circumstances, the unforgiving nature of HIV replication, the complexity of the HAART regimens, and associated short and long-term toxicity all pose particularly difficult challenges for patients.

It needs to be recognized that adherence to HAART is a central issue of concern and it is clear from the literature that the factors that influence a patient's ability to adhere are multiple and complex. A multitude of variables have been shown to affect...
adherence to HAART, some more than others (McAllister 2000). In addition to that small studies of Antiretroviral therapy in developing countries show that there is already resistance circulating among patients who are starting their first "official" course of therapy. (Mugyenyi 2002)

Socio economic factors of patients on HAART regimens

The literature consistently demonstrates that demographic characteristics are not strong predictors of adherence though some correlates of adherence are described below together with socio economic factors.

Age
Age may influence adherence. Studies have found that apart from the most elderly adherence increases with age (Wenger, Gifford, Liu, Chesney & Golin, 1999). In two studies associated with HAART, adherence non-adherence showed a positive correlation with younger age (Klosinski & Brooks, 1998; Jones, Nakashima & Kaplan, 1999).

Level of Education
A Lower level of general education and poorer literacy impacts negatively on some patient's ability to adhere (Moralez, Figueiredo, Sinkoc, Gallani & Tomazin, 1999; Sipler, Cross, Lane, Davis & Williams, 1999) whilst a higher level of education has a positive impact (Catz, Heckman & Kochman, 1999; Schilder, et al., 1998).

Financial concerns
Literature reveals that patients on higher incomes have less difficulty with adherence (Pratt, Robinson, Loveday, Pellowe & Franks, 1998; Martinez, Marques, Valdes & Santana, 1998). However, poverty is an increasing feature of the face of HIV especially in the third world where many people are living below the poverty line (Grierson, et al 2000). In the Futures II study, which surveyed 924 Australian HIV positive people, more than half of the respondents reported experiencing some difficulty in meeting the cost of daily living (Grierson, et al., 2000). Medications and clinic visits cost money and may stress an already stretched budget. In the developing countries, there is no medical insurance or disability pension for people living with HIV infection (Katabira 2002).
Social support
Living alone and a lack of support have been associated with an increase in non-adherence (Williams & Friedland, 1997) and social isolation is predictive of non-adherence (Besch, 1995). Not living alone, having a partner, social or family support, peer interaction, and better physical interactions and relationships are characteristics of adherent patients (Eraker, et al., 1984; Pratt, et al., 1998; Motashari, Riley, Selwyn & Altice, 1998; Brown, Inouye, Powell-Cope, Holzemer & Nokes, 1998).

Side effects of HAART on adherence

The drug regimen
Almost all PLWHA who are currently using anti-HIV drugs are on a regimen of 3 or more drugs (HAART) (Grierson, et al., 2000). The likelihood of a patient's adherence to a given regimen declines with polypharmacy, the frequency of dosing, the frequency and severity of side effects, and the complexity of the regimen (Williams & Friedland, 1997). Drug hypersensitivity is far more common in patients with HIV (Carr & Garsia, 1997) and regimen associated toxicity is a common predictor of, and reason for, non-adherence across many studies (Murri, et al., 1999; Ickovics & Meisler, 1997). Side effects associated with each individual antiretroviral drug are well described, and whilst not universal for every patient can be predicted. Usually they defect after the first few weeks of therapy but for some, they persist. Anticipation and fear of side effects also impacts upon adherence (Broers, et al., 1994). Poor adherence has been associated with patients’ desire to avoid embarrassing side effects in certain situations, for example, whilst on a date or attending a job interview (Burgos, et al., 1998).
A typical HAART combination commonly consists of three agents or drugs (Stavudine, Lamivudine and Nevirapine or Efavirenz) and usually plus other medication for prophylaxis of opportunistic infections. This can result into a high pill load, thrice-daily dosing, dietary and dosing idiosyncrasies, large capsules or tablets, and specific storage instructions. This regimen complexity significantly impacts upon a patient's ability to adhere (Ickovics & Meisler, 1997; Cockburn, Gibberd, Reid & Sanson-Fisher, 1987; Haynes, Taylor & Sackett, 1979; Mehta, Moore & Graham,
Additional medications taken for symptomatic relief like analgesics, cough remedies and others common in patients with advanced HIV disease, further add to the pill burden and toxicity. In Uganda, the regimen requires Lamivudine, Stavudine and Nevirapine or Effavirenz as first line. Second line Stavudine, Didanosine and Kaletra or Zidovudine, Didanosine and Kaletra.

