Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Protocol

Version 8.5

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University of Washington

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Study Investigators

Principal investigator

Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of Washington

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Dr. Chung is the PI and will directly lead the planning, implementation, and analysis of the study. He will meet weekly with the study team, direct the study, and guide the study coordinator. He will check progress on enrollment and follow-up with the study coordinator and study doctor. In addition, Dr. Chung will serve as the point person to explain the study and share data results with others and report adverse effects associated with the study. The University of Washington will provide administrative, laboratory and data support to this project.

Co-investigators

Nelly Mugo, MBChB, MMed, MPH, Gynaecologist, Department of Obstetrics and Gynecology, Kenyatta National Hospital

P.O. Box 19676, University of Nairobi, Nairobi, Kenya

Phone: 271-4159

Dr. Mugo is a Co-investigator of the study and will assist Dr. Chung in the study's planning and implementation. As a gynaecologist, she will ensure that the study medical staff will provide excellent care and maintain high clinical standards. She will oversee the gynecological care and proper medical procedures by meeting regularly with the study doctor

and nurses. Dr. Mugo will be involved in any gynecological complications related to the study.

Samah Rafie Sakir, MBChB, Medical Director, Coptic Hospital of Kenya
Ngong Road, Nairobi, Kenya
Phone: 0733-392807
As Medical Director of the Coptic Hospital, Dr. Sakir will work with Drs. Chung and Mugo to implement the study at the Coptic Hope Center for Infectious Diseases. He and the Coptic Hospital will provide the clinical infrastructure where HIV patients will be enrolled and followed in the study. Dr. Sakir will manage the health care workers at the Hope Center and ensure that clinical data that is collected from the Hope Center and shared with the study is accurate and timely.

Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington
325 Ninth Avenue, Box 359909, Seattle, WA 98104 U.S.A.
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Dr. John-Stewart will lend her epidemiology expertise to the analysis of the study. She has significant experience in conducting and examining randomized clinical trials in Kenya. Dr. John-Stewart will help analyze the data, prepare any manuscripts, and give feedback on implementation of the trial.

Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington
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Dr. Richardson will contribute statistical support to the study and will be deeply involved in statistical analysis of its findings. She will prepare the method to randomize subjects and will analyze results of the study.

Dr. Hugo De Vuyst, MD, PhD, epidemiologist, Infections and Cancer Epidemiology, International Agency for Research on Cancer (IARC-WHO).

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Dr. De Vuyst will contribute his expertise and epidemiological skills in issues of cervical cancer screening, HPV and HIV in developing countries. He will help analyze the data and its association with HPV results.

Silvia Franceschi, MD, Epidemiologist, Head of Infections and Cancer Epidemiology Group, IARC-WHO

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Dr. Franceschi will contribute her extensive epidemiological expertise in the field of cervical cancer, HPV and HIV.

Martin Steinau, PhD, Team Lead HPV DNA, Chronic Viral Diseases Branch (CVDB), Division of High-Consequence Pathogens and Pathology (DHCPP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) 1600 Clifton Road, MS G41, Atlanta, GA 30329-4027

Tel: +1-404-639-0561

Dr. Steinau will coordinate the HPV-related study activities and data-analysis. He will contribute his expertise and epidemiological skills in issues of cervical cancer screening, HPV and HIV in developing countries. He will oversee the testing of HPV samples at CDC, ensure quality control, and help analyze the data and its association with HPV results.

Elizabeth R. Unger, PhD, MD, Chief CVDB, DHCPP, NCEZID, CDC
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Dr. Unger will contribute her expertise in the field of cervical cancer, HPV and HIV. She will supervise and manage the laboratory where the HPV sample testing will occur and help analyze the results of the study.

Nelly Yatich, DrPH, MPH, Clinical Assistant Professor, Department of Global Health, University of Washington
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Dr. Yatich will work closely with Drs. Chung and Mugo to implement the study at the Coptic Hope Center. She will provide mentorship to the research team at weekly meetings, provide mentorship to the Data Manager in data analysis, and guide the study coordinator. She will provide other on the ground support as needed.

Dara A. Lehman, MHS, PhD, Staff Scientist, Human Biology, Fred Hutchinson Cancer Research CenterAffiliate Assistant Professor, Department of Global Health, University of Washington

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Dr. Lehman will lead efforts to quantify the HIV-1 RNAlevels of cervical and plasma samples collectd from subjects enrolled in the study comparing cervical cancer treatments in HIV-positive women.

Summary and Objectives

The recent scale-up of antiretroviral treatment programs in resource-limited settings provides an unprecedented opportunity to implement a comprehensive cervical cancer screening and treatment program for women who, by virtue of having HIV, are at significant risk for cervical disease. Unfortunately, even if screening is offered free of charge to millions of women living with HIV, it is unclear which treatment modalityfor pre-cancerous cervical lesions will be most effective since HIV appears to affect outcomes of treatment by increasing the recurrence and severity of cervical disease. Cervical treatment may also increase shedding of HIV from the cervix which may put discordant couples at risk and possibly spread HIV more widely. This study proposes to randomize HIV-positive women with cervical intraepithelial neoplasia grade 2 and 3 (CIN 2 and 3) to cryotherapy vs. loop electrosurgical excision procedure (LEEP) and measure the recurrence of cervical disease in each group over 2-years of follow-up as well as HIV shedding from the cervix for 3 weeks after treatment.

Our hypothesis is that compared to cryotherapy, LEEP is significantly more likely to prevent recurrence of cervical lesions over 2 years of follow-up and less likely to cause shedding of HIV-1 from the cervix over 3 weeks of follow-up.

The objectives of this study are:

1. To compare the rate of recurrence of cervical intraepithelial neoplasia among HIV-positive women receiving cryotherapy versus LEEP over 2 years of follow-up
2. To compare the shedding of HIV-1 from the cervix between HIV-positive women receiving cryotherapy versus LEEP over 3 weeks of follow-up

Background

The introduction of antiretroviral medications on a large-scale in resource-limited settings through funding from agencies such as the President's Emergency Plan for AIDS Relief (PEPFAR) has decreased the number of HIV-positive women dying from AIDS. As a result, many HIV-positive women are leading longer, healthier lives. However, despite immune reconstitution many are still at risk for diseases related to their HIV infection including cervical cancer.[1] Cervical cancer is the leading cause of cancer death among women in resource-limited settings, and HIV-positive women are more likely to be infected with human papillomavirus (HPV), the primary cause of cervical cancer, and progress to invasive, life-threatening disease than those who are HIV-negative.[2-6] Thus, although many women may be saved by antiretroviral therapy through PEPFAR support, they may later die of a disease that could have been detected and prevented at the same facilities where they received their antiretroviral treatment.[7]

The importance of adequate cervical cancer screening among HIV-positive women is being recognized by the Kenya PEPFAR program, Office of the Global AIDS Coordinator (OGAC), and other clinics around the world which are treating HIV-positive women.[8] While there is a body of published knowledge on the screening and treatment of women in resource-limited settings, very little has been studied on the relevance of these findings on HIV-positive women.[9, 10] For example, it has been suggested that visual inspection with acetic acid (VIA) along with cryotherapy be recommended as a "screen and treat" approach on the same day for women located in resource-limited settings.[11, 12] The benefits are obvious; VIA is simpler to administer than a Papanicolaou test (Pap smear), does not require laboratory support, and is up to 20 times less expensive. Similarly, cryotherapy, a low technology treatment option, can be offered on the same day as VIA decreasing loss-to-

follow-up due to referral and waiting times, and is cheaper and easier to administer than LEEP. As a result, some HIV treatment programs in resource-limited settings are beginning to utilize this approach for their female patients. As PEPFAR begins to consider supporting cervical cancer screening among HIV-positive women enrolled in its programs, it will be essential that decisions are grounded in scientific evidence since any approach may have tremendous consequences on morbidity, mortality, and transmission of HIV-1.[13]

The issue is that there is no evidence that a "screen and treat" approach is as effective among HIV-positive women as it appears to be among HIV-negative women. In fact, there is data to suggest that this approach may be problematic. In HIV-negative women, VIA appears to be more sensitive but less specific compared to Pap smear.[9, 14] HIV-infected women have a higher prevalence of aggressive cervical disease and are more likely to experience recurrent HPV and genital infections.[5, 15] The presence of florid disease may alter the sensitivity and specificity of VIA in the presence of HIV disease, making it more sensitive but less specific than Pap smear. VIA may therefore detect more cervical abnormalities in HIV-infected women that are not truly cancerous. Coupled with cryotherapy, this may result in many HIV-positive women receiving unnecessary treatments that inflame the cervix and cause it to shed increased levels of HIV virus.[16] Increasing cervical shedding of HIV after cryotherapy may increase HIV transmission and infectivity in a manner analogous to male circumcision which appears to increase the risk of female partners acquiring the disease.[17]

The standard of care for screening and treatment in the US, according to the American Society for Colposcopy and Cervical Pathology (ASCCP), is based on Pap smears and excisional (cold-knife conization, loop electrosurgical excision procedures, laser conization, and electrosurgical needle conization) or ablative treatments (cryotherapy, laser ablation, electrofulguration, or cold coagulation).[18] Women who are found to have high-

grade lesions on cytology may either have their lesion treated right away with LEEP or have a colposcopy-directed biopsy. If the woman has a biopsy and the histology results show a CIN 2 or 3 and the colposcopy is satisfactory, treatment may be undertaken with either ablative or excisional therapy. If colposcopy is unsatisfactory or the CIN 2/3 is recurrent, treatment should be a diagnostic excisional procedure, which is an excisional procedure followed by a pathological examination of the sample tissue.

According to the Kenyan Ministry of Health, cervical cancer screening and treatment practices include VIA and cryotherapy at the district level health centers and below, and Pap smears with follow-up colposcopy with biopsy and LEEP at tertiary and provincial level hospitals.[19] In our study, participants will be screened using Pap smear with confirmatory histology and treated with cryotherapy or LEEP. Our screening and treatment methods are consistent with standards of care set at Kenyan tertiary and provincial level facilities. As mentioned above, one of the reasons to study cryotherapy and LEEP is to understand how to refer HIV-positive women for cervical treatment within the Kenyan government health system. The reason we are utilizing cytology and histology as a screening method is the lack of evidence confirming the sensitivity and specificity of VIA among HIV-positive women. Given that the outcome of measurement in this study is recurrence of CIN, it is considered scientifically necessary and within Kenyan standards of care to use these accurate, evidence-based tests.

In terms of risk of serious complication, cryotherapy and LEEP are quite safe. In a study from Zambia, Pfaendler, et al. found that the overall complication rate of LEEP to be 3.7%, all of which was managed on-site in the clinic.[20] Likewise, in a study of cryotherapy in India, the overall complication rate was found to be 3.0%.[21] In a large study from Peru that followed 1,398 women, who underwent cryotherapy for a mean of 12 months, no serious complications, including pelvic inflammatory disease, severe cramps or bleeding, or

anaphylactic reactions, were found.[22] In a comparison study between cryotherapy and LEEP, cryotherapy was found to have a 2% complication rate and LEEP, an 8% complication rate, and the difference was not significant.[23]

There has been some controversy surrounding cervical treatment and whether or not it is associated with adverse pregnancy outcomes. Sadler et al. showed in their retrospective analysis of 652 women that had undergone LEEP, laser ablation or laser conization that LEEP did not increase the incidence of preterm delivery.[24] However, the authors did note a significant increase in premature rupture of membranes. Acharya et al., in their matched cohort of 428 women undergoing LEEP, also found no correlation between the procedure and premature delivery or low birth weight, but they did find a significantly higher number of women with pregnancy complications, which included premature contractions, infections and cervical incompetence.[25]

Finally, there is evidence that cryotherapy may be less effective compared to LEEP in preventing the recurrence of cervical intraepithelial neoplasia though the literature is equivocal. Overall, there have been few studies comparing the efficacy in treatment between cryotherapy and LEEP, especially in HIV-infected women. Chirenje et al. found a significant difference in the failure rate of cryotherapy versus LEEP, however his numbers were small with only 6 high-grade recurrences in the cryotherapy arm (14.3%) and 2 in the LEEP arm (4%).[26] Moreover, neither HIV nor HPV shedding was measured and follow-up time was only one year. In another randomized study comparing cryotherapy and LEEP, this time a larger study in non-HIV-infected women, no significant difference was found between the two arms in terms of failure, defined as either recurrence or persistance.[23] Additionally, in a 2000 Cochrane review, it was stated that "evidence suggests that there is no obviously superior surgical technique for treating cervical intra-epithelial neoplasia."[27]

If cryotherapy is found to result in a greater number of failures, it may require more frequent and careful follow-up screening than LEEP, and therefore may not be as cost-effective or therapeutic for the patient. As a result, the individual and public health risks of a "screen and treat" approach for cervical cancer screening and treatment among HIV-positive women may be much greater than its benefits.

Rationale

The University of Washington (UW) in collaboration with the Coptic Hope Center for Infectious Diseases has been providing cervical cancer screening to its female HIV positive patients in Kenya since 2006. The UW/Coptic Hope Center has enrolled over 8,000 HIV-positive women in its two Nairobi sites and offers a robust patient population for cervical screening. The UW/Coptic Hope Center has already screened over 2,000 HIV-positive women for cervical cancer using both Pap smear and VIA, and has worked in partnership with Kenyatta National Hospital (KNH) to provide LEEP to those with detectable lesions. Most recently, the collaboration has received a grant from the Puget Sound Partners for Global Health to compare VIA versus Pap smear among women enrolled at the Hope Center and to examine HIV-1 cervical shedding in a small subset who receive cryotherapy. Unfortunately, funding is only available for one year and will not allow any comparison with LEEP or a study of cervical disease recurrence after intervention.

Kenya is an appropriate site to conduct this study due to a high incidence of cervical cancer and lack of cervical screening coverage. The incidence of cervical cancer in Kenya is much higher compared to the West and measures between 43 and 45 cases per 100,000 compared to 8.4/100,000 in the USA.[28, 29] Of 3,902 women who presented to KNH with reproductive tract malignancies between 1989 and 1998, 85% had invasive cervical cancer.[28] In a sampling of 1,353 patients at the same institution in Kenya, only 22% reported having received a previous Pap smear.[30] Although the government of Kenya has advocated the use of VIA as a primary method to screen for cervical cancer, no specific recommendations are made concerning HIV-positive patients. Cervical cancer screening for HIV-positive women in Kenya should be a high priority since HIV-infected women in Kenya with invasive cervical cancer are 10 years younger than HIV-negative women at initial presentation.[6, 31]

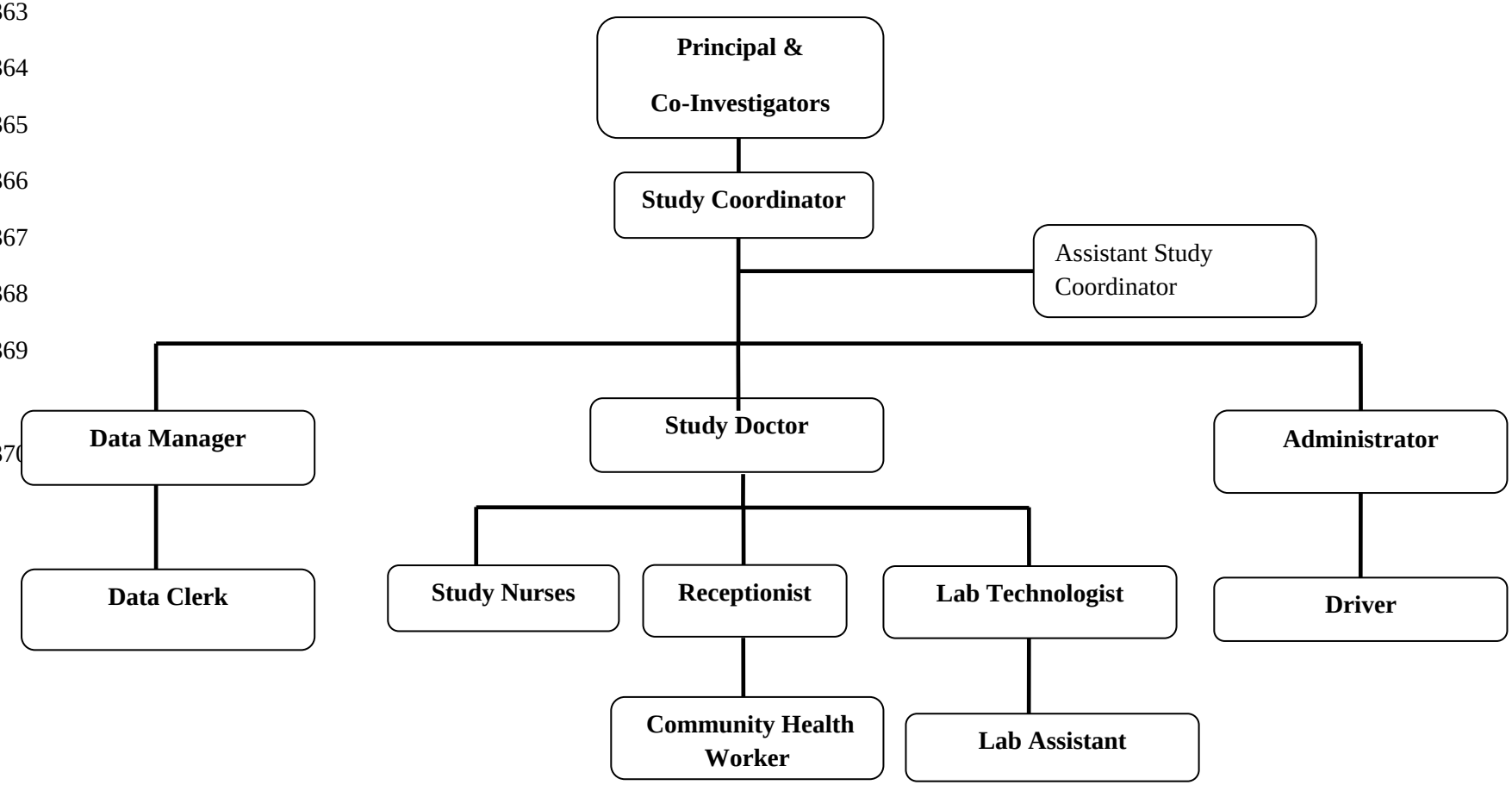
Based on the high incidence of cervical cancer in Kenya and building upon our programmatic and research work in cervical cancer screening among HIV-positive women, we propose to study the effect of LEEP versus cryotherapy on the recurrence of cervical intraepithelial neoplasia and the shedding of HIV-1 from the cervix. Our hypothesis is that compared to cryotherapy, LEEP is significantly more likely to prevent recurrence of cervical lesions over 2 years of follow-up and less likely to shed HIV-1 from the cervix over 6-weeks of follow-up. This evaluation will inform PEPFAR policies on the best method to treat pre-cancerous lesions in HIV-positive women and elucidate the importance of cervical treatment interventions according to immune status and antiretroviral therapy. Such information is directly relevant to the care of HIV-positive women in Kenya and other resource-limited countries which are significantly impacted by cervical cancer.