**Dietary restrictions attached to a drug**

Dietary conditions add to the complexity and often require adjustments in lifestyle. Patients can find their meal schedule compromised by anti-HIV drugs that require dosing on a fasted stomach. This can be particularly difficult if work-mates, family or friends are unaware of the patient's HIV status (Grierson, et al., 2000). Complicated regimens with rigid dosing intervals may also interrupt sleep. The physical aspects of a particular medication (taste, size, formulation etc.) may also impact on a patient's ability to be adherent (Crespo-Fierro, 1997).

**Treatment Characteristics affecting adherence**

**Physical state and disease stage**

Prior opportunistic infection (Singh, et al., 1996), symptom severity (Bond & Hussar, 1991) and low CD4+ counts (Erlon & Mellors, 1999) can predict adherence. One patient describes disease progression as, ‘Creating a sense of urgency for treatment’, and another, ‘As I first entered the study, I had a T-cell count below 10. I was at the hospital 20 some times on different occasions. The grim reaper was standing above me’ (Erlon & Mellors, 1999).

Seeing an improvement in the immune and virologic indices used to monitor HAART (T-cells and HIV viral load) may be a powerful incentive to maintain adherence (Kaplin, Golin, Beck, Lui & Hays, 1999; Pratt, et al., 1998). Caution should be exercised, however, in stressing a patient's improved laboratory indices without assurance that adherence is almost faultless. These values, in the short term, may improve despite sporadic adherence and this may reinforce a patient's level of poor adherence. Lack of symptoms (despite laboratory evidence of the need for HAART) may affect adherence (Jones, et al., 1999; Murri, Ammassari, DeLuca, Cingolani &
Antinori, 1999; Ickovics & Meisler, 1997). Most patients with untreated HIV infection have a median AIDS-free time of 11 years, and HAART is often commenced when patients have laboratory evidence of disease progression but are essentially asymptomatic and feeling well. In Uganda, the policy is to initiate treatment in patients with documented HIV infection and:

- WHO stage IV disease irrespective of CD4 cell count
- Advanced WHO stage III disease including persistent or recurrent oral thrush and invasive bacterial infections irrespective of CD4 cell count or total lymphocyte count.
- When CD4 count of 200/mm$^3$ or less for patients in WHO stage I, II or III
- Tuberculosis with a CD4 cell count between 200-350/mm$^3$

**Depression and severe anxiety**

Depression and severe anxiety are variables that predict non-adherence (Klosinski & Brooks, 1998; Ickovics & Meisler, 1997; Besch, 1995; Hirschhorn, Quinones, Goldin & Metras, 1998). Most people with HIV, at some time in the course of their illness, experience a psychiatric disorder (Buhrih & Judd, 1997) and depression and/or anxiety are reported in up to 70% of patients with symptomatic HIV-disease (Hayman & Buhrih, 1994). Adherent patients demonstrate significantly less depression or other psychiatric disturbance (Singh, et al., 1996; Pratt, et al., 1998; Catz, et al., 1999).

HIV involvement of the central nervous system can affect memory. AIDS related dementia (AIDS Dementia Complex – ADC) is a common finding in patients with advanced HIV disease and is characterized by abnormalities in cognitive as well as motor function (Wright, Brew, Nurrie & McArthur, 1997). Although studies describing adherence and ADC were not found, cognitive deficits do impact negatively on adherence to a HAART regimen (Meisler, et al., 1993). Even when cognition is unimpaired, it is difficult to remember to take medications.

**Beliefs and knowledge**

A patient's beliefs about their illness and the effectiveness of medication are predictive of adherence (Wenger et al, 1999) A patient's level of knowledge about HIV disease, a belief that HAART is effective (Klosinski & Brooks, 1998) and
prolongs life (Stone, et al., 1998), and a recognition that poor adherence may result in viral resistance and treatment failure (Wenger, et al., 1999) all impact favourably upon a patient's ability to adhere. Conversely, a lack of interest in becoming knowledgeable about HIV (Kammann, Williams, Chesney & Currier, 1999) and a belief that HAART may in fact cause harm adversely affecting adherence (Johnston, Ahmad, Smith & Rose, 1998; Brigido, et al., 1998; Horne, Pearson, Leake, Fisher, Weinman, 1999).

Aspects of the clinic and service provision
The effect that the clinic setting has on adherence should not be underestimated. Clinic characteristics that impact on adherence include: proximity to the patient's home or place of work, the expense of getting there, lengthy delays between appointments, clinic opening and closing times, long waiting times, lack of services such as child care, privacy, confidentiality, and unsympathetic or inconsiderate staff (Kammann, et al., 1999; Crespo-Fierro, 1997; Nemecheck & Tritle, 1998).

Difficulties with HAART re-supply
Obtaining a prescription before a clinic visit are reported as obstacles to adherence (Weidle, et al., 1998; Burgos, et al., 1998). For just over half of PLWHA a prescription for HAART lasts for 3 months in developed countries, however 40% receive a prescription for one month and 12% for 2 months (Grierson, et al., 2000). In addition, some dispensing pharmacies will only dispense one month's medication at a time. Not all pharmacies are able to dispense anti-HIV drugs, as a result, some PLWHA attend their local pharmacy for most prescription medicine and a specific pharmacy for their anti-HIV therapy. In developing countries the story is very worrying as lengthy waits in a few hospitals that do not have extended hours may also impede adherence (Grierson, et al., 2000).

Strategies to improve completion of prescribed regimen

Treatment satisfaction
Simple regimens and regimens that 'fit into' a patient's life style enhance adherence (Wenger, et al., 1999; Holzemer, et al., 1999; Mallolas, et al., 1998; McNabb, et al.,
As a regimen increases in complexity, its inconvenience makes it difficult to incorporate into daily living. Much recent research is currently aimed at simplifying HAART to twice daily or even once daily dosing. (Grierson, et al., 2000).

**1.6 Definitions of Key concepts**

**ADHERENCE**  Taking medicines exactly as recommended

**ANTIRETROVIRALS (ARVs)**  Drugs designed to suppress the progression of HIV/AIDS, Consist of a double or a triple combination of ARV drugs.

**CD4 T-CELL**  Cells that recognize and help destroy bacteria in the body. The count determines the stage of AIDS.

**CLIENTS**  Persons who use the services

**COMPLEX REGIMENS**  Drugs that have been manufactured to suppress the HIV virus.

**PROTEASE INHIBITOR**  Introduced when combinations of highly active antiretroviral regimens have failed to work.

**UNDETECTABLE VIRAL LOAD**  when the virus is not detected in the blood after a lab test

**VIRAL LOAD**  Levels of virus found in the blood per 10 ml
1.7 METHODOLOGY

The study will consist of a variety of methods. Both quantitative and qualitative methods will be employed in the data collection. The two approaches tend to complement each other; hence, it is the intention of this study to triangulate qualitative and quantitative methods of gathering data.

Qualitative methods to be used include exit questionnaire, semi-structured interviews, observations and focus group discussions. Quantitative methods will include retrospective review of patient medical records to extract baseline data.

Sampling strategies and sample size

Quantitative and Qualitative sample selection

The quantitative information collected in this study will be mainly to describe and profile the facilities under study. The qualitative sample will be chosen using purposive and Multi-stage cluster sampling. In this way, the National and regional hospitals will be purposively selected, the district hospitals will be selected using Multistage cluster sampling. In this way, three regions will be selected from the whole country. Afterwards, three district hospitals will be selected from sub-regions using simple random sampling. As part of the sample the study will include the only national referral Hospital [Mulago], four of the regional referral Hospitals and three district hospitals. These regional and district hospitals will be selected by simple random sampling. The study will purposively include JCRC and MILDMAY International center the largest non-government organizations [NGO] supplying ARVs in Uganda.