Timeline and Dissemination

The duration of the evaluation activity is approximately6years from the beginning of the funding cycle. It is estimated that it will take at least 3 years to screen at least 2,400 women and randomize approximately 400 women with high grade intraepithelial lesions to LEEP vs. cryotherapy. These randomized participants will be followed for 2 years after screening or randomization. Including preparation and analysis, it is expected that it will take approximately 6years to complete this study.

Results of the study will be shared directly with the USG/GOK technical teams through annual reports and regular e-mail contact with designated contacts at the CDC in Atlanta and Nairobi. Reports will include analysis from regular DSMB meetings. After initiation of the study, we will confer with the CDC on whom to report to in Kenya and Atlanta. At that time, we will also determine how frequently the USG/GOK technical teams would like to be appraised of the study and its results. At a minimum, we will seek to be in phone and/or e-mail contact with USG contacts quarterly to ensure that the study and its data is relevant to USG technical working groups and policies established around cervical cancer screening in PEPFAR-supported clinics. Dissemination of study findings will also occur through public presentations and publication in internationally recognized journals. CDC and USG staff/agents will not participate in the study as co-investigators or study collaborators. They will not participate directly in the study development, analysis, or manuscript preparation.

Cervical Screening Organogram



Personnel

Study Coordinator

- Manage directly the Study Monitor, Data Manager, Study Doctor, Administrator, and Lab technologist around aspects of the PHE cervical treatment study and R01 resistance study
- Monitor the progress of research activities and ensure the smooth and efficient day-to-day operation of research and data collection activities
- Initiate and coordinate activities that improve the conduct and performance of the study
- Conduct weekly clinic meetings that are led by Study Doctor with study staff
- Conduct weekly data meetings that are led by the Data Manager to ensure data is collected in a timely fashion, is cleaned, and clearly analyzed
- Conduct and lead weekly study-related administrative meetings
- Directand be responsible for the study budget and petty cash that is managed by the administrator
- Act as the primary administrative point of contact for research staff and as the principle operational liaison for Coptic administration and regulatory bodies
- Analyze recruitment rates, determine if rates match expectations, and implement plans that will promote recruitment
- Analyze retention rates and implement plans that will promote retention
- Supervise and coordinate the provision of support services to investigators
- Prepare periodic and ad hoc reports as required by investigators, funding agency, and/or regulatory bodies

- Be responsible for renewing, updating and modifying IRB applications at UW and KNH that are associated with this study
- Be responsible for generating Adverse Events, protocol violations and deviations, and unanticipated problems reports
- Be responsible for liaising with the DMSB as needed
- Perform any other duties and responsibilities that may be given by the PI or co-investigator

Assistant Study Coordinator

- Assist the Study Coordinator in monitoring the progress of research activities and ensuring the smooth and efficient day-to-day operation of research and data collection activities
- Implement and be responsible for renewing, updating, and modifying existing standard operating procedures (SOPs) and develop new ones as needed
- Be responsible to ensure that all staff are following SOPs
- Implement quality control procedures throughout the conduct of the study
- Review the accuracy, completeness and timeliness of completed study related records, case report forms and other documents
- Compare reported data with original source documents
- Review study related processes relative to applicable regulatory requirements, including GCP and Human Subjects Protection regulations
- Verify the following items for the study: protocol compliance (i.e. subject recruitment and eligibility criteria, informed consent and randomization procedures); that only designated

investigator(s) and/or appropriate research staff are performing study functions; that regulatory compliance is being maintained (i.e. that investigators are providing and maintaining all study related documents as required.)Be responsible for study compliance with all regulations

- Communicate any serious deficiencies noted during monitoring to the Study Coordinator
- Ensure that a record of all correspondence, monitoring reports and other written documentations are maintained by the Administrator
- Participate in all study meetings
- Organize and coordinate all training activities
- Respond to and be responsible for implementing all matters that may arise from CDC and Study Monitor visits
- Perform any other duties and responsibilities that may be given by the Study Coordinator
-

Study Doctor

- Oversee and ensure that patients in the study are receiving good medical HIV care and inform the study coordinator of any complications
- Identify subjects that require medical attention and refer them for care at the Hope Center
- Draw blood or obtain specimens from patients if the lab assistant or lab technologist is unable or unavailable
- Oversee the cervical screening clinic and ensure it is well-stocked with necessary medical supplies and equipment to perform the study

- Meet with the data clerk or data manager to correct data entry errors
- Review and confirm eligibility of each patient for study
- Administer questionnaires
- Conduct gynecological examinations, HIV and HPV swabs, colposcopy, biopsies, and cryotherapy and LEEP
- Assist the study nurses in performing their duties if they are unable or unavailable
- Confer and communicate with Hope Center clinicians and medical staff if any questions or problems arise concerning medically related issues
- Work closely with clinic staff at the Hope Center to ensure high recruitment for research study
- Work with data manager and receptionist to analyze data and prepare reports
- Present weekly summaries along with the study nurse and receptionist marking progress in enrollment and tracking of subjects in the study
- Will be responsible for reporting adverse effects to the principal investigator and co-investigators
- Perform any other duties and responsibilities that may be given by the principal investigator or the study coordinator

Study Nurses

- Conduct gynecological examinations, HPV swabs, and Pap smears

- Check age, previous cervical screenings and gynecological history before enrollment into the program
- Provide adequate knowledge and education about the study to patients so they can sign an Informed Consent
- Administer the Informed Consent and store it safely
- Administer questionnaires
- Review and confirm eligibility of each patient for research study
- Assist the study doctor in any medical procedures
- Attend weekly clinic meetings
- Maintain, and in the absence of the community health worker, clean and organize the cervical screening clinic
- Transport equipment and supplies for cleaning and autoclaving
- Meet with the data clerk or data manager to correct data entry errors
- Draw blood or obtain specimens from patients if the lab assistant or lab technologist is unable or unavailable
- Perform any other duties and responsibilities that may be given by the study coordinator or study doctor

Administrator

- Manage petty cash and study budget
- Liaise with payroll administrators to ensure salaries are paid correctly and on time

- Make purchases, photocopy data collection tools, and keep inventories of supplies
- Maintain communication between the clinic and office
- Attend and take minutes at weekly administrative and clinic meetings and present them at the next meeting
- Reconcile receipts to send to Seattle
- Communicate with Seattle when more funds are needed
- Manage the driver and arrange transportation
- Arrange for study trainings in coordination with study coordinator
- Maintain and organize files of personnel, correspondence, applications, IRB records, receipts, budget, inventories, etc…
- Coordinate staff evaluation procedures
- Oversee and record the attendance of office and clinic staff in coordination with the study nurse
- Make monthly reports of project expenses
- Facilitate in renewing personnel medical insurance and liaise between insurance and the hospital of matters of personnel appointment
- Make weekly reports of administrative issues
- Prepare IRB and government applications for the shipment of samples
- Remind study coordinator when IRB renewals are due and work with study coordinator and principal investigator to submit, modify, and renew IRB applications
- Ensure office tidiness

- Perform any other duties and responsibilities that may be given by the principal investigator or study coordinator

Receptionist

- Follow subjects enrolled in the study and ensure they are retained in the study and proper follow-up is done both at the research clinic and the Hope clinic

- Keep track of all the patients enrolled and determine if any patient has missed appointment and take action to report and bring these patients back under care and supervision

- Handle money given by the administrator and account for it by keeping the various logs (i.e. calling log, transport log and client transport reimbursement forms) and meet weekly with the administrator for reconciliation

- Track Excel spreadsheet of patient appointments, recruitment, and follow-up in the study clinic

- Develop report of clinic flow weekly for study clinic meetings
- Present weekly summaries marking progress in enrollment and tracking of subjects in the study in coordination with the study doctor

- Will work with the study doctor, lab assistant, and community health worker to follow-up subjects by phone and home visits

- Perform any other duties and responsibilities that may be given by the principal investigator or study coordinator

Data Manager

- Oversee the work of the data clerk as below and assume any of the duties of the clerk that may be required due to his absence or inability to perform
- Manage the data clerk
- Contribute to the design and modification of protocols, which define what and when data are to be collected
- Design and approve forms on which data are collected
- Be responsible for data collection forms and informed consents (both old and new) that are used in the study
- Manage data information entered by the data clerk on study patients with Hope Center
- Ensure that patient study files are properly filled, documented, and stored
- Manage data backup on weekly basis
- Coordinate the transfer of data with the Coptic Hope data manager to the research databases with the data clerk
- Desingan SPSS database and manage both the SPSS and Access databases for the study
- Ensure the databases meet requirements for the entry and reporting of clinical data
- Maintain daily, weekly, and monthly work schedules for the data office with the data clerk and ensure their completion
- Check for errors in the data, correct the errors, and maintain cleanliness of the data
- Check and manage the data log book of errors produced by the data clerk
- Coordinate the data-checking process and produce a monthly report on the data quality

- Thoroughly clean the data every 3 months to ensure cleansing of errors
- Sort out any data entry or error problems weekly with the study doctor and study coordinator
- Run frequencies and range checks to identify extreme values monthly
- Present weekly and monthly reports of data analysis
- Assist the study doctor and receptionist in the presentation of weekly summaries marking progress in enrollment and tracking of subjects in the study
- Assist the receptionist and study doctor in the preparation of monthly summary tables on number of women enrolled in each study arm and to consolidate the weekly reports
- Prepare laboratory shipping lists with the lab technologist
- Be responsible for maintaining the security of the data
- Generate study ID numbers
- Be responsible for linking and de-linking data
- Train clinical research staff to help improve the quality of the data being collected
- Assist in standardizing data management procedures such as documentation for study operating procedures
- Develop and maintain documentation and data management guidelines
- Perform other duties that may be given by the principle investigator or study coordinator

Data Clerk

- Enter questionnaire data and laboratory testing information into a computer database

- Scan, verify, and check data in Teleform
- Prepare new patient files and ensure all files contain the required questionnaires
- Maintain Access, Excel, and SPSS computer databases for the study
- Maintain daily, weekly, and monthly work schedules and ensure their completion
- Conduct weekly data quality checks with guidance from the data manager
- Check for errors in the data, correct the errors, and maintain cleanliness of the data
- Inform the data manager and study coordinator and of any data entry problems on a weekly basis
- Keep a data log book of data entry queries and inconsistencies
- Back-up all data weekly (Friday)
- Back-up all data to an off-site disk weekly (Friday)
- Coordinate the timely movement of questionnaires, data forms, and information between the Hope Center, the Coptic research wing, and the KNH data office
- Ensure that the computers, printers and scanner are in good order and free from viruses
- Perform any other duties that may be given by the data manager, study coordinator, and principal investigator

Lab Technologist

- Oversee the work of the lab assistant as below and assume any of the duties of the lab assistant that may be required due to his absence or inability to perform
- Manage the lab assistant

- Ensure enrolled patients have their blood samples and/or other specimens collected at all visits according the study schedule
- Ensure equipment and supplies are available, working, and well maintained
- Ensure the lab is maintaining good laboratory practices
- Maintain and manage the inventory of laboratory supplies and equipment
- Collect laboratory specimens (including blood) from study participants if the lab assistant is absent or unable to perform
- Keep track of laboratory specimens by updating and maintaining the lab database
- Prepare for the shipment of lab specimens (HIV and HPV)
- Prepare media for collection of samples
- Be responsible for maintaining appropriate freezer temperature
- Monitor freezer temperature by keeping an accurate temperature chart if lab assistant is unavailable
- Be responsible for and enact proper emergency procedures if the freezer is not functioning
- Oversee and manage collection and storage of the following specimens: urine for pregnancy, HPV swab, HIV swab/CVL, Pap smear, and biopsy specimens
- Coordinate the delivery of lab specimens (Pap smear and biopsy) and collection of results with the pathologist
- Coordinate collection, delivery, and recording of CD4 counts

- Track specimens and results in lab book
- Perform other duties that may be given by the study coordinator or principal investigator

Laboratory Assistant

- Collect laboratory specimens (including urine and blood) from study participants
- Track CD4 results from the medical records office and update the CD4 results log in coordination with clinic lab tech, clinic data manager, and study senior data analyst
- Ensure timely transportation of questionnaires and research files between Coptic and KNH offices
- Assist the lab tech in the collection and storage of the following specimens: urine for pregnancy, HPV swab, HIV swab, Pap smear, and biopsy specimens
- Assist the lab tech in the delivery of lab specimens (Pap smear and biopsy) and collection of results with the pathologist
- Track specimens and results in lab book
- Assist the lab tech in the delivery of specimens and collection of results
- Assist the lab tech in the processing and freezing of samples
- Monitor freezer temperature by keeping an accurate temperature chart and inform the lab technologist and study coordinator if there is a failure
- Remove frost and clean the freezer
- Record and present minutes at clinic research meetings if the administrator is not available

- Clean and help organize study clinic
- Assist the receptionist in following subjects enrolled in the study and ensure they are retained in the study and proper follow-up is done both at the research clinic and the Hope clinic
- Assist the receptionist in keeping track of all the patients enrolled and determine if any patient has missed appointment and take action to report and bring these patients back under care and supervision
- Ensure completed questionnaires are delivered to the data clerk within 24 hrs
- Will perform home visits as necessary in coordination with the receptionist and study doctor
- Will help phone subjects for follow-up in coordination with the receptionist and study doctor
- Perform other duties that may be given by the laboratory technologist, study coordinator, or principal investigator

Community Health Worker

- Accompany clients for possible enrollment from the Hope Center to the cervical screening clinic or study lab for urine testing
- Accompany clients between the study lab, Coptic lab, and the cervical screening clinic
- Help clients schedule appointments at the Hope Center
- Clean and help organize study clinic

- Will perform home visits as necessary in coordination with the receptionist and study doctor
- Will help phone subjects for follow-up in coordination with the receptionist and study doctor
- Perform duties given by receptionist or study coordinator

Driver

- Transport specimens and data files
- Assist the administrator in purchase of supplies and equipment
- Maintain car and ensure it is running well and has fuel
- Perform duties given by administrator or principal investigator
- Pick supplies from the office to the clinic

Study Population & Recruitment

The study will be a prospective randomized clinical trial enrolling HIV-positive women who receive care at the Coptic Hope Center for Infectious Diseases in Nairobi, Kenya. The study clinic will screenat least 2,400 HIV-positive women from the Coptic Hope Center for cervical cancer and, of whom, approximately 400 will be enrolled and randomized to receive treatment.

It is estimated that at least 2,400 women will need to be screened in order to identify 400 women with high-grade intraepithelial lesions. This is based on a prospective analysis of 500 HIV-positive women who underwent Pap smear screening at the Hope Center between July and November 2009. In this analysis, 187 (37%) women had normal cytological results, 292 (59%) had abnormal cytological results, and 21 (4%) had results which were indeterminate due to inflammation, inadequate sample collection, or insufficient data. Abnormal cytological results included 77 women (15%) with atypical squamous cells of undetermined significance (ASCUS), 121 (24%) low-grade squamous intraepithelial lesions (LSIL), and 92 (18%) high-grade squamous intraepithelial lesions (HSIL).

Adult HIV-positive women receiving care at the Coptic Hope Center who are not pregnant by clinical examination or history, have an intact cervix, have not received prior cervical treatment, do not have a history of a bleeding disorder, do not have any known allergy to study medications OR their alternatives, have initiated sexual intercourseand are above 18 years of age will be informed of the study by non-study clinicians and health care workers. Subjects will be excluded by the study at initial cervical cancer screening if they are HIV-negative, male, below 18 years of age, pregnant by clinical examination or history, post-hysterectomy, post-cervical cancer treatment or have known allergies to study medications.