Methods of data collection

Quantitative data collection

Data for the Quantitative part of the study will be collected by a structured socio-demographic interview guide. Some of the information to be collected will include age, marital status, and religious background, schooling experience, background, knowledge, attitude, perception and practice on the use of ARVs.

Qualitative data collection
The bulk of data for this study will be based on qualitative methodologies. This is because the key problem for this study, namely; non-adherence to ARVs can best be captured using qualitative methodologies. In this regard, the following qualitative methods will be used: Focus group discussions, structured observation, semi-structured interviews Exit interviews and secondary data review.

**Focus group discussion (FGD)**
Focus group discussions (FGDs) with clients directly using ARVs enrolled at the selected sites will be conducted and organised into groups by age and sex. The purpose of focus group discussions will be to identify difficulties that are being encountered by people taking ARV treatment. The focus group discussion moderator will have a focus group discussion guide, which is purposively selected to keep the research focussed to the themes of the study. While taking notes, the focus group recorder will be taking observation notes as well. Two FGDs will be conducted in the community served by the each facility, one in urban and one in either peri-urban or rural setting.

**In-depth interviews**
These will involve the use of semi-structured, open-ended interview guides with flexible probing ideal for investigating personal experiences from the subjective perspective of each respondent about ART. This may serve as a back up to the FGD findings. At each facility, we shall conduct semi-structured interview for one doctor, one Pharmacist, one receptionist, one counselor and one nurse. This will be to establish the health worker’s perspectives on the problem of non-adherence and also to assess the quality of care they offer to patients and other factors.

**Exit interviews**
These will be conducted for 8 patients at each facility [4 male and 4 female] to assess the quality of care received.

**Structured Observation**
While discussions are going on it will be possible for the researchers to observe both the respondents and also others who are not included in the sample, aspects such as interactions between clients and service providers in health facilities, stigmatised actions, time spent at the facility and the organization procedure. *Observational notes* will be taken and later used in data analysis this will help to patch up gaps that may have been left out during focus group discussion or during in depth interview but best noted.

**Secondary data review:**

A register of HIV clients at the each facility will be used with the hospital’s permission to help back up findings from focus group discussions and in-depth interviews. Annual/quarterly reports, work plans, strategic plan documents and conference/workshop presentations will be reviewed among others. Review of patients’ records will help determine level of adherence and gather clinical data of patients. Records for all patients interviewed will be retrieved to back up information regarding ARV use and adherence.

This will not be sampled, all data available will be used.

**Data collector selection and training**

After completing study materials and permission granted, the key members of the research team will select and train data collectors. The selection criteria will put into consideration a multi-disciplinary component including 2 social Scientists and 2 pharmacists with vast experience in conducting health related research. A workshop will be organised to train data collectors in the various methodologies that will be employed in the process of data collection and critical ethical issues. As part of the training, the data collectors will conduct a pre-test of the instruments with the guidance of principle investigator. The pre-test will be conducted with two FGDs, 4 HIV infected clients and service providers involved at one facility. The pre-test will serve to rectify and revise instruments as well as the research procedures in general.

**Data cleaning, entry and Analysis**
Data checking and cleaning will be done by all the research team members before entry into the computer statistical programme SPSS or EPI-INFO. Focus group discussions and in-depth interviews will be transcribed and translated as data collection is in progress. All relevant sources of data will be considered to allow for triangulation. Differences or contradictions between data sources (for example between key informants answering structured questionnaires and focus group discussions) will be examined and explanations sought. Quantitative data will be coded and entered into computer using SPSS or EPI-INFO programmes. Qualitative data will be analysed progressively as they get collected in the field. In general, however, the analysis will follow the Spradley (1997) “Ethnoclassification “ system, whereby information gathered will be classified according to themes and domains and presented in form of taxonomies that reveal emerging patterns.

Report writing and dissemination of results
At every stage of report writing, the key stakeholders will be involved to supplement on the findings from the field. After approval of the final report by WHO, dissemination of results of the study will be done through a workshop with all the key stakeholders. In addition, a paper will be prepared to be presented at a conference organised by the funders.

1.8 ETHICAL ISSUES
Approval and permission will be sought from the health research unit of the Ministry of Health of Uganda. Due care will be taken to ensure that all those who accept to participate in the study do so voluntarily, and give their informed consent. A Hospital counsellor associated with the research will purposively recruit HIV infected adults for participation. To this end, the researcher will explain to the people in the study areas the aims and objectives of the study. Those who agree to participate will be given a chance to ask for any clarification about points on which they are not clear. They will be informed that any information collected during the course of the study will be kept confidential and that no personal name will appear on research documents, instead ID numbers will be used.

1.9 STAKEHOLDER’S INVOLVEMENT
The following will be stakeholders in the research:
Uganda AIDS control programme
TASO
PLWHHA associations
Support groups
Health workers including Doctors Pharmacists, nurses, counselors
Religious and non-government organizations involved with the care and treatment of HIV/AIDS
A stakeholder’s workshop will be held in November after the submission of the second draft of the proposal to make sure that their inputs are incorporated in the final proposal.

Technical assistance
We shall need the staff of the University of Amsterdam input when designing the research tools, availing us with appropriate software.
References

Africa Health, 1999 Volume 21, Number 3,


Mugyenyi, P. (2002). HIV/AIDS Situation in Africa. Statement By Dr. Peter Mugyenyi Joint Clinical Research Center Kampala Uganda


# APPENDIX 1
## RESEARCH BUDGET

<table>
<thead>
<tr>
<th>ITEM</th>
<th>NO. OF DAYS</th>
<th>RATE PER DAY (USD)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> PERSONNEL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(a) Principle Investigator 1</td>
<td>30</td>
<td>55</td>
<td>1650</td>
</tr>
<tr>
<td>(b) Research Associates</td>
<td>20</td>
<td>40x2</td>
<td>1600</td>
</tr>
<tr>
<td>(c) Statistian</td>
<td>10</td>
<td>40</td>
<td>400</td>
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<tr>
<td><strong>2</strong> TRANSPORT</td>
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<tr>
<td>(a) Hire-4 wheel vehicle</td>
<td>20</td>
<td>50</td>
<td>1000</td>
</tr>
<tr>
<td>(b) Fuel</td>
<td>20</td>
<td>24.75</td>
<td>495</td>
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<td><strong>3</strong> FIELD ALLOWANCES</td>
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<tr>
<td>(a) Principle Investigator 1 (Food, lodging &amp; Incidentals)</td>
<td>5</td>
<td>60</td>
<td>300</td>
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<tr>
<td>(b) Research associates</td>
<td>20</td>
<td>40x2</td>
<td>1600</td>
</tr>
<tr>
<td>(c) Data collectors</td>
<td>20</td>
<td>30x4</td>
<td>2400</td>
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<tr>
<td><strong>4</strong> OTHER COSTS</td>
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</tr>
<tr>
<td>(a) Stationary &amp; supply</td>
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<td>95</td>
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<tr>
<td>(b) Communication (Telephone, email)</td>
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<td></td>
<td>263</td>
</tr>
<tr>
<td>(c) Interviews &amp; focus group discussion costs</td>
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<td></td>
<td>300</td>
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<tr>
<td>(d) Survey materials (Training materials, printing of survey instruments, clipboards &amp; bags and calculators for interviewers)</td>
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<td>297</td>
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<tr>
<td>(e) Computing expenses (Disks, printer inks, printer paper, Data entry &amp; verification services)</td>
<td>215</td>
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<td></td>
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<tr>
<td>5 Administrative costs</td>
<td>1,248</td>
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<tr>
<td>6 Contingency</td>
<td>624</td>
<td></td>
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<tr>
<td><strong>Grand Total</strong></td>
<td><strong>12,487</strong></td>
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</tbody>
</table>

**SUMMARISED BUDGET**

**BUDGET**

| Personnel | USD 3650 |
| Transport | USD 1495 |
| Field Allowances | USD 4300 |
| Other costs | USD 1794 |
| Sub-Total | USD 11239 |
| Administrative costs [10%] | USD 1248 |
| **Grand Total** | **USD 12487** |
## Annex 2