Potential participants will be identified by Hope Center clinical officers seeing patients as part of routine HIV medical care at the Hope Center. Clinical officers will use "Pre-Screening Talking Points" to inform patients about the study. If subjects are interested then they will be directed to the study clinic in a physically separate room staffed by study personnel. We will also use recruitment leaflets that will be distributed at the Hope Center Reception. The leaflets will have the contact information of the study staff. At the study clinic, a study staff member will inform potential subjects of the study using "Screening Talking Points". If subjects remain interested and are eligible then they will be enrolled (see Study Flow I). An appointment calendar will be kept by the study receptionist on an MS Access database to track who has attended the clinic and received screening.

Interested women will be referred to the study clinic (Room A) which will be staffed by two study nurses trained to perform Pap smears on the same day after obtaining informed consent for screening. Women who enrolled in the screening portion of the study and obtained a Pap smear will be asked to return to the study clinic (Room A) for results 2 weeks later. If Pap result is positive for HSIL, the subject will be referred to a separate room (Room B) where a study doctor and a study nurse will obtain a biopsy to confirm CIN 2 and 3 by histology. From this point, the subject will return to Room B and see the study doctor and nurse for further follow-up. Four to sixweeks after biopsy, the subject will return for her results and to discuss treatment options. At this point, study staff will obtain informed consent for randomization and follow-up, and the study doctor will randomize histology-confirmed subjects (approximately 400 women) to LEEP or cryotherapy. Criteria for being ineligible for cryotherapy include if a polyp or anatomic defect prevents access to the cervix and/or if the lesion size is >75% of the cervix or is larger than the cryoprobe tip, or if the lesion is not visible in its entire extend or extends more than 2 to 3 mm into the endocervical canal. If any of these subjects are diagnosed with severe cervical disease confirmed by

histology at these later screening time points, they will be offered LEEP by the study or referred for appropriate care.

Patients who require further care for cervical disease unavailable at the study clinic (eg. hysterectomy) or who decline to enroll in the treatment portion of the study will be referred to KNH. Through patient tracing the study doctor and staff connected to the KNH gynecology department will make best efforts to assure that patients receive proper care. Referral notes and copies of results for histopathology, cytopathology, CD4 count, and HIV viral load will be sent with the patient during referral. All study specific documentation including study numbers and title will be removed. Only the subject's name and age, as is relevant to the referral, will be on the documents sent for clinical care at KNH or Coptic Hospital. Subjects will receive government subsidized care at these sites but the study will not pay for these interventions or treatment.

Study clinic visits will be conducted separately from regular medical visits a patient may make at the Hope Center. Subjects will continue to follow-up with their doctors at the Hope Center, schedule their visits through the Hope receptionist, and pick up their medications at the clinic. However, study clinic visits will be conducted by staff employed by the study in physically separate locations from routine medical visits. Study appointments will not conflict with the HIV clinical care that patients receive through coordination between the study receptionist and the clinic receptionist. Study doctors will not provide HIV care or treatment, and subjects will remain enrolled as patients at the Hope Center and receive the same care as prior to enrollment. Before lab tests for the study are performed, confirmation from the subject (and if necessary, the laboratory) will be made to assure no tests, such as Pap smears ordered as standard of care or blood draws, are unnecessarily repeated.

Medical information collected by clinic staff at the Hope Center will be made available to the study team after written informed consent by the subject. This will contain all information collected at the Hope Center including laboratory data. Only clinic staff will collect medical information from subjects related to the management of their HIV disease. Study data for the PHE will be collected on separate forms and scanned, cleaned, and analyzed at a location unassociated with the clinic and its medical records. Only study staff will collect study data on forms described in this protocol. If institutional IRBs approve, we will make study data available to the clinic staff at the Hope Center after written informed consent is signed by the subject. As soon as a participant's results become available, the study staff will enter the results in a form that is stored in the participant's Hope Fileas a means of communicating the results to the participant's clinicians. This will be done in coordination with the medical records department at the Hope Center. If clinical information is discovered about a subject that needs immediate attention, clinical staff will be available on site at all times to assist in care of the patient and will be informed by the study staff.In the event that a participant needs emergency care, the study clinical staff will be prepared to stabilize patients and emergency services are available at Coptic Hospital 24 hours a day. Moreover, clinical care is available at KNH at any time if needed or preferred by the patient. Participants will be given careful instruction as to which symptoms would necessitate them seeking additional medical care, especially after receiving treatment. The participant will receive contact information of study staff whom they should contact in case of an emergency or if they need guidance as to how to manage a certain symptom or condition. Study staff can share pertinent information with clinic staff in these situations by phone or in person as the study clinic is located on the hospital grounds.

Participants will be consented for screening by study staff at their enrollment visit and for randomization and follow-up at their biopsy result visit.If an

exitedsubjectbecomeseligible for re-enrollment due to re-reading of cytology results (See QA/QC section), then re-enrollment consenting will be done at the disclosure visit for the new results. All consenting study staff members will be able to describe study procedures in English, Kiswahili and possibly another local language. Other nursing and study staff are available and should be contacted in the case of a participant who presents for enrollment but is not conversant in any of the languages the consenting staff member speaks. Consent documents will be prepared in both English and Kiswahili at a basic reading level. The English version will be used by study staff to produce the Kiswahili version and several members of the staff will review the document to assure its accuracy and readability.

Participants will be encouraged to ask questions at any point during the consent process and will be given a copy of the document to review on their own. If a participant has a question that cannot be answered by the consenting staff member, other study staff will be available for consultation. The patient may also contact other study staff at her convenience. The participant may also interrupt the consent process at any time if she needs more time to consider her participation.

Subjects with initial Pap smear results that areNormal or ASC-USwill be exited from thestudy after receiving their Pap smear results. Subjects with LSIL Pap smear results will be offered Colposcopy. According to the 2012 ASCCP guidelines, participants found with LSIL in the absence of HPV co-testing should be recommended colposcopic evaluation and biopsy. These biopsy histology results will be treated the same as other study histology, including possible treatment randomization for CIN 2/3 and CIS. This will enable researchers to monitor lesions which may escalate from low-grade to high-grade in subjects who may be eligible for subsequent randomization. Results from repeat Pap-smears will be treated the same as results from initial Pap smears: Women with Normal/ASC-US results will be exited from the study. Subjects with HSIL/ASC-H/HSIL-invasion-not-ruled-out and results

suggestive of cervical carcinoma (i.e. high grade intra-epithelial lesions) will undergo colposcopy with biopsy, and may potentially be eligible for randomization upon confirmed histology results. If a subject with high grade intraepithelial lesions detected on study-related Pap smears is later found to have normal or ASCUS on a follow up Pap smear (study related or not) that occurs prior to or in lieu of a colposcopic evaluation, the subject will still be required to have a study related colposcopy and biopsy.

Subjects who have biopsy-confirmed CIN 2, 3 or CIS will be eligible for the randomization and treatment portion of the study. They will be presented with the consent information upon receipt of biopsy result. Subjects with biopsy results suggestive of cervical carcinoma will be exited from the study and referred for further evaluation and management at KNH. Subjects with CIN I biopsy results will be asked to return to the clinic for repeat Pap smear in 6 months and will remain in the study.If a subject receives three consecutive CIN1histology results, she will be offered LEEP treatment by the study doctor. These participants will be treated and followed the same as other non-randomized LEEP participants.

Of note: Women with normal or with ASCUSPap smear results (that are exited from the study) will be referred for subsequent cervical screening follow-up at the Hope Center Cervical Cancer Screening Program (CCSP). This program is administered by the Coptic Hospital and is supported by the Coptic Mission, PEPFAR, and other donor funding. The CCSP offers free cervical cancer screening to HIV-positive women enrolled in the Coptic Hope Clinic. Currenttly, a single visit ‘screen-and-treat’ strategy for cervical cancer prevention and treatment will be used.The screen-and-treat method involves visual inspection of the cervix followed by treatment of precancerous lesions by cryotherapy at the same visit. Patients who cannot be treated with cryotherapyare referred to KNH for subsidized cervical

care and treatment. As all study subjects are drawn from the Coptic Hope HIV clinic, they areall eligible to be screened, treated, and followed at the CCSP.

If woman exited from her normal or ASCUS Pap smear result prefers to rescreen with the study, she may be re-enrolled using the re-enrollment consent form.

Study Procedures

1. SCREENING visit (at least 2,400 patients) (see Study Flow Diagram I, Enrollment)

- At screening, subjects who agree to participation will:
    - Sign a written informed consent
    - Answer the "Enrollment" questionnaire which will ask her sociodemographic background,sexual history, and cervical cancer screening history.
    - Complete "Address and Intake" questionnaire.
    - Undergo a physical examination including a pelvic examination with a Papanicolaou smear of the cervix. The results of the physical examination will be entered in the "Pap Smear" questionnaire
    - Women found to have evidence of an STI will undergo syndromic management according to the following algorithm:
        i. Vaginal discharge without abdominal pain
            1. Treat for vaginitis:
                a. Nystatin 1 pessary everyday x 5 days and
                b. Metronidazole 2g x 1
            2. If no improvement after 7 days, treat for cervicitis:
                a. Norfloxacin 800mg x 1 and
                b. Doxycycline 100mg BD x 7 days
        ii. Lower abdominal pain
            1. If due to surgical or gynecological causes, refer

2. If cervical motion tenderness, treat for pelvic inflammatory disease:
    a. Norfloxacin 800mg x 1 and
    b. Doxycycline 100mg BD x 7 days and
    c. Metronidazole 400mg BD x 10 days

iii. Genital ulcer disease (GUD)

1. If multiple lesions grouped together with a history of recurrence, treat for Herpes simplex genitalis:
    a. symptomatic treatment
2. If other GUD, treat empirically:
    a. Erythromycin 500mg three times per day x 7 days and
    b. Benzathine penicillin 2.4 million U IM stat

2. Two-week visit for RESULTS (at least 2,400 patients)

- Patients will return to the clinic two weeks later for Pap smearresults which will be entered on the "Colposcopy" questionnaire. We expect that an estimated 1,700 women will have results (no dysplasia or ASCUS)that do not require study biopsy/colpo procedures. These patients will be ineligible for randomization.
- Women with no dysplasia or ASCUS Pap smear results will be exited from the study. They will be followed up at the Coptic Hope Cervical Cancer Screening Program (CCSP). The Hope screening program offers free cervical screening through visual inspection with acetic acid (VIA). Women who are screened and exited from this study with normal Pap smear results will be followed up at CCSP one year after initial screening. Women who are screened and exited from this study with ASCUS Pap smear results will befollowed up at CCSP 6 months after initial screening. Women who have exited the study due to a cytologic diagnosis of no dysplasia or ASCUS will

be eligible to re-enroll in the study and obtain a study related screening pap smear, approximately 12 months after their last normal/ASCUS study related pap smear.

- Women found with unsatisfactory results will have their Pap smear repeated.
- Women with LSIL will be offered Colposcopy. According to the 2012 ASCCP guidelines, participants found with LSIL in the absence of HPV co-testing should be recommended colposcopic evaluation and biopsy.
- Any patient who receives a cytological diagnosis of high-grade intraepithelial lesion (HSILand ASC-H, and HSIL-invasion-not-ruled-out or SCC) (~18% of the patient population or approximately 400 patients), will be recommended to undergo colposcopy as per 2012 ASCCP guidelines. If a subject with high grade intraepithelial lesions detected on study-related Pap smears is later found to have normal or ASCUS on a follow up Pap smear that occurs prior to or in lieu of a colposcopic evaluation, the subject will still be required to have a study-related colposcopy and biopsy. Prior to participating in any cervical procedure, including biopsy, women will undergo a rapid pregnancy test. Pregnant subjects will be exited from the study and followed-up in the CCSP. These women will also be referred for prevention of mother-to-child transmission (PMTCT) care at Hope Center. If the pregnancy result is negative, they will be referred to the study doctor for colposcopy-directed biopsy which will clarify the extent and severity of disease. Results of the colposcopic examination will be entered in the “Colposcopy” questionnaire (see Study Flow I).For patients who have glandular epithelium abnormalities (AGC) on Pap or squamous epithelium abnormalities without visible lesions on colposcopy, endocervical sampling with curettage will be performed in order to identify possible abnormalities in the endocervical canal.

- After undergoing abiopsy, women will be given free condoms and advised to abstain from sexual activities for at least 10 days.

3. 6-8-weekvisit for RANDOMIZATION (~400 patients) (see Study Flow II)

- Subjects who have undergone biopsy will return four to six weeks later for a follow-up visit to be giventhe results of the biopsy. Biopsy resultswill be entered in the "Treatment" questionnaire.

- Those with biopsy results that are positive for a high grade pre-cancerous lesion (CIN 2/ 3 or CIS) and if the lesion is amenable to cryotherapy or LEEP as per Kenyan national guidelines, will be eligible for randomization. If they are willing to undergo informed consent for the treatment study, they will be randomized to receive either cryotherapy or LEEP (see Study Flow II). Those who decline to participate in the treatment study will be exited and referred to KNH for treatment. Randomization questionnaire will also be completed during this visit.

- Those patients who do not have lesions which are amenable to cryotherapy due to size or access will not be randomized but will be offered free LEEP and followed up every 6 months for 2 years, the same way as randomized participants. Those who havelesions that are neither amenable to LEEP nor cryotherapy due to size or severity of disease, or anatomy does not allow proper access to the cervix, will be referred to KNH for subsidized care at this government hospital. The study will not pay for this treatment. Patients will be given follow-up appointments in the study clinic after referral to determine outcomes. They will have the option to continue to be followed at the CCSP.

- Those with CIN 1 will not be randomized or exited but will be asked to return to the study clinic after 6 months for a repeat Pap smear.

- Those who show no dyplasia on histology will be exited from the study and referred to the CCSP for further follow-up.
- It is expected that approximately 400 patients will be eligible for randomization. During randomization, a sealed envelope will be opened by the study doctor that will reveal the randomization arm that has been assigned to the study ID number. Randomization assignment will be performed on a computer by Dr. Barbra Richardson, the study statistician, in Seattle, and preparation of the envelopes will be performed by the study data manager in Nairobi in conjunction with Dr. Richardson. This is the standard used for all randomized clinical trials conducted by the University of Washington in Kenya. Study investigators and the study doctor will not have access to the randomization sequence. Study investigators and staff will not be blinded to randomization.
- Those eligible for randomization will have an HIV cervical viral level swab taken before treatment (LEEP or cryotherapy).
- After receiving LEEP or cryotherapy, women will be given free condoms and advised to abstain from sexual activities for at least 4 weeks. Women will also be offered an information sheet on the treatment procedure and abstinence information to take home for their spouse or partner. Information includes treatment given, recommended abstinence period and reasons for abstaining from sexual intercourse. These information sheets will be optional to maintain patient confidentiality and safety, especially for people who have not disclosed their status.
- Patients undergoing randomization will have the following performed:

- Blood (10mls) will be drawn to check for HIV viral load and CD4 count
- Cervix will be swabbed to assess the presence of Human Papillomavirus (HPV) prior to LEEP or cryotherapy
- Cervix will be swabbed for HIV viral level prior to LEEP or cryotherapy
- LEEP or cryotherapy performed based on randomization envelope
- Those undergoing LEEP will have the LEEP piece taken for histology
- "Randomization" questionnaire completed
- "Treatment" questionnaire completed

4. First, second, and third-week visits for cervical HIV-1 SHEDDING after treatment (~400 patients) (see Study Flow II)

- Patients who have been randomized and received treatment (approximately 400 patients)will be followed every 1 week for 3 weeks AFTER the treatment intervention to assess healing and measure HIV-1 viral shedding from the cervix. These events can be called the 7-9, 8-10, and 9-11-week visit time points and will probably coincide with the eigth, ninth, and tenth week after enrollment. However, for purposes of measuring HIV viral shedding, it is most important that these time points occur 1, 2, and 3 weeks after the treatment intervention. These terms are consistent and are used for descriptive purposes. They will return 3 times over a 3-week interval and have the following performed:
  - Blood (10mls) will be drawn to check for HIV viral load
  - Cervix will be swabbed to assess the presence of HIV-1
  - "Shedding" questionnaire completed

Shedding information will be considered valid if it is obtained ± 3 days of the scheduled visit. We will collect shedding information for the first three weeks after treatment but if a patient misses those visits but comes back within six weeks, we will still collect the samples just for comparison purposes.

5. Six, twelve, eighteen, and twenty-four months after randomization visits for RECURRENCE (approximately 400 patients) (see Study Flow II)

- After the 9-11-week visit, randomized participants and those who undergo LEEP but are not randomized because their lesions are not amenable to cryotherapy will return at 6, 12, 18, and 24 months after treatment is administered. At the 24 month visit, the subject will be exited from the study. At these 6-month interval visits, the following will be performed in order:
    - Pap smear to detect recurrence of cervical intraepithelial lesions
    - Same Pap smear swab will be used to assess the presence of Human Papillomavirus (HPV)
    - Blood (5 mls) will be drawn to check for CD4 count
    - "Pap Smear" questionnaire completed
- Pap smear results that are normal, ASCUS, will be filed in the participants file and disclosed at the next scheduled follow-up visit. If pre-cancerous lesions by cytology have recurred then patient will be contacted to return to the study clinic to undergo colposcopic directed biopsy prior to treatment. Results of the colposcopic examination will be entered in the "Colposcopy" questionnaire..
    - If histology-confirmed lesians can be treated by LEEP, then the patient will receive a free LEEP and "Treatment" questionnaire will be filled.
    - If histology-confirmed lesions are too large or cancerous for LEEP then patient will be referred to KNH for subsidized care at this government

hospital. The study will not pay for this treatment. Patients will be given follow-up appointments in the study clinic after referral to determine outcomes.

- Phone calls and home visits will be performed sequentially in the case of a subject who has been lost to follow-up (LTFU) after screening or randomization (see LTFU section). LTFU will be prepared and discussed at weekly clinic meetings. Written reports will be prepared from these meetings and sent to co-investigators.Home visits will be performed by community health workers trained to be discreet in their approach to finding patients. They will not wear clothes that would identify them as health workers and will only use public transportation or unmarked private vehicles. They may ask about the participant's health or whereabouts.

6. Specimen transportation

Blood samples will be processed at the study clinic and will be sent to the US for processing at a later date when enough samples have been collected, approvals have been obtained, and the laboratory is ready to receive the specimens. The Pap smear and biopsy samples will be transported to the pathologist on a daily basis and the results will be brought back after processing. HPV collection media will be stored at room temperature at the study clinic and may be transported outside of Kenya at a later date. Biopsies will be transported to the pathologist and the results brought back within 2 weeks after processing. The paraffin-embedded tissue blocks remaining after the histology processing will be brought back and stored at the study clinic. A transport log book will be used for this purpose. A results log will be kept to account for results received from the pathologist.

7. Infection Control

Hand washing with soap, disinfecting used linen and equipment, proper waste disposal, single use needles and syringes, use of gloves and autoclaving of equipment at the Hope Center will be adhered to.

8. Transport Fees

No money for transport will be given on enrollment for this will be treated as a scheduled clinic day at the Hope Centre. All subjects screened will get Ksh 300 on return to the clinic after initial enrollment and screening. If a woman would like more time to consider entry into the study, she will be given money for travel at the time she returns with the intent to enroll in the study. Subjects will receive travel money on presentation to the study office on their scheduled visit day and a list of subjects (by study ID) who get travel money will be maintained by the receptionist on daily basis. The receptionist will be getting transport money from the administrator. A top up will be done whenever the amount fall below Ksh 3,000. Maximum amount to be collected from the administrator at any given time will be Ksh 10,000.

9. Notification of Results

Cytology results: Subjects will be notified of their screening cytology results at a study visit scheduled two weeks after their screening visit. If on routine cytology QC re-readings, consensuscytology results are discordant from the initial reading and alternative management is required, subjects will be notified and called back for appropriate follow-up. Subjects with new cytology results of LSIL will be offered colposcopy and biopsy according to 2012 ASCCP guidelines.If the new cytology results are HSIL, ASC-H, or HSIL cannot rule out invasion, patients will be presented with evaluation, treatment and follow-up options,which includes continuation in the study (even if previously exited). Subjects will be given consent information to re-enroll into the study. A Colposcopy form will be completed at this visit. Cytology results from bi-annual follow-up visits for randomized participants and non-

randomized LEEP participants will be disclosed at the next scheduled follow-up visit if the result is Normal of ASCUS. If pre-cancerous or cancerous lesions by cytology have recurred then patient will be contacted to return to the study clinic to undergo colposcopic directed biopsy prior to treatment.

Histology results: If the participant needs a biopsy (i.e., HSIL, ASC-H, HSIL cannot rule out invasion, or ICC), they will need to return 4-6 weeks later for histology results. If study staff or a participant feel that having a counselor present at any of these visits would help facilitate the conversation, this can be arranged though utilization of Hope Center counseling staff.

Participants who do not come to their scheduled appointments will be called or visited at home using the contact information provided at enrollment (process described thoroughly below in the Loss to Follow-up & Mortality section).

10. Exit

Subjects will exit the study after an interview with the study doctor or study nurse. An "Exit" form will be completed. Participants will be notified that if they wish to know the final results of the study, they may contact the study office 6 months or a year after their participation is complete.

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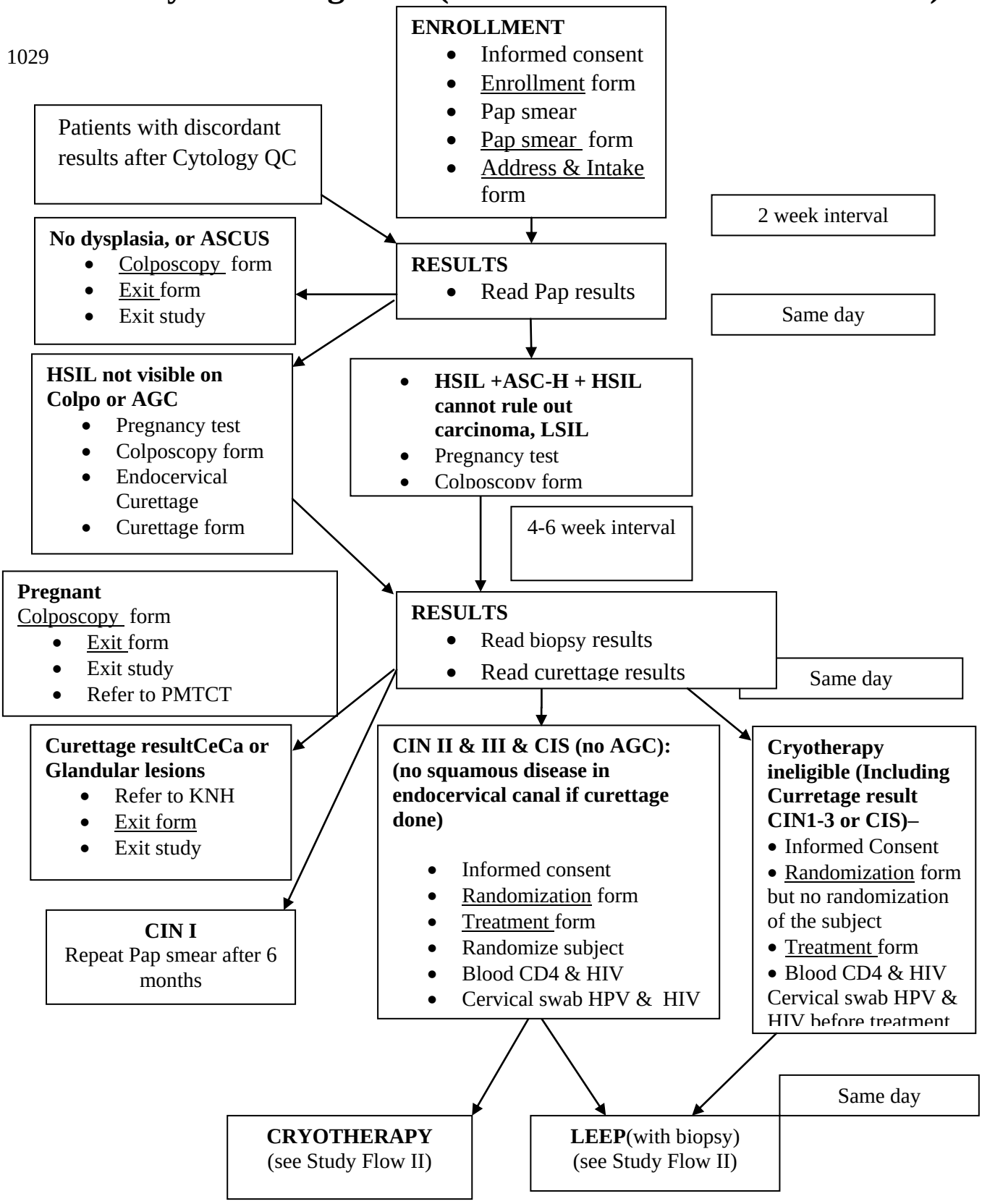
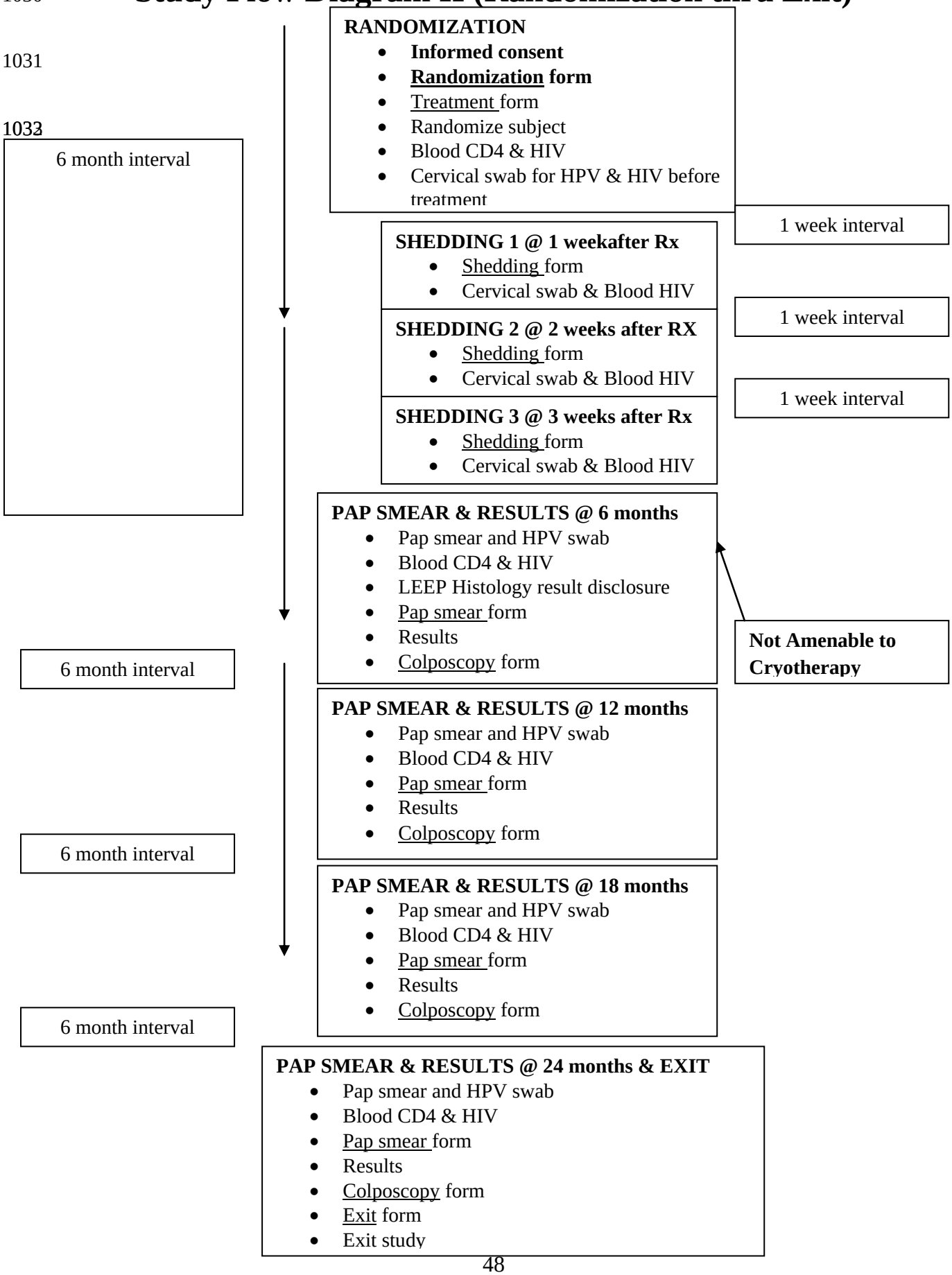
1028 # Study Flow Diagram I (Enrollment thru Randomization)

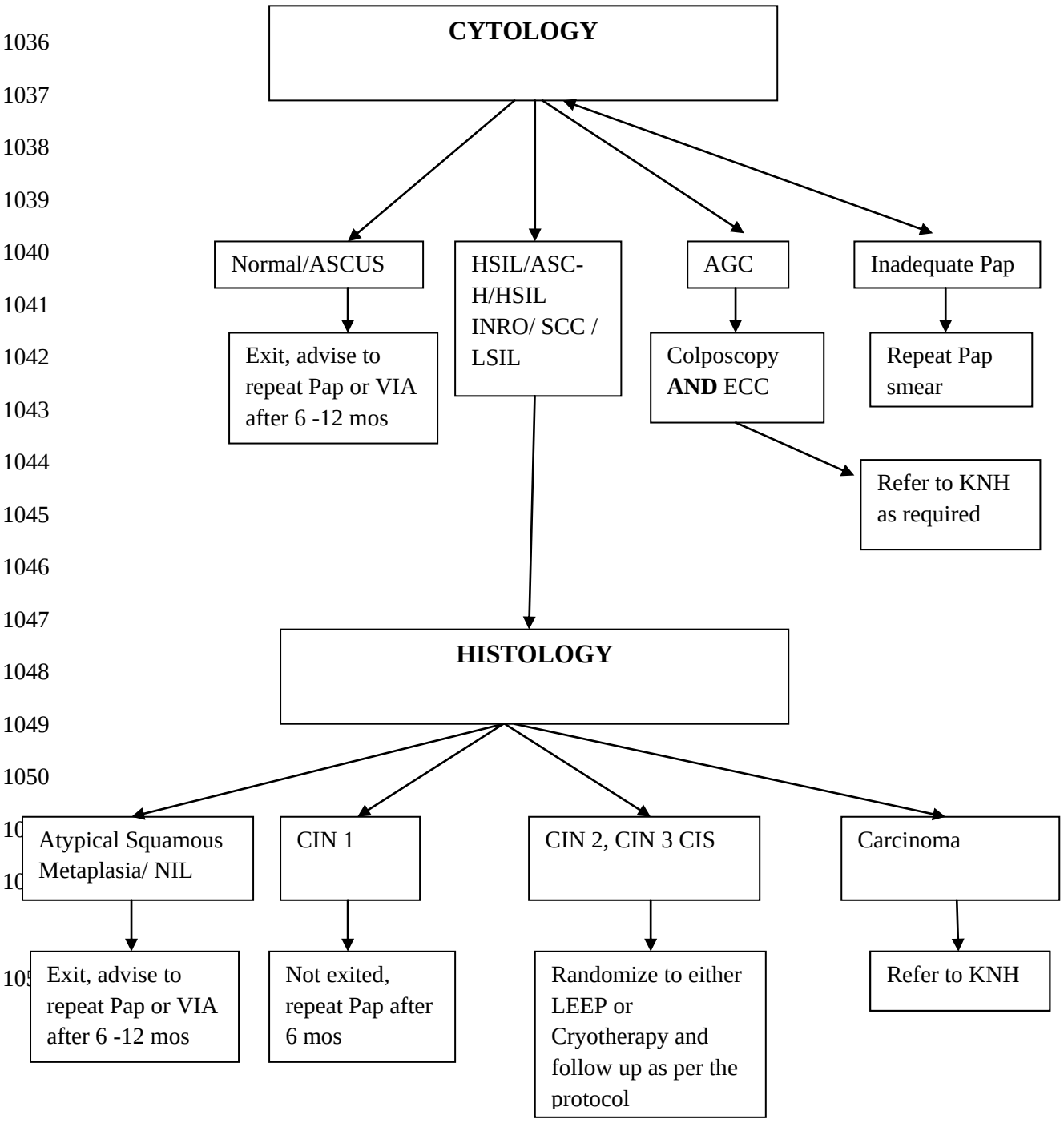
1029



Study Flow Diagram II (Randomization thru Exit)



Study Flow Diagram III (Study Tests)



Loss to Follow-up & Mortality

Tracing of randomized participants

If a randomized subject fails to appear for a scheduled study clinic visit then she will be contacted by phone the next day by the receptionist. If the first phone call after a missed visit does not reach the patient or someone who is in contact with the patient, then calls will be repeated at least twice a week for two weeks.If the patient is reached by phone, another visit will be scheduledas soon as possible within one month. If the patient also fails to return for this rescheduled visit, the receptionist will call again the following day. If again the patient does not return for the next rescheduled visit (the third scheduled visit of its kind), or if at least 4 calls have been unsuccessful in reaching the subject, an attempt will be made to visit her at home by a community health worker. If a home visit is unsuccessful in reaching the subject, or if home-visit is successful but the subject fails to return to the study, then she will be considered lost to follow-up (LTFU). If a phone call or home visit reaches the subject, then an appointment will be made for the subject to return to the study clinic. (See Study Tracing Diagram for randomized patients).

Tracing of non-randomized participants

If a non-randomized subject fails to appear for a scheduled visit, including 6-month repeat Pap smear visit after a prior LSIL or CIN1 resultshe will be contacted by phone the next day by the receptionist. If the phone call does not reach the patient or someone who is in contact with the patient, then a second call will be made the following week. If both calls are unsuccessful in reaching the subject, or if the visit is rescheduled but the subject again fails to show up, thenher Coptic Hope file will be flagged, and she will be considered LTFU. If a

phone call or home visit reaches the subject, then an appointment will be made for the subject to return to the study clinic.