### WORKPLAN

<table>
<thead>
<tr>
<th>Duration</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
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<tbody>
<tr>
<td>1. Finalising research proposal</td>
<td>2 weeks</td>
<td>x</td>
<td>x</td>
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<tr>
<td>2. Seeking permission from Ministry of Health</td>
<td>1 week</td>
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<td>3. Meeting with stakeholders</td>
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<tr>
<td>1. Develop Research tools</td>
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<td>5. Submission of first draft</td>
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<td>5. Incorporation of experts’ comments</td>
<td>1 week</td>
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<td>7. Submission of second draft</td>
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<td>6. Incorporation of second comments</td>
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<td>7. Submission of final draft</td>
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<td>10. Train Data Collectors</td>
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<td>11. Pre-test and review the tools</td>
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<td>12. Collect Data</td>
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<td>13. Analyse Data and write report</td>
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<td>xx</td>
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<td>14. Submit first draft of report</td>
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<td>5. Incorporation of feedback or comments</td>
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<td>17. Convene Stakeholders meeting</td>
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<td>18. Disseminate and publicise findings</td>
<td></td>
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</tbody>
</table>
ANNEX 3: CURRICULUM VITAE OF KEY PARTICIPANTS

ALICE NAKIYEMBA
CONTACT ADDRESS
BUSOGA UNIVERSITY, P.O.BOX 1227, JINJA-UGANDA
Tel: +25677450371
Email: nakiyembaa@yahoo.com

DATE OF BIRTH: 23RD JANUARY 1971
NATIONALITY: Ugandan, SPECIALITY: Community Training and Education

EDUCATION
MA. Sociology Makerere University Kampala, BA. Social Sciences (Hons), Makerere University (1998), Diploma. In Education Secondary Institute of Teacher’s Education Kyambogo (1994)

PROFESSIONAL/WORK EXPERIENCE
2001 – TO DATE BUSOGA UNIVERSITY
DEAN/LECTURER FACULTY OF SOCIAL, CULTURAL AND DEVELOPMENT STUDIES


EXPERIENCE IN TRAINING, RESEARCH AND PROJECT EVALUATION
September 1997 District research assistant for Law Reform Commission on Rape and defilement project in Kamuli district, July 1999. District research assistant for law and advocacy for women in Uganda on domestic violence project in Iganga District, May 2000. District research assistant for law and advocacy for women in Uganda to assess the effectiveness of the Decentralized courts on the justice of women in Kamuli District, February – March 2001. District research assistant for Regional Center for quality health care project Makerere University. This was to assess the quality of care of reproductive Health services in rural areas in Kamuli district, September 2002. Worked as a field assistant with Makerere University Faculty of Social Sciences on a four year project on Public policy, changing Gender relations and identities in Uganda in collaboration with Gotoborg University in Sweden, November 2003. Team member for the team which carried out the Mid-Term Review for Goal Bugiri HIV/AIDS four year project in Uganda, December 2003. Part of the consultancy team which carried out the mapping of civil society organizations in Uganda phase I for Uganda Programme for Humanistic Development [UPHOLD] in 20 Districts, March 2004. Team Leader for the Mid-Term Review for The Aids Intervention Programme [TAIP] Jinja a five year project, May 2004. Worked as a consultant with Mayuge District to train Secondary school teachers in Counselling skills of HIV/AIDS for youth, Trained the youth out of school in Mayuge district in the basic life skills for HIV/AIDS, June-July 2004. Part of the consultancy team which carried out the study of Civil society organizations in Uganda phase II for Uganda Programme for Humanistic Development [UPHOLD] in 20 districts in Uganda.

SPECIAL TRAINING UNDERTAKEN
Participatory rural appraisal methodologies in research, Project Monitoring and Evaluation, Training of trainers, Strategic planning and management, Leadership skills, Proposal writing and resource mobilization, Field data collection using qualitative and quantitative methodologies, Consultancy skills, Gender Mainstreaming.