Tracing of patients with new QA/QC Cytology results

Both enrolled participants and patients who have been exited from the study may need to be contacted to receive new cytology results based on laboratory QA/QC. Women whose final QA/QC cytology result has been downgraded from the initial result that was disclosed to them, or women whose final results do not require treatment (Normal, ASCUS) will be followed in the same manner as non-randomized subjects: two weekly phone calls and flagged Hope file. These patients will be operationally considered lost at this same point.

Women whose final results have been upgraded to ASC-H, HSIL, or SCC, and women whose final results are unsatisfactory but had at least one reading of ASC-H, HSIL, or SCC, will receive additional follow-up efforts. This includes at least 6 phone calls over 4 weeks, with at least one call over the weekend. Home visits will also be conducted for these patients when possible. These subjects will be defined as LTFU on a case-by-case basis when all efforts to contact them have been completed.

Tracing of patients with cancer

Any woman who receives an initial or final laboratory result of SCC (cytology) or ICC (histology), whether she is randomized, non-randomized, or exited, will receive the same extensive follow-up efforts as noted above, This includes at least 6 phone calls over 4 weeks, including a phone call over the weekend, and a home visit when possible. These subjects will be defined as LTFU on a case-by-case basis when all efforts to contact them have been completed.

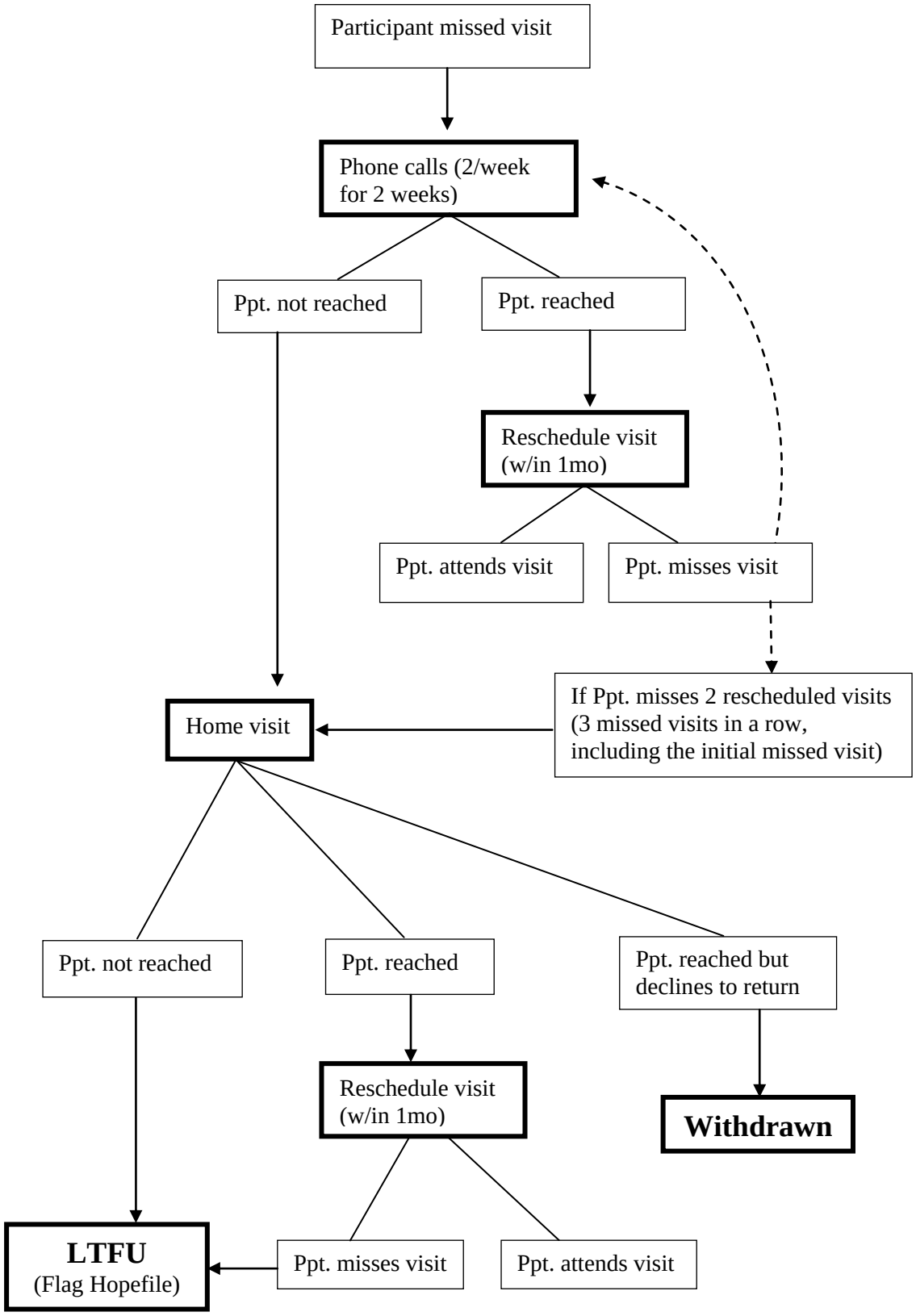
Documentation of tracing

All attempts at contacting the patient either through phone call or home visits will be documented in the participant's chart notes. All attempts at home visit will be recorded on the "Patient Contact" form. If a subject is LTFU, this will be recorded on the "Patient Contact" form, in addition to reasons for loss. If a subject withdraws or asks to dis-enroll from the study, the "Exit" form will be completed. If a subject is determined to have died through phone call or home visit, then the "Verbal Autopsy" form will be completed. Information on loss or death will be shared with the Hope clinic team and social worker so that they may update their files.

Statistical considerations for LTFU

Those who are LTFU or dropout after randomization will contribute time and data to the outcomes of measurement for as long as they have remained in the study. They will continue to remain in the arm to which they have been randomized and analyses comparing interventions will include these participants. If, for example, they reach the 6 month time point but did not appear at 12 or 24 months, then data from this subject will be included until 6 months after randomization in a survival analysis.The study coordinator and study doctor will oversee loss and mortality data in coordination with the receptionist.

Study Tracing Diagram for Randomized Participants



Statistical Methods

The sample size was calculated to detect a 10% difference in treatment outcomes between LEEP and cryotherapy (4% versus 14%)[26] with 80% power and a 0.05 significance level. Accounting for the possibility of a 20% loss-to-follow-up rate over two years, we estimated that 400 women with high grade lesions would need to be enrolled in the study with 200 women randomized to each arm. It is estimated that 200 women in each arm will allow detection of a 0.25 $\log_{10}$ HIV virus level difference in cervical shedding between the two arms with greater than 90% power. Based on results from an ongoing cervical cancer screening study implemented at the Hope Center in 2009, our estimation of the prevalence of high-grade intraepithelial lesions is about 18%. Given this estimate and the number of women who are likely to be eligible for randomization, we calculate that we need to enroll 2,400 women for initial screening.

The primary analysis of the study will be to compare treatment outcomes between the LEEP and cryotherapy intervention arms in an intent-to-treat analysis. Treatment outcomes will be measured by Pap smears taken every 6 months during two-year follow-up. Pap smears demonstrating high-grade intraepithelial lesions will be considered positive and compared against negative or low-grade intraepithelial lesions. A Chi-square test will be used to compare the percentage of positive Pap smears between the intervention arms at 6, 12, 18, and 24 months. Secondary analyses will compare cervical HIV-1 RNA viral shedding between the treatment arms. A comparison of the average area under the curve (AAUCMB) of long-transformed HIV-1 RNA cervical viral loads will be performed between the two arms using an analysis of covariance (ANCOVA) model.

Our analysis will include contraceptive history as a potential confounder. While there has been some suggestion in the literature that HIV infectivity among women on oral

contraceptives is increased,[33, 34] a recent study from the UW did not show a significant increase in levels of HIV RNA in cervical samples obtained from women on hormonal contraception.[35] A more recent multicenter randomized controlled trial performed in Asia and Africa also did not find an association between hormonal contraceptive use and increased HIV transmission.[36] However, increased viral shedding due to hormonal contraceptive use remains an important and interesting question and one that we will examine in our study.

The analysis will control for immunological status through measurement of CD4 count as well as presence of and duration on antiretroviral medications. Given that the study will recruit patients from an antiretroviral treatment clinic, it is expected that the majority of subjects will be on antiretroviral medications (~75%). Type and duration of antiretroviral drugs (ARVs) will be obtained through accessing clinical medical files and CD4 count measurements will be obtained regularly during study follow-up. The impact of ARVs on recurrence of cervical intraepithelial lesions is unclear and may have minimal effect.[37, 38] Also, despite ARV use, HIV shedding has still been detected in the genital tract.[39] Therefore, we are confident that the sample size will still be adequate to detect differences between treatment modalities among women on antiretroviral medications.

Data Management

Introduction

Data will be captured on paper forms or electronically using Open Data Kit (ODK) application which has a data collection component to be used on a mobile device, and a centrally managed data store component. ODK is supported by the University of Washington (UW). Data will be cleaned, and analyzed at UW project offices located at KNH in Nairobi, Kenya. This office, which supports several UW studies, will provide administrative and database management support to this research project. Study data will be collected separately from Hope clinic data and will not be linked to the Hope dataset. The forms have been used in a recent cervical screening study and improvements have been made as a result. Analysis of the data will be conducted using SPSS version 16.0 (SPSS Inc, Chicago, Illinois, USA) by UW statisticians and epidemiologists associated with the study. Data will be managed by the Data Manager and the data clerk.

See Appendix B for data collection forms

Facilities

Cervical Cancer Screening room at Coptic Hope Center for Infectious Diseases

The on-site facilities available for cervical cancer screening include two examination beds, one office desk, and one computer, and at least one tablet PC. Electronic and paper data collection forms and paper informed consent forms will be administered here. The address and intake form, which captures patient identifier data will be completed on paper forms only.

UW study clinic and laboratory at Coptic Hope Center for Infectious Diseases

At this site, there is one clinic room and laboratory dedicated to this study. The clinic will have one examination bed, one desk, and one computer. Data collection forms will be filled out at the study clinic and in the Cervical Cancer Screening room. Any paper data forms, including address and intake and lab request forms will be sent to the UW offices in KNH for scanning daily but returned for storage at this site, while the lab forms will be sent to the Lancet laboratory.

UW data and administrative offices at Kenyatta National Hospital

The study has an administrative and a data management office in the UNITID building at KNH. There are five computers, one laser printer, one scanner and a one copier. All computers except the data computer have internet access. All computers have antivirus software which is kept up to date by the data manager. Only non-identifiable data will be collected electronically and stored on a local ODK Aggregate (server) which is maintained by NASCOP. All data collected using the ODK will be downloaded from the nNASCOP server onto the data computer and converted in SPSS format.

<u>Databases</u>

The study data will be recorded in SPSS, MS Access, or written notebooks and include:

Data Collection Forms – this SPSS database includes all questionnaires that are electronically and manually filled at the study.clinic In total there are 16 questionnaires to be filled

- Enrollment
- Pap Smear
- Colposcopy
- Randomization

- Treatment
- Address and Intake
- Shedding
- Patient Contact
- Verbal Autopsy
- Exit
- Cytology Report
- Colposcopic Biopsy Histology Report
- Endocervical Curettage Histology Report
- LEEP Biospsy Histology Report
- CD4 Report
- Follow-up Form

Cervical Cancer Screening Appointment and Tracking – this MS Access database will track patients from the Hope Center who are referred to the study clinic by scheduling appointments and recording dates that screening tests are performed.

Laboratory – this database contains an inventory of all specimens collected, stored, and analyzed.

Specimen Collection – a written notebook provides a written record that tracks when the specimens have been collected and where they are going. Specimens include:

- Blood for CD4 count
- Blood for HIV viral level
- Cervical swab for HIV viral level
- Cervical swab for HPV

- Pap smear
- Colposcopy-directed biopsy
- Endocervical curettage specimen
- LEEP specimen

Storage – a written notebook which tracks specimens which are stored in the freezer and where they are kept. Stored specimens include:

- Cervical swab for HIV
- Cervical swab for HPV
- Blood plasma and cells for HIV

Laboratory Results – a written notebook which tracks the results of laboratory analyses that are performed in Kenya. Results tracked include:

- CD4 count
- Pap smear result
- Colposcopy-directed biopsy result
- LEEP biopsy result
- Endocervical curettage biopsy result

Management

Entry

The data collection forms will be completed either manually on paper forms or electronically on ODK. The following collection forms will be completed manually in paper forms: , address and intake form (which captures patient identifier data), Cytology Report, Colposcopic Biopsy Histology Report, Endocervical Curettage Histology Report, LEEP Biospsy Histology Report and CD4 report, all of which serves as lab request forms.

Each subject has a folder in which all paper forms and questionnaires are stored. These folders are stored in a locked cabinet at the UW study clinic at Coptic. Newly filled-out questionnaires are brought to the UW KNH data office from the study clinic daily. Questionnaires are scanned into the computer database the same afternoon, and folders are returned to the clinic the following morning. Scanned data is verified by Cardiff Teleform software and later cross-checked against the paper questionnaire on the same day by the data clerk after it is exported into SPSS.

For data captured electronically, only non-identifiable data will be collected electronically and stored on a local ODK Aggregate (server) maintained by NASCOP. The Address and Intake form which collects the patients identifiable information will be completed on paper, sent to the UW office in KNH for scanning daily, and returned for storage in the Coptic study clinic where they will be kept in a locked cabinet. Once the data is collected using the encrypted electronic forms, it will be transmitted to the Nascop server through an encrypted path.. As an added layer of security, all electronic data forms (even though they contain no identifiable data) are encrypted on the data collection devices prior to transmission to the local server. The Principal Investigator, the Data Manager and the data collectors will have access to the ODK server with different rights.*Quality*

The data clerk maintains a data logbook where all the data entry queries or errors encountered during data entry are recorded. Data entry queries or errors are then discussed with the study

staff at least once a week. Discussions are held with both study staff and data clerk together at the study clinic and corrections are made to the database by the data clerk upon returning to the data office. The data manager ensures that all errors are attended to on a regular basis.

The data manager ensures that all the data is clean at all times. Questionnaire (Address and Intake) data is checked for entry accuracy at the time of scanning. In addition, data checking is done on the databases every week and the data manager takes responsibility for organizing the data checking process. A summary report on the data quality and data entry accuracy is then produced by the data manager and distributed to the project investigators.

Data checking is done using the following methods:

Ranges and Validity rules

A range of acceptable values and skip patterns (checks) has been inbuilt for all the appropriate variables during the programming of the data collection form using the xml form. Any values that fall outside this range cannot be accepted by the database. Validity rules are also set where certain variables can only be entered if they comply with a particular rule. For example, the database does not allow outside limit or blank entries for the patient identification numbers and all unreal dates are rejected. The data manager works with the data clerk to identify any inconsistent data on a weekly basis. Inconsistency checks are done when the files are in SPSS. The manager then consults with study clinicians to resolve the inconsistencies.

Line listings for data captured non-electronically

The main objectives of line listings include:

- identifying any errors made during data entry

- estimating the accuracy rate of the data clerk, monitor and asses his/her data entry performance

The data manager produces 10% line listings of all the enrollment and follow-up files on a quarterly basis. The data team members then check the line listings against the hard copy questionnaires. Errors are highlighted on the line listings and the error rate approximated thereafter. If the error rate is higher than 0.3% then the whole database should be checked.

After the checking has been completed, the data manager lists all the corrections that need to be done in the patient charts on the data entry sheet; this helps the data entry clerk easily identify the corrections that need to be done.

Missing values

Restrictions have been put on all questions that are required to be answered. These checks prevent the interviewer from skiping any question that requires a response.

Safety, Security, & Storage

Data security in ODK

- ☐ All data collection devices(Tablets) will have a security code for unlocking to prevent unauthorized users
- ☐ All the electronic forms will be encrypted before loading to the ODK collect
- ☐ The data will be uploaded to Nascop server through a secured pathPrivate key will be used to decrypt the data. ONLY the Data manager will have access to the private key
- ☐ Once the data is decrypted , it will be converted into SPSS format.
- ☐ All databases are backed up every Friday by saving the most current files on two CD disks and external harddrive and uploaded to the UW-server. All computers are password-protected, preventing access by any unauthorized persons. Data is backed

up on a weekly basis by the data clerk and the data manager. Data is saved on an external hard-drive that remains in the office as well as on a CD that is kept off-site. All data on CD disks will be password protected by the data clerk. All patient records are filed according to numerical order of the patients' identification. Folders are kept in a locked storage cabinet at the study clinic for reference by research personnel. Once the subject completes the study or is lost to follow-up, her records are brought to the KNH office for storage. Participant study ID will be generated by the data manager who will be responsible for linking and de-linking data.

Schedule

Daily

Electronic questionnaire entry – The nurses will complete the forms electronically and upload (send) the data to the ODK server. The data will then be downloaded from the server and saved onto the data computer in SPSS format

Specimen entry – Specimens that are collected in clinic are entered into the *Clinic Specimen CollectionBook*. Results are entered in the *CD4 Results Book, Pap Smear Results Book, and Biopsy Results Book.*

1339

1340

1341 .

Laboratory Procedures

Sample collection

- Study nurse will collect Pap smear specimens and cervical swabs for HPV and HIV
- Study doctor will collect cervical biopsy specimen under colposcopy and perform endocervical curettage when necessary
- Study nurse or lab assistant will collect blood specimens
- Specimens will be gathered in the laboratory before transfer
- Lab assistant or technologist will record details in lab book**.** Information includes:
    - Specimen Study ID
    - Date
    - Visit type
    - Time sample was collected
- Pap smear, cervical biopsy, and endocervical curettage specimens will be placed in a cool box and transported to the designated laboratory before 4 pm by the lab assistant or technologist. Designated laboratory will record reception of samples in a book including: specimen study ID, date, time, and number of specimens. Results will be filled in the relevant "Histology Report" and "Cytology Report".
- One set of blood samples will be sent to the Coptic Hospital for CD4 count. These results will be filled in the "CD4 Report".
- One set of blood samples will be centrifuged at the study laboratory by the lab technologist located at the Hope Center and frozen in a -80^{O}C freezer for storage. Shipment of samples for analysis of viral levels will be performed on these samples.
- Cervical swabs for HIV will be prepared in the study laboratory and frozen in a -80^{O}C freezer for storage. Cervical swabs for HPV will be stored in storage medium

(preservCyt) at <25° C. Shipment of samples for viral analysis will be performed on these samples.

Pap smear and cervical tissue biopsy

- Papanicolaou test: after the application of a speculum, a cervex brush will be inserted to its full length into the endocervical canal so that the shorter outer brush hairs are in contact with the ectocervix. The cervex brush will then be gently pushed whilst being turned 5 times in an anticlockwise direction (2.5 complete turns), in order to collect cells from both the endo- and ecto-cervix. Care will be taken not to touch the tip of the brush in order to avoid cross-contamination. Using the brush, a Pap smear will then be prepared by smearing the brush on a clean glass slide and fixing immediately with 95% isopropyl alcohol for at least 30 minutes at the study clinic. The slide will then be transported to the laboratory to be stained, and the cytology will be reported by a study pathologist from Aga Khan University Hospital using the Bethesda classification.
- Samples from the colposcopy-directed biopsy of the cervix, endocervical curettage specimen and the LEEP specimen will be fixed in 10% buffered formaldehyde solution and transported for haematoxylin-eosin staining. The histopathology results will be read by a study pathologist from Aga Khan University Hospital, and the biopsy samples will subsequently be preserved and fixed in paraffin. Biopsy blocks will be collected and may be sent to the IARC for further analysis.

Cervical swabs for HIV and HPV

- Dacron swabs will be used to collect samples for HIV from the cervix. Endocervical secretions will be collected by rotating the swab 360 degrees in the outer part of the endocervix.
- For HIV-1 DNA testing, the dry swab will be stored as such in the -80^{O}C freezer.

- For HIV RNA testing, the swabs will be collected in a cryovial containing 1 ml of freezing media and then stored at -80^{O}C.
- Cervical samples for HPV will be taken using cervex brush. The brush will be inserted to its full length into the endocervical canal so that the shorter outer brush hairs are in contact with the ectocervix. The cervex brush will then be gently pushed whilst being turned 5 times (2.5 complete turns), in order to collect cells from both the endo- and ecto-cervix. Care will be taken not to touch the tip of the brush in order to avoid cross-contamination.The brush containing cervical cellular material will be placed in a vial containing PreservCyt media (Cytyc Corporation) and labeled with the subject identification number of the participant. The brush will be fully rinsed in the media by pressing 10 times against the bottom of the vial, forcing the brush hairs to separate. Finally the brush will be vigorously shaken in the media to remove any residual cells. The brush will NOT be left in the vial, but discarded. It is very important to close the vial very tightly to avoid possible leakage during transport. Cell samples will be stored at the Hope Center at <25° C, and then later transported to the US or to IARC in Europe.

Shipping

- The UW has extensive experience measuring HIV-1 viral RNA from cervical swabs and plasma. While measuring plasma HIV-1 RNA viral levels is available in Kenya, HIV-1 RNA analysis from cervical swabs has not been performed here. In order to maintain high quality standards, samples will be analyzed in Seattle. Plasma HIV-1 RNA will also be analyzed in the same laboratory so that the results, taken from two different body compartments on the same day, are comparable. The KNH IRB has approved laboratory analysis of cervical samples in Seattle for a current study on cervical cancer screening and is therefore expected to approve similar testing for this study. Analysis of samples locally

is dependent on significant funding to develop a laboratory locally that could perform PCR analysis.

- Samples for HPV testing will be shipped to the IARC in France and then to the Netherlands or to the US directly where the PCR testing will be conducted. The KNH IRB has also approved laboratory analysis of cervical samples in Europe for a current study (mentioned above) and is therefore expected to approve similar testing for this study.

Analysis for HIV-1 viral levels

- HIV swabs will be stored at -80°C until shipment to Seattle. The swabs will be tested for HIV RNA using a Gen-Probe HIV-1 viral load assay (San Diego, California, USA) which has been validated for use in Kenyan HIV subtypes.[40] The assay has a lower limit of 50 copies/swab in genital secretions. HIV-1 DNA will be examined in the cervical swabs by detecting proviral DNA using a nested PCR for the viral *gag* region which should detect as little as 1 copy of DNA. This technique has been validated in a number of other studies.[39, 41]

Analysis for HPV subtypes

- Frozen pellets of exfoliated cervical cells collected in PreservCyt will be extracted and tested following standard operating procedures of the HPV Laboratory at CDC as implemented under the ongoing Quality Management System. The Linear Array HPV Genotyping Test (Roche Diagnostics), based on L1 consensus PCR with type-specific hybridization, will be used. The assay detects 37 HPV types: HPV6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 42, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 64, 66, 67, 68, 69, 70, 71, 72, 73, 81, 82, 83, 84, 89, and IS39. The probe for HPV 52 (called XR) cross reacts with

HPV 33, 35, and 58. If the XR band and any cross-reacting types are identified, HPV 52 will be identified with a type-specific quantitative PCR assay. Samples negative for both, beta-globin and all HPV types will be reported as negative. Results will be recorded in database and securely transmitted to Dr. Chung for linking to epidemiologic and clinic data.

Quality Assurance and Quality Control (QA/QC) for Cytology and Histology Specimens

A Cytology and Histology QA/QC procedures document is attached to the protocol as an addendum.

- Loss of slides or blocks: If any cytology or histology slides or blocks are misplaced during the course of QA/QC procedures, the patient will be contacted to return for repeat Pap smear or biopsy, as necessary.

Quality Assurance/Quality Control of Study Procedures

- *LEEP:* The senior gynecologist on the study will work closely with the study doctor to ensure quality procedures with a low rate of complications through regular weekly meetings and contact through cell phone and e-mail. The complication rate and type will be reviewed on a bi-monthly basis. This information will be collected by the "Adverse Event" form which hasbeen added. All LEEP specimens will also be evaluated by histopathology with confirmatory reads as detailed above.

- *Cryotherapy:* As with LEEP, the study doctor will be well trained and mentored by the study gynecologist to perform quality procedures with low rates of complications, and the complication rate and type will be reviewed on a bi-monthly basis. This information will be collected by the "Adverse Event" form which hasbeen added.

- *Colposcopy and endocervical curettage:* The study gynecologist will supervise the study doctor to conduct colposcopy with biopsy and curettage. He will receive support and in-service trainings as deemed necessary.

Ethics

A. INTRODUCTION

Field and laboratory procedures will be performed in Nairobi, Kenya, while data analysis will be done in both Nairobi and Seattle, Washington. The study will be reviewed by the Institutional Review Board (IRB) at the University of Washington and the Kenyatta National Hospital (KNH) Ethical Review Committee (ERC). The study will not recruit subjects prior to approval from both the University of Washington IRB and the KNH ERC. In accordance with the International Conference on Harmonisation Good Clinical Practices (ICHGCP) section 4.5.4, the investigators may deviate from protocol prior to IRB approval in order to eliminate immediate hazard to trial subjects.

B. DECEPTION

If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

No deception or withholding of complete information is required for this activity.

C. SUBJECTS

1. How many subjects will you need to **complete** this study?

Number: approximately 400 Age range: above 18

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.

a. Age (minors, elderly): N/A.Sexually active women are at greatest risk for cervical cancer. Adolescents will be excluded due to their high rate of regression of cervical lesions, with 90% clearing the HPV virus by 24 months. In terms of cervical dysplasia, it was been shown that in adolescents with high grade lesions, a majority will clear these lesions within 1 to 3 years. The current ASCCP guidelines state that wome with HSIL cytologyshould be managed with colposcopy.

b. Gender: N/A. Cervical cancer affects the female reproductive system only

c. Ethnic and racial minority populations: N/A.Study is performed in Kenya where the majority of the population is black

3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)

HIV-positive, female, over the age of 18, intact cervix, initiation of sexual intercourse

4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)

HIV-negative, male, below 18 years of age, pregnant by clinical history or physical examination, post-hysterectomy, post-cervical cancer treatment, history of a bleeding disorder, no prior initiation of sexual intercourse

5. Describe the subject recruitment strategies you will use for each group of subjects. (Attach advertisements, flyers, contact letters, telephone contact protocols, Health Sciences recruitment web site template, etc.)

Adult female subjects who attend the Hope Center for Infectious Diseases will be informed by a doctor at the clinic of the study and their potential eligibility using the attached form (Pre-Screening Talking Points). If the subject expresses interest, the doctor will contact the study nurse who will accompany the subject to the study clinic located less than 50 yards away. We will also use recruitment leaflets that will be distributed by the study staff at the Hope Center Reception. The leaflets will have the contact information of the study staff.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy.

Doctors from the Hope Center who see the subjects at a medical follow-up or screening visit will approach subjects to take part in the study in a confidential, private room. We will also use recruitment leaflets that will be distributed by the study staff at the Hope Center Reception. The leaflets will have the contact information of the study staff.

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

Doctors or study staff who inform subjects of the study will follow the "Pre-Screening Talking Points" and let them know that their decision whether to participate in the study or

not will not affect their clinical care at the Hope Center. In addition, women who wish to be screened but do not want to enter the study will receive free screening. The study nurse will reiterate these points during the informational interview using the "Screening Talking Points" to gauge the interest of the patient before signing an informed consent. Talking Points are enclosed in the Appendix.

8. Will you give subjects gifts, payments, services without charge, or extra course credit?

☐ No ☒ Yes If yes, explain:

Subjects will receive free treatment for pre-cancerous lesions amenable to cryotherapy or LEEP. Medical personnel will provide free medical services, gynecological examination, treatment, and free condoms. Randomized subjects will also receive money for transportation to return to clinic.

9. Will any of the subjects or their third-party payers be charged for any study procedures?

☒ No ☐ Yes If yes, explain:

10. Where will the study procedures be carried out?

The study will be carried out in Nairobi, Kenya at the Coptic Hospital. IRB approval for this PHE has been granted by Kenyatta National Hospital (KNH) in Kenya and the University of Washington (UW).

D. RISKS AND BENEFITS

1. Describe nature and degree of risk of possible injury, stress, discomfort, invasionofprivacy, and other sideeffects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as

well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

The study may collect personal information that may be embarrassing for the subject to talk about. As part of the study, the subject may meet other patients from this clinic whom she may know from outside the clinic. We will be collecting blood samples using a needle and syringe. The puncture of the needle may be uncomfortable and leave a bruise and may cause infection or fainting. Collection of biopsy samples through the pelvic exam may cause: mild discomfort as the subject is examined, small amount of bleeding from the vagina for 1-2 days, and mild to moderate cramping for 5 minutes that is similar to mild menstrual pain. If the subject undergoes cryotherapy or LEEP, then she may experience mild abdominal cramps for less than 10 minutes, discharge from the vagina for about 2 weeks, and/or bleeding for several days. Possible serious complications include excessive bleeding or infection. Additionally, some studies have shown that cervical treatment is associated with pregnancy complications including premature rupture of membranes, premature contractions, infections and cervical incompetence.

If the subject undergoes a biopsy, she is requested not have sex for 10 days. The reason is that if her partner is not infected with HIV, then he may be at greater risk of becoming infected with HIV after the biopsy procedure because of a possibility of increased HIV shedding from the cervix. The participant may also be at increased risk of

infection at the site of the biopsy. If the subject has received cryotherapy or LEEP, then, for the same reasons as the biopsy, we suggest that she not have sex for 4 weeks after it is performed.

Subjects will be prescribed antibiotics to protect against infection after cervical treatment or as treatment for an sexually transmitted infection or other vaginal infection discovered on pelvic exam. Possible side-effects from antibiotic use include (but are not limited to) nausea or anorexia, vomiting, diarrhea, photosensitivity, rash, anaphylaxis possibly leading to death, dizziness, headache, confusion, tinnitus or hearing loss, seizures, arrhythmias, neutropenia, thrombocytopenia, hyper/hypoglycemia, tendon rupture, liver disease, kidney disease and peripheral neuropathy.

2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors, fetuses in utero, prisoners, pregnant women, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group.)

The clinical procedures of collecting blood, fluid, and tissue samples will only be performed by certified medical staff trained in these tasks. Any complications arising from these procedures will be handled by a doctor and covered by the study.

Study investigators may decide to withdraw a study participant from the study if they find further enrollment

may expose the participant to harm or the investigator determines the participant will not be able to abide by study safety requirements, e.g. in the case of mental health problems or drug/alcohol dependency problems.

3. Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures?

☐ No ☒ Yes If yes, explain how you will handle this situation.

The intent of this cervical cancer screening study is to detect pre-cancerous and cancerous lesions of the cervix which may not be known to the subject and then treat those lesions free of charge. If the lesions are too large or are cancerous then we will refer them to the neighboring government hospital for subsidized care.

4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

The benefit of this research for the individual is that we may be able to detect and treat pre-cancerous disease of the cervix before it becomes cancerous and deadly. By participating in this study, an individual may avoid the development of a life-threatening disease.

5. Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

The benefit of this research for society is that it may identify the most effective method to treat cervical dysplasia in HIV-positive women who are at much higher risk

for cervical cancer and who number in the millions in resource-constrained settings around the world. Results of this research may impact international guidelines and the way millions of dollars of donor funding is spent on the care of HIV-positive women.

As discussed above, the medical care offered through the research conforms to the standard of care established by the Kenyan MOH at tertiary care and provincial level health care facilities. Options are available to clients enrolling in the study to obtain Pap smears at these locations along with cryotherapy and LEEP treatment. At the same time, the treatment interventions that are being offered in the study do not offer unreasonable risks and provide likely clinical benefit. Both procedures are widely recommended in both developing and developed settings and one method is not known to be better than the other among HIV-positive women. As previously discussed, given the paucity of evidence-based literature there is scientific and medical equipoise in addressing this question and offering these two treatment methods.

The benefits of the procedures being offered outweigh the risks. The risks of LEEP and cryotherapy are low. In the study previously mentioned from Zambia, Pfaendler, et al. found that the overall complication rate of LEEP to be 3.7%, all of which was managed on-site in the clinic.[20] Likewise,

in a study of cryotherapy in India, the overall complication rate was found to be 3.0%.[21] Both LEEP and cryotherapy may result in infection or bleeding, though the rates are low and the great majority can be managed in the clinic where the procedure was performed. Pfaendler et al. found bleeding as a complication in 14/697 (2.0%) and infection in 12/697 (2.0%) while performing LEEP. Nene et al. in the study from India mentioned above had 9 (1.9%) cases of mild bleeding and infection in 8 (1.4%) cases. The benefits of treatment through LEEP and cryotherapy, on the other hand, are very high. It has long been known that HIV-positive women are at higher risk of cervical disease and faster progression of lesions.[42, 43] From preliminary studies performed on our HIV-positive patient population, we have found that the prevalence of high-grade lesions is around 8% in women 30-39 years old and taking antiretroviral medications.[44] Additionally, studies have shown that either method of treatment is extremely effective in treating CIN.[27]

E. CONFIDENTIALITY OF RESEARCH DATA

1. Will you record any direct subject identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ☐No ☒ Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

We will be recording names and assigning a study number that will be used on all study visits. This is to ensure

accurate follow-up of study participants. This will be handled by the senior data analyst.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☐No ☒ Yes If yes, explain why this is necessary and for how long you will keep this link.

The link between the study participant's name and study number is necessary to facilitate follow-up during the 1 month study period. This link will no longer be needed after follow-up is completed and will be removed after 5 years. This will be handled by the senior data analyst. Data and specimens will be stored for 10 years after completion of study follow-up before being destroyed.

3. Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).

All names and numbers will remain in confidential files that are accessible only to the investigators and study staff. Computer databases containing information about study subjects will be protected by passwords which allow access to only the investigators.