WORKSHOPS AND SEMINARS ORGANISED AND ATTENDED
Organized and facilitated on an In-country training workshop on sustainability of water sources British Council In-country training programme funded by the department for international development (DFID). District planning workshops for Jinja, Iganga, Kamuli and Bugiri Districts. Organized and attended feedback workshops for DFID Mid-Term and final evaluation of Busoga Trust water development project

PUBLICATIONS
A Gender analysis of secretarial training and employment in Kampala, The role of female youth in the women liberation movement, Factors influencing utilization of reproductive Health services among young people.
CURRICULUM VITAE
RICHARD KWASA

CONTACT ADDRESS: Pharmacy Department
Jinja Regional Referral Hospital
P.O.Box 43
Jinja-Uganda
TEL: +256-77-408948
Email: kwasarichard@yahoo.com


NATIONALITY: UGANDAN

SPECIALITY: Pharmacist

PROFESSIONAL EXPERIENCE

2003 TO DATE: Pharmacist Jinja Regional Referral Hospital
Duties:
-Manage drug supply in the Hospital
-Promote rational drug use in the Hospital
-Supervising Intern pharmacists in the Hospital
-Spearheading the implementation of the Ministry of Health drug policies in the Hospital
-Facilitating the promotion of rational drug use at lower health units in the region
-Principle coordinator of DPPP in Jinja Hospital
-Secretary to Jinja Hospital Pharmacy and Therapeutic committee
-pharmacist in charge of a clinical Trial of a new Anti-malarial drug being carried out in Jinja Hospital by African Centre for clinical Trials [ACCT] on behalf of PFIZE pharmaceuticals

1998-1999- MBARARA University of Teaching
2000-2002- Gilead group of community pharmacists: Supervising pharmacists in charge of the Jinja branch
2003- Attended a joint workshop for Ministry of Health Uganda and Global fund Antiretroviral Therapy
2004 –Worked as area manager for a WHO survey on medicine prices in Uganda
2004- Attended a course in Pretoria on promoting Rational Drug use in community
Akurut Chantal Dorothy
Medical Research Council Programme on AIDS
P.O Box 49 Entebbe Uganda
Tel: 256 075 653 554 office: 075 731732
Email: Dorothy.Akurut@mrcuganda.org; dakurut@yahoo.com

M.A. Sociology Waiting to defend paper Makerere University Kampala

B.A. SS (Hons) 3.42 Makerere University Kampala

Makerere university Diploma in Education attainable at institute of teacher education

A scientific officer Social Sciences: Skilled in all areas of psycho social work, social communication with experience in coordinating medical/health projects, Program development, monitoring and evaluation and people minded. Able to work with those who have been marginalized and traumatized and also to work with a wide variety of professional and voluntary staff in cross-cultural setting. Able to use a variety of computer packages including MS Office programs word, excel, Power Point and statistical packages such as: Access, SPSS, Epi info. Qualitative packages like Survey, Ethnograph, very compatible with proposal writing and analysis of qualitative data using survey, QSR Nudist Nvivo and QSR merger for Nvivo packages.

Employer: Medical Research Council Program on AIDS in Uganda
Job title: Scientific Officer Social Sciences
Department: Social Sciences
Duration: 2003 January to date.

Employer: Uganda Case Western Reserve University (CWRU) Research collaboration and Makerere/University Kampala
Study: Feasibility of Clinical trials of Vaginal Microbicides for the prevention of HIV infection in Kampala Uganda
Job title: Study Coordinator/Research Associate
Employer: Case Western Reserve University

Employer: Joint Clinical Research Center (JCRC) Kampala Uganda in Collaboration with Case Western Reserve University Cleveland
Study: HIVNET 007 ALVAC-HIV VACCINE TRIAL.
Job title: ALVAC Research Associate/ Study coordinator
Duration: 1998 – September 2001

Study: HIVNET 013 Discordant Couples
Job Title: Research Assistant/Data coordinator
Duration: 1997-1998
Employer: Joint Clinical Research Center /Case Western Reserve University
Study: HIVNET 21 PAVE A
Job Title : Research assistant on site/coordinator

Employer: AIDS Information Center
Duration : April 1992 to Feb 1995
Job title Research Assistant/ coordinator