Notebooks, folders and CDs will move between the study clinic site and the KNH data office in a direct manner to minimize handling of data. Information will be transported by private vehicle used by the study. There will be two CDs to back up study data, one to be kept with the administrator at an off-site location and one with the senior data analysis in a locked closet at KNH. Data files on the

computer and CDs will be password protected, accessible only by data staff. Additionally, patient identifying data will be kept in a separate, locked folder from the clinical data to maximize confidentiality when reading clinical materials. All data, including physical medical files, will be physically locked when not in transport – both at the study site and at the office at KNH – to assure that only designated staff will have access to the files. The study coordinator will be responsible for ensuring patient confidentiality for both electronic data and the medical files.

4. Will you place a copy of the consent form or other study information in the subject's medical or other personal record?

☒ No ☐ Yes. If yes, explain why this is necessary.

5. Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future?

☐ No ☒ Yes If "Yes," explain and include this information in the consent form.

Specimens may be tested for HPV at a later date. Data and specimens are requested to be stored from the participant for 10 years following enrollment for possible use in other HIV and cervical studies in the future. Approval from the UW and KNH IRBs will be obtained before any of these studies are performed.

F. ADDITIONAL INFORMATION

1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes:

☐ Pending ☐ Approved ☒ NA

2. Will you need access to subjects' medical, academic, or other personal records for screening purposes or during this study?

☐ No ☒ Yes. If yes, specify types of records, what information you will take from the records and how you will use them.

Subjects will be enrolled at the Hope Center for their HIV care and their medical records contain information on what type of treatment they have received and the severity of their condition. We will access these records to determine what type of antiretroviral treatment they've been exposed to and their clinical status according to medical examination and laboratory values including CD4 count. This information is included in the consent form.

3. Will you make audio-visual or tape recordings or photographs of subjects? ☒ No ☐ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see them.

4. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)?

☒ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly or describe safety testing procedures you will use.

G. REPORTING OF ADVERSE EVENTS

1. Describe how unanticipated adverse events related to study participation will be reported to the local IRB/Ethics Committee.

The IRBs of host institutions and the sponsor, CDC, will be notified of adverse events by the PI within 72 hours of his

becoming aware if the adverse events fall into one of two categories:

1. related to research procedures and unexpected and severe
2. related to research procedures and expected, but more severe or occurring at a greater frequency than expected

Severe adverse events related to the study include any death, any non-HIV-related hospitalization, severe infection including PID, severe bleeding or cramping and severe cervical stenosis. Any adverse events will be recorded by study staff on Adverse Events Reporting Forms at the time of the incident or at the next study visit. Documenation of severe adverse events which meet the criteria listed above will be brought to the attention of study PIs within 24 hours by the study doctor and/or study nurse via phone or email, and be assessed.

Other Adverse Events that do not meet the criteria above will be reported to the IRBs as per their specific guidelines.. All serious and non-serious adverse events will be reported to the DSMB during its regular meetings. All Adverse Event reports that are sent to the IRBs and DSMB will also be sent to the study sponsor.

Adverse Events

Specification of Safety Parameters

Safety parameters for this study will include signs and symptoms of local genital irritation and of systemic effects that could be related to either Pap smear screening or study treatment procedures (LEEP or cryotherapy), side effects from any medications prescribed as part of this study, and any other health complications that subjects may experience while enrolled in this study. Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters.

Adverse Events (AEs)

An AE is any untoward medical occurrence or unintended clinical sign, including an abnormal laboratory finding, symptom or disease,in a clinical investigation subject that occurs during the course of the study. The occurrence is considered an AE whether it is associated with the use of a medical treatment or procedure, or considered unrelated to that medical treatment or procedure. The occurrence of an AE may come to the attention of study personnel in various ways--during study visits, during interviews of a study participant presenting for medical care, or during a review by a study monitor.

All AEs will be:

- recorded on the appropriate AE CRFby the study physician and nurses
- summarized by the data team
- followed through resolution by a study clinician
- reviewed and evaluated by a study clinician
- Study-related SAEs will be immediately reported to the host IRBs and ERCs, and to the study sponsor.

In this study, the following situations will be considered AEs:

1. Occurrences related to Pap smear, LEEP or cryotherapy procedures:

Symptoms such as abdominal pain that lasts longer than 2-3 days, vaginal bleeding and/or discharge, fever, or chills will be assessed at each study visit after obtaining either Pap smear or cervical biopsy.

2. Occurrences related to side effects from prescribed medications related to the study:

If a medication(s) are prescribed for treatment of an infection, subjects will be assessed for any potential side-effects at each visit. These symptoms may include: upset stomach, vomiting or diarrhea, sensitivity to light, rash, severe allergic reaction that could cause death, dizziness, headache, confusion, ringing in the ears or hearing loss, seizures, heart problems, blood disorders, problems with blood sugar, liver disease, kidney disease, and pain or numbness in the arms or legs.

3. New medical problem(s) or worsening of an existing medical problem(s)

Study staff will inquire about any new medical problem or worsening of an existing medicalproblem since the subject's last visit.

Any medical condition that is present at the time of the Enrollment Visit should be considered as the baseline for this pre-existing condition and not reported as an adverse event. However, if there is an increase in the frequency or severity of the condition, it will be recorded as an adverse event. Anticipated day-to-day fluctuations of pre-existing conditions, which do not represent clinically significant exacerbation, will not be considered adverse events.

All AEs will be graded for severity and relationship to study procedures or treatment.

Classification of Severity of Adverse Event:

For adverse events that do not fall under the three categories listed above (occurrences related to study procedures, medications, or new or worsening existing medical problems), the following guidelines will be used to quantify severity:

Mild: adverse events that require minimal or no treatment and do not interfere with the patient's daily activities.

Moderate: adverse events that result in a low level of inconvenience for the patient's daily activities or concern with the study treatment or procedures. Moderate events may cause some interference with functioning.

Severe: adverse events that interrupt a patient's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating.

Life threatening: any adverse event that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.

Changes in the classification of severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity. Adverse events characterized as intermittent require documentation of onset and duration of each episode.

All AEs will be categorized by the study physician.

Relationship of Adverse Event to Study Procedures:

All AEs must have their relationship to study procedures assessed by the study clinician.

The terms used to assess the relationship of an AE to the study procedures are:

1. **Related**- There is a reasonable possibility that the AE may be related to the study agent.
2. **Not Related**- There is not a reasonable possibility that the AE is related to the study agent.

When an AE is assessed as "not related" to study agent(s), and alternative etiology, diagnosis, or explanation for the AE should be provided.

Outcome of Adverse Event:

All AEs must have their outcome assessed as either "resolved without sequelae", "resolved with sequelae", "ongoing", "death", "unknown." The study clinican is responsible for assessing outcomes and recording them on the appropriate CRF.

Definition of Serious Adverse Event (SAE*)*

An SAE is defined as an AE that meets one of the following conditions:

- Death during the period of protocol defined surveillance
- Life-threatening event (defined as a subject at immediate risk of death at the time of the event)
- An event requiring inpatient hospitalization or prolongation of existing hospitalization during the period of protocol defined surveillance
- Results in congenital anomaly or birth defect
- Results in a persistent or significant disability/incapacity
- Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based

upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Data Safety and Monitoring Plan

Introduction

The data safety and monitoring board (DSMB) will act in advisory capacity to the CDC, UW, KNH, UoN, Coptic Hospital, and IARC – WHO to monitor patient safety and evaluate treatment interventions for this study. Dr. Scott McClelland (UW) will be Chairman of the DSMB.

After its first meeting around study initiation, the DSMB will be responsible for reviewing interim safety and efficacy analyses at five time points during the 3 year study period. These meetings and reviews of interim analyses are expected to occur at approximately 4, 9, 15, 21, and 27 months after study initiation.

1) The first meeting will take place when 100 participants have received the study intervention, and this is expected to occur around 4 months after study initiation.

2) The second meeting will take place when 75 participants have received Month 6 Pap smear results, and this is expected to occur around 9 months after study initiation.

3) Thereafter, DSMB meetings and interim analyses will occur every 6 months after this second meeting or approximately at 15, 21, and 27 months after study initiation.

The DSMB will have the following responsibilities:

1. Review the research protocol and plans for data safety and monitoring;

2. Evaluate the progress of the trials, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome;
3. Protect the safety of the study participants and review interim or cumulative data for evidence of adverse events;
4. Review safety and progress report from an unblinded statistician who will use both blinded and unblinded data;
5. Make recommendations to the institutions involved and the PIs concerning continuation, termination or other modifications of the trials based on the observed beneficial or adverse effects of the treatment under study;
6. Review report on interim analysis of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis and have the approval of the DSMB;
7. Ensure the confidentiality of the trial's data and the results of monitoring; and
8. Review issues that have been identified by the study team and upon request by the study team, review problems that are identified by the monitors in relation to patient safety.

DSMB Recommendations

The DSMB may conclude each review with recommendations to continue the trial without change, modification of the trial, or termination of the trial based on pre-defined criteria established at the beginning of the trial.

Recommendations for modification of the design and conduct of the trial may include:

1. Modifications of the study protocol based upon the review of the safety data;

2. Suspension or early termination of the study because of serious concerns about subjects' safety, inadequate performance or rate of enrollment;
3. Suspension or early termination of the study because study objectives have been obtained according to pre-established statistical guidelines;
4. Optional approaches for trial design when the DSMB determines that the incidence of primary study outcomes is substantially less than expected, such as recommendations to increase the number of trial centers or extend the recruitment period/follow-up period; and,

Confidentiality

Confidentiality will be maintained during all phases of DSMB review and deliberations. Only voting members of the DSMB will have access to interim analyses of outcome data by treatment group. Exceptions may be made when the DSMB deems it appropriate. DSMB members must maintain strict confidentiality concerning all privileged trial results ever provided to them. The DSMB will review data only by masked study group (such as ‘Intervention 1’ versus ‘Intervention 2’ rather than cryotherapy versus LEEP) unless the DSMB determines that the identities of the groups are necessary for their decision-making. Any request to unmask data must be made in writing.

Membership

The DSMB will be composed of four members chosen from both the U.S. and Kenya. The members include:

1. R. Scott McClelland, MD, MPH, Associate Professor of Medicine, Epidemiology and Global Health, UW;
2. Elizabeth Brown, ScD, Associate Member, FHCRC, Research Associate Professor, Department of Biostatistics, UW;

3. James Kiarie, MBChB, MMed, MPH, Professor of Obstetrics/Gynecology, KNH; and
4. David Eschenbach, MD, Professor, Women's Health, Chairman, Department of Obstetrics and Gynecology, UW
5. *Ad hoc* specialists may be invited to participate as non-voting members at any time if additional expertise is desired.

Meetings

The first meeting will take place either prior to trial initiation or early after the trial has been initiated to discuss the protocol. A designated DSMB member and the PIs will prepare the agenda to review initiation of the trial and reporting of adverse events. The DSMB will also review monitoring guidelines and approve or give recommendations..

Once the trial has been initiated, the DSMB will meet, as outlined above, to examine the accumulated safety and enrollment data, review study progress and discuss other factors (internal or external to the study) that might impact continuation of the trials as designed. A DSMB meeting may be requested by DSMB members or the Principal Investigators at any time to discuss safety concerns, and includes the occurrence of any Significant Adverse Event (SAE) that is associated with the study. The study team will provide the logistical management and support of the DSMB meetings. The meetings will be convened by teleconference to decrease travel cost. An emergency meeting of the DSMB may be called at any time should questions of patient safety arise.

Meeting Format

The meetings will mainly be open sessions. These sessions will be attended by the Principal Investigators or designee. Other research staff may attend the open sessions but this is up to the discretion of the PI. Issues discussed at open sessions will include conduct and

progress of the study, including patient accrual, compliance with protocol, and problems encountered. Patient-specific data and treatment group data will not be presented in these sessions.

Closed sessions may be requested by the DSMB at any time and will be attended by voting DSMB members and the unblinded statistician. Any other trial staff may be requested to attend by the DSMB. All safety and efficacy data will be presented at this session. The discussion at the closed session is completely confidential.

Should the DSMB decide to issue a termination recommendation, the full vote of the DSMB will be required. In the event of a split vote, majority vote will rule and a minority report will be appended. An appeal may be filed by study PIs if a termination decision is made.

Study Stopping Criteria

The DSMB may recommend stopping the study for the following reasons:

- The data show a significantly increased risk of serious adverse effects in one of the treatment arms.
- Interim efficacy analyses show significant treatment benefits or futility in the one treatment group. The interim efficacy analyses are based on pre-specified stopping boundaries for the primary endpoint of the study which preserve the study wide Type I error rate.
- It becomes clear that successful completion of the study is not feasible (e.g. there is an excess of patient dropout, missing data, lack of recruitment etc).

Interim Efficacy Analyses

This study will employ interim analyses to assess accumulating study data for early evidence of treatment efficacy. The primary outcome, recurrence of cervical intraepithelial neoplasia grade 2 or 3, will be compared between groups at the following approximate times: months 9, 15, 21 and 27, and for DSMB safety, upon cumulative enrollment and intervention of 100patients. The decision criteria for stopping the study at each interim analysis are based on O'Brien-Fleming superiority boundary with Type I error controlled at alpha-level$\alpha = 0.05$. In the event that interim analyses are conducted at times other than the preplanned times (e.g. unequal information accrual) the stopping criteria will be adjusted to maintain overall type I error rate of $\alpha=0.05$. We will use Lan-DeMets alpha spending approach,to make the necessary adjustments. The decision criteria for stoppage are based on a power of 80%to detect a treatment group difference at the end of study.

Report

A formal report prepared by an assigned administrator will be reviewed and approved by the DSMB chair, who will prepare a summary. The minutes and summary will be sent to the full DSMB within three weeks of the meeting. Once approved by the DSMB, the chair of the DSMB will sign on behalf of the board and the report will be forwarded to the participating institutions within 4 weeks of each meeting. The PIs will submit the results of these meetings to the UW Institutional Review Board (IRB),the KNH Ethics Review Committee (ERC), and the Centers for Disease Control (CDC) which is the study sponsor. Each report will conclude with a recommendation to continue or to terminate the study. This recommendation will be made by formal majority vote. A termination recommendation may be made by the DSMB at any time by majority vote. The report will not include un-blinded data or any discussion of the un-blinded data.

Any new findings discovered by the DSMB during the course of the study that may affect the willingness of subjects to remain in the study will be shared by the study doctor or nurse through direct discussions and printed pamphlets.

Sponsor Monitoring

As the study sponsor, the Centers for Disease Control (CDC) may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:

- CDC staff ("internal")
- authorized representatives of CDC (e.g., a contracted party considered to be "external")
- both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the Investigator's facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any study-related materials may be reviewed and the Investigator along with study staff should be available for discussion of findings.

The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the IECs/IRBs to review compliance and regulatory requirements.

Acronyms

AIDS – Acquired Immunodeficiency Syndrome

CCSP – Cervical Cancer Screening Program, Coptic Hope Center for Infectious Diseases

CDC – Centers for Disease Control

CIN – Cervical Intraepithelial Neoplasia

CIS – Carcinoma in situ

CVL – Cervicovaginal Lavage

HIV – Human Immunodeficiency Virus

HPV – Human Papillomavirus

IRB – Institutional Review Board

KNH – Kenyatta National Hospital

LEEP – Loop Electrosurgical Excision Procedure

OGAC – Office of the Global AIDS Coordinator

Pap – Papanicolaou

PEPFAR – President's Emergency Plan for AIDS Relief

PHE – Public Health Evaluation

RNA – Ribonucleic Acid

UNITID – University of Nairobi Institute of Tropical and Infectious Diseases

UoN – University of Nairobi

USA – United States of America

USG – United States Government

UW – University of Washington

VIA – Visual Inspection with Acetic Acid

Pre-Screening Talking Points for Clinic Staff

Dr. Michael Chung is conducting a research study at the Hope Center. This study examines what methods may best treat disease in a woman's private parts called the cervix. This disease is like a wound on the skin and can go away by itself. But in some cases, especially in women who have HIV, these wounds might become cancer. The study wants to see how treatment can prevent this problem from becoming cancer and how treatment might affect HIV. Those patients who enroll in the study will be given free screening for cervical disease that may develop into cancer and will also provide free treatment. Dr. Chung and other doctors from the University of Washington in America, the University of Nairobi, and Coptic Hospital are leading this study. You appear to be eligible to be in this study and can possibly enroll in this trial if you like. The study offers free screening for cervical disease and if treatment is received, further follow-up free testing and treatment over 2 years.

Participation in the research study is voluntary and does not affect your medical care at the Hope Center in any way. Free screening for cervical disease is also available at the Hope Center Cervical Cancer Screening Program even if you do not participate in this study.

The study may help you detect cervical disease that may be treated and prevent cervical cancer in the future. Are you interested in learning more about the study from the study nurse or doctor? They can explain the study in more detail if you are interested. If you are, we will send you to the study clinic right now. If not, you may go home or continue receiving care here from the pharmacy and laboratory.

Screening Talking Points for Study Staff

You are being invited to participate in a research study at the Hope Center. The study is being conducted by Dr. Michael Chung and other doctors from the University of Washington in America, Kenyatta National Hospital, and the Coptic Hospital. This study examines what methods may best treat disease of the female private parts called the cervix, and how treatment affects HIV levels. This disease is like a wound on the skin and can go away by itself. But in some cases, especially in women who have HIV, these wounds might become cancer.