Job description/Keys tasks

Following up patients who had tested positive for HIV

5: PRESENTATIONS/ SEMINARS/CONFERENCES/ ATTENDED

Oral Presentations:

D. Akurut. B. Wolff. S. Biraro
Role of HIV/AIDS awareness in sexual partnership formation and preventive behaviors adoption in rural South Western Uganda.
MRC Seminar Sessions 28th May 2004

D. Akurut. C. Turyatemba, Dr. A Kebba, E. Mugisha, A. Mugisha Chekekwo.
Mammelang session: HIV/AIDS within the community: Female Genital mutilation
XIII International Conference on AIDS : Breaking the silence
July 17th –22nd 2000 Durban South Africa.

D. Akurut. C. Turyatemba, Dr. A Kebba, E. Mugisha, A. Mugisha ,C. Kataliwa
Poor Cultural Practices and frustration of National Health policies
Third European Conference on HIV AIDS
February 13th 2000-16th Amsterdam Holland.

D. Akurut. C. Turyatemba, Dr. A Kebba, E. Mugisha, C. Akola ,C. Kataliwa
Human Rights Violations: Female Circumcision a perpetuator of HIV/AIDS
ICASA Conference on HIV/AIDS and STDs: Setting Priorities.
September 11th-16th 1999 Lusaka Zambia.

Co- Author/poster presentations.

E. Mugisha, Dr. A. Kebba, M. Kabugo C. Turyatemba, D. Akurut, G. Gumoshabe
Poster presentation: Sexual Behavior in a group of people asking for HIV Antibody testing for Preventive reasons in Uganda.
ICASA Conference on HIV/AIDS and STDs: Setting Priorities
September 11-16 1999 Lusaka Zambia

Poster presentation: Clinical Trials and Community participation perspectives in HIV/AIDS research programs in Uganda.
XIII HIV/AIDS International Conference, Durban, South Africa, July 2000

E. Mugisha, Dr. P. Muyenyi, R. Byaruhanga, C. Turyatemba, D. Akurut, K. Kataliwa


C. Turyatemba, Dr. P. Muyenyi, Dr. A. Kebba, E. Mugisha, D. Akurut: The Education of Clients and Caregiver vs adherence on HAART: The JCRC Experience.

**CONFERENCES/WORKSHOPS/TRAININGS ATTENDED.**

15th-26th September 2003 Ethiopia Addis Ababa
Training in Social Science Research Methodology offered by the Research Methodology Training institute of the Organization for Social Science Research in Eastern and Southern Africa

10th July-11th, 2003 Kampala Uganda
4th Annual Scientific conference for Uganda Society for Health Scientists. ARVS: "TO CARE IS TO PREVENT"

17th-20th June 2001 Abidjan Cote d’ Ivoire
HIV Management Exchange workshop (SMART)

17th Feb. 2001 Kampala Uganda.
Organized a workshop on Treatment of HIV/AIDS
Hotel Africana
Was responsible for all the workshop organization

9-14th July 2000 South Africa Durban
XIII International Conference on AIDS: Breaking the Silence
Good Research Practice: GRP allowed ready verification of quality and integrity of research data, the rights, safety and well-being of participants must be safeguarded. Issues of consent and confidentiality are paramount. Management of conflicts of interest was considered.

June 1996 UNAIDS induction course on Vaccine Trials
Preparatory demonstration seminar on. Who is eligible for the Vaccine?
This workshop was conducted in preparation for the ALVAC Vaccine trial, which was to take place at JCRC.


May 1994 Workshop on HIV/AIDS, Family Planning and Reproductive Health (AIC)
Here the consequences that an HIV positive mother will go through during pregnancy.

The possibility of getting a baby whom is infected.
Challenges of nursing an infected child when the mother also is infected.

Different family planning methods to help prevent pregnancy for the infected mother and prevent further infection.
Compliance, stigmatization and accepting Family Planning

Akurut D. (1989) Cultural practices that perpetuate spread of HIV/AIDS a case study of Sabiny in Kapchorwa district. A dissertation presented for the Award of a Bachelors Degree in Social Sciences (Sociology)