You do not have to join the study. Whether or not you join the study will not impact your care at the Hope Center in any way. If you are eligible and participate in the study, you will receive free screening and treatment that will help detect and remove disease from your cervix that may lead to cancer. You will be asked questions and undergo a pelvic examination where our doctor and nurse can examine you to detect any areas that look like disease. After undergoing screening, we will ask you to return in 2 weeks to receive the results from the test. Most likely you will not need further treatment or tests after this. If, however, we find a result that might be disease, we will conduct another test to confirm the disease and the need for follow-up treatment.

If you are positive for cervical disease, you may enroll in a study to receive treatment. If you do, we will ask you to return every week for 3 weeks to examine you and test for any HIV that may be shed from your cervix after treatment. We will follow you for the next 2 years at 6 months intervals to test if there is any further disease. If it does, we will treat you. We will also draw blood from you in order to

see how much HIV is in your blood and what is your CD4 count. All of this is free of cost.

Free screening for cervical disease is also available at the Hope Center Cervical Cancer Screening Program regardless of whether you participate in this study or not.You are referred to us because the clinical officer has determined that you are a woman who may be eligible for this study.

- Are you over 18 years of age?
- Are you pregnant?
- Have you had a hysterectomy?
- Have you ever received treatment for cervical disease?
- Have you ever had a problem with bleeding?
- Have you initiated sexual intercourse?

If you are interested in the study, I will explain more about it from the informed consent form which I will give or read to you. If you still want to be in the study after reading or being read the informed consent, you can sign the form and we can enroll you in the study

Post-Medical Care Information

Cervical Cancer Screening

Pap smear or biopsy

After receiving a Pap smear or biopsy, you may have any of the following symptoms which are normal:

- Slight belly discomfort (like menstrual cramps, should not last more than 1-2 days)
- Slight bleeding from the vagina

We recommend you take paracetamol or ibuprofen for pain or cramps.

It is very uncommon to have severe problems but if you experience any of the following, **please notify the clinic or screening staff** (see contacts below) right away:

- Pain in the belly that lasts longer than 2-3 days
- Much bleeding from the vagina
- Bleeding from the vagina that is increasing in amount, or comes with belly pain
- Fever, chills

After a biopsy, it is important to wait 10 days before having sex. This will protect you and your partner from infection. (Please discuss with the screening nurse or doctor if you cannot wait and don't forget to take condoms!)

Treatment (cryotherapy or LEEP)

After receiving treatment, you may have any of the following symptoms which are normal:

- Belly pain like during your period (should not last longer than 1-2 days)
- Slight bleeding from the vagina for up to 1 week
- Clear fluid from the vagina (as long as 2 weeks)

The following symptoms are not normal and you should **contact screening staff** and **have medical attention as soon as possible** if you have:

- Severe belly pain
- Bleeding from the vagina that continues or is a large amount
- Fever, chills
- Cloudy (white) fluid from the vagina

After treatment, it is important to wait 4 weeks before having sex. This will protect you and your partner from infection. (Please discuss with the screening nurse or doctor if you cannot wait and don't forget to take condoms!)

Medications

You may receive medications (antibiotics) after treatment or to treat an infection found during your exams. Please follow the directions about how to take the medications carefully. If you have a severe problem after taking the medication or have any of the follow symptoms, please **stop the medication and contact screening staff**:

- upset stomach, vomiting
- severe diarrhea or diarrhea with blood
- sensitivity to light, rash
- dizziness, severe headache, confusion, ringing in the ears or hearing loss
- seizures (uncontrolled jerking of the body)
- heart problems

Screening Staff Contacts:

****EMERGENCY NUMBERS (24 HOURS): 020-272-2710 or 0733-771-288**

- Office 1: 0728-456-540
- Office 2: 020-271-2947
- Dr. Michael Chung: 020-271-2947
- Dr. Nelly Mugo: 020-273-6744
- Dr. Samir Sakr: 020-272-4737

Information for Spouses and Partners
Cervical Cancer Screening and Treatment

Treatment (cryotherapy or LEEP)

Your wife or partner has undergone the following treatment as part of a cervical cancer screening and treatment program:

☐ Cryotherapy

☐ LEEP

After treatment, it is important to wait 4 weeks before having sex. This is because HIV shedding may increase substantially (but temporarily) at the site of cryotherapy or LEEP. This shedding may increase the risk of HIV transmission to an uninfected partner or lead to HIV re-infection. If abstinence is impossible during the healing period, it is important to use a condom every time you have sex for at least 4 weeks after treatment.

Screening Staff Contacts:

If you need more information, you may call the following numbers Mon-Fri between 8am and 5pm: Office 1: 0728-456-540

- Office 2: 020-271-2947
- Cell: 0721-289-733
- Dr. Samir Sakr: 020-272-4737

Maelezo kwa mabwana na wapenzi.

Ukaguza na matibabu ya saratani ya mlango wa kizazi.

Matibabu ya Cryotherapy au LEEP

Mke au mpenzi wako amefanyiwa matibabu yafuatayo kama mojawapo wa mpangilio wa ukaguzi na matibabu ya saratani ya mlango wa kizazi:

☐ Cryotherapy

☐ LEEP

Baada ya matibabu ni muhimu usionane kimwili na mke au mpenzi wako kwa mda wa wiki nne. Hi ni kwa sababu idadi ya virusi vinanyosababisha ukimwi inaweza kuongezeka (kwa muda tu) katika sehemu iliyofanyiwa Cryotherapy au LEEP. Ongezeko la idadi ya virusi kwa mlango wa kizazi inaweza kuongezea hadhari ya kuambukiza mpenzi ambaye hajaambukizwa, au ongezeko la uambukizi mpya wa virusi vinavyosababisha ukimwi.Iwapo haiwezekani kujinyima kufanya mapenzi wakati huu ambapo mke au mpenzi wako anaendelea kupata nafuu, ni muhimu kutumia mpira wa kondomu kila wakati mnapoonana kimwili kwa mda wa wiki nne, baada ya kupokea matibabu.

Numbari za mawasiliano :

Iwapo ungependa kupewa maelezo zaidi, unaweza kupiga simu kwa numbari zifuatazo Jumatatu hadi ijumaa kuuanzia saa mbili asubuhi mpaka saa kumi na moja jioni.

Afisi 1: 0728-456-540

Afisi 2: 020-271-2947

- Rununu: 0721-289-733

STUDY WRITTEN CONSENT FORM

Cervical Treatment Study: Screening

INITIAL CONSENT

Full Title:

Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Investigators:

Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of Washington, 020 271-2947

Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology, Kenyatta National Hospital, 020 273-6744

Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

Hugo De Vuyst, MD, PhD, Epidemiologist, International Agency for Research on Cancer, World Health Organization, +33-472738521

Silvia Franceschi, MD, Epidemiologist, International Agency for Research on Cancer, World Health Organization, +33-4728404

Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington, +1-206-731-2425

Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-206-543-4278

Emergency telephone number staffed 24 hours a day: 020 271 2947, 0723 914 057 or 0721 289 733

Ethical Review Committee Chairperson: Professor A. N. Guantai, 020 2726300, Ext. 44102, 4435544355, can be contacted for questions about research subject rights

Researchers' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you information so you can decide if you want to be in the study. Please read the form carefully. You may ask questions about the purpose of the research and what we would ask you to do for the study. You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the research or this form. You may ask questions at any time (before, during, and after the study) about anything. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form. Please let us know if you would rather use the Kiswahili consent form.

Purpose of the Study

The reason we are doing this research project is to screen for disease which may lead to cervical cancer. Participation in this project lasts for up to 1 month. You were asked to participate in this project because you are:

- HIV-positive,
- currently receiving care at the Hope clinic,
- not pregnant,
- do not have a history of problems with bleeding,
- have not had a hysterectomy (an operation to remove the uterus),
- and have initiated sexual intercourse.

Cervical cancer is the most common cancer among young and middle-aged women in Kenya. More women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-infected women, cervical cancer is not common. However, in HIV-infected women, cervical disease that is not cancer is common. This disease is caused by a virus called the human papillomavirus (HPV). It is very important to find this disease and treat it before it becomes cancer. This study will screen you for cervical disease. If you screen positive for cervical disease, you may choose to enroll in a treatment study, or you will be referred elsewhere for treatment. The treatment study will be explained to you in detail before you decide. This screening study will have over 2,400 participants. By doing this study, we hope to provide free and comprehensive screening for HIV-positive women to prevent cervical cancer.

Procedures (see Appendix)

All participants will be asked to come for 1 to 3 visits over 1 month. All study visits will take from 20 to 40 minutes (Visit 1: consent process – 10 minutes, Pap smear – 20 minutes; Visit 2: review of Pap smear results – 10 minutes, colposcopy and biopsy – 30 minutes; Visit 3: review of biopsy results and discussion of treatment options – 30 minutes)

Visit 1:

If you agree, you will first undergo a pelvic exam with a Pap smear to see if you have a something like a wound (called a lesion). This lesion may possibly develop into cancer. A pelvic exam means that a doctor or nurse will examine your female parts. The Pap smear involves brushing the cervix with a small brush to collect material that can be looked at under a microscope (like a large magnifying glass).

Visit 2:

You will then return to this clinic 2 weeks later to find out the results of this test. Most of the time the results will show no disease or that we just have to repeat the Pap smear or visual inspection (VIA) every 6 months. If this is the case, then you will exit the study at this point and receive further follow-up at the Coptic Hope Cervical Cancer Screening Program (CCSP) or be asked to come back to the study clinic for a repeat Pap smear after 6 months. If we find lesions that need to be treated at these visits, we will discuss your treatment options with you in detail.

If you are screened and we find a lesion that needs to be looked at carefully, you will first have a pregnancy test. If you are pregnant, nothing more will be done until after you deliver. We will send you for special care at the Hope center to make sure you do not pass HIV to your baby (this care is called PMTCT), and you will exit the study and receive further follow-up at the CCSP. If you are not pregnant, we will look at your cervix with a type of magnifying lens called a colposcope. We will look closely at the cervix and take a piece out, about the size of a grain of rice. This is called a biopsy. We will look at this tissue biopsy under a microscope and share the results with you 4-6weeks later. This test is very good and will help us decide whether you need to have treatment.

There are some cells found in the cervix and the lining of the uterus. These are called 'glandular cells.' When Pap smear results show that your glandular cells are abnormal, the doctor will perform a procedure referred to as 'Endocervical Curettage (ECC).' This is a procedure where a spoon-shaped instrument called a 'curette' is used to scrape abnormal material from the passageway between the cervix and the uterus. This procedure obtains a small sample, which is then sent to the lab to be examined for abnormal cells. ECC is performed during colposcopy and takes just a few minutes to perform. You can expect to feel mild cramping, much like menstrual cramps following the procedure. If you are found to have abnormal cells but the doctor cannot see them by means of a colposcope, you will undergo ECC as described above.

Visit 3: You will return to this clinic in 4-6weeks for the biopsy results. If we find cervical disease that needs treatment, we will discuss your treatment options with you. You may choose to enroll in a further treatment study, which will be explained in detail at this time. If you prefer not to enroll in another study, you will be referred for treatment at Kenyatta National Hospital (KNH) and standard care at Coptic Hope Center. Whether you choose to accept study treatment or referral, you will be exited from this screening study at your third visit.

Contacting Participants

We will ask you to give us contact information like a phone number so we can call you if you do not come to a scheduled visit. We may ask about your health or where you are during these calls. It is important for you to come to all of your scheduled visits. If we cannot contact you by phone, we may try to visit you at your house. If this happens, we will not wear clothes that show we are health workers. You should tell us if you do not want to be contacted in this way. If you do not return for your Pap smear or biopsy results, we will also "flag" your Coptic Hope file so that you can be notified that you have available study results at your next clinic visit.

If study quality control procedures indicate that your Pap smear result is discordant from the original result you were given, we will ask you to return to the clinic to receive your new results and to discuss potential treatment options. At this point, you may be asked if you would like to re-enroll in the study.

Risks and discomforts of being in the study

This is an explanation of problems you may have through your participation in this study. Other problems not listed may happen as well.

Screening

Collection of samples through the pelvic exam may cause:

- mild discomfort as you are examined,
- a small amount of bleeding from the vagina for 1-2 days afterwards and
- mild to moderate cramping for around 5 minutes that is similar to mild period pain.

If you receive a biopsy, we ask that you do not have sex for 10 days. The reason is that if you are HIV-infected and your partner is not, then he may be at greater risk of becoming infected with HIV. If your partner is HIV positive, he may be at greater risk of getting re-infected with resistant HIV. Also, you need time to heal and will put yourself at higher risk of infection unless you give yourself this time. If you need help talking about these issues with your partner, a nurse, doctor or counselor can help you. We will give you free condoms to use if it is impossible for you to not have sex.

Another possible discomfort you may face is the worry or anxiety that you may have disease on your cervix. You may talk about this with a study nurse or doctor or if you would like talk to a counselor, we can help to arrange this.

We may find on screening that you have an infection. In this case we will give you a prescription for antibiotics. Side effects of these antibiotics may include: upset stomach, vomiting or diarrhea, sensitivity to light, rash, severe allergic reaction that could cause death, dizziness, headache, confusion, ringing in the ears or hearing loss, seizures (jerking of the body), heart problems, blood disorders, problems with blood sugar, liver disease, kidney disease and pain or numbness in your legs or arms. If you experience any of these problems, please report to study staff right away.

<u>Confidentiality</u>

The study staff will ask you for personal information that may be embarrassing to talk about like how many sexual partners you have had. You may choose not to answer any question. As part of the study, you may meet other patients from this clinic whom you know from outside the clinic. We have no plans to release your information to anyone other than the study researchers or appointed monitors. Sometimes committees that oversee research will examine study information to make sure nothing illegal or unethical is being done. Your personal information will be protected if this happens and will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or audit study activities. The reason for this would be to make sure that the study is being done the way it is supposed to be done. It would also make sure that your rights and health are protected. Your personal medical information will be kept confidential.

Alternative to taking part in this study

If you choose not to take part in this study, you will continue to receive medical care at the Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer screening at this clinic without having to enroll in this study.

Benefits of the study

Your participation will help us understand more about cervical disease. By participating in this study, you receive free screening for cervical disease. If you would like to know the results of the study you can contact the study office 6 months or 1 year after you leave the study.

Compensation for injury

There is no cost to you for participating in this study other than your time. The study will pay for all screening costs for tests provided at the study clinic. If any physical injuries happen to you as a result of study participation, the study will cover the costs of care. If you think you have an injury or illness related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or Dr. Nelly Mugo (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you or refer you for treatment.

Specimen and Data Storage and Use of your Samples for Future Studies

We would like to save your medical information and Pap smear, colposcopy and endocervical curettage samples in Kenya at the Coptic Hospital and Kenyatta National Hospital for future research. This research may be done by the University of Washington or by other researchers who are working with us on this study for ten years after the end of follow-up in the study. We will use these data and samples only for research related to cervical cancer and HIV. Before your samples leave the clinic, they will be assigned a code. Your name will not be on them. Your name will be linked to the code only for five years after the study is completed. After that time, the link between your name and the code on your samples and data will be destroyed. The Institutional Review Boards are committees that watch over the safety and rights of research participants at Kenyatta National Hospital and the University of Washington. They must approve any future research studies using your samples. If you do not want to have your samples saved for future research, you can still be in this study and your samples will be destroyed once testing for the study is completed. If you agree to store your samples now, but change your mind before the end of the study, let the study staff know and we will make sure that your samples do not get stored for future research. We will not sell your samples. Tests done on your samples may lead to a new invention or discovery. We have no plans to share any money or other benefits resulting from this invention or discovery with you.

Other information

Your medical information is confidential (or kept secret) and we will keep your records in a locked office. Your medical records and information about your participation in the research will be available to you and to the study team but not to anyone outside of the study without your agreement. If you agree, we will share the information from this study with your doctors at the Hope Center. This information may help them treat your HIV and give you better care. All of your records will be kept in locked areas and all computer information will be password protected.

University of Washington staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. You may refuse to participate or may leave from the study at any time without penalty or loss of benefit or help to which you have a right to. We will tell you if there is any new information about the treatments we are studying so you can decide if you want to leave the study. Your relationship with staff and services at Coptic Hope Center for Infectious Diseases will not be affected in any way if you do or do not participate or if you enter the program and leave later. Please inform study staff if you decide you would like to leave the study. You may be asked to give some final samples but you may refuse.

Study staff may decide to take you out the study if they find you may be harmed if you continue to participate. You may also be taken out of the study if the staff think you will not be able to follow study safety requirements.

Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr. Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

Signature of study staff_____ Date _____

Printed name of study staff_____

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I give permission to the researchers to use my medical records as described in this consent form. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Ethical Review Committee at Kenyatta National Hospital 726-300. I will receive a copy of this consent form if I would like one.

Please mark, initial and date one option:

_____I DO agree to store my samples and data for future research

_____I DO NOT agree to store my samples and data for future research

Signature or thumbprint of participant _____ Date _____

Printed name of participant_____

Copies to: Investigator and Subject

STUDY WRITTEN CONSENT FORM

Cervical Treatment Study: Screening

RE-ENROLLMENT CONSENT

Full Title:

Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Investigators:

Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of Washington, 020 271-2947

Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology, Kenyatta National Hospital, 020 273-6744

Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

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Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-206-543-4278

Emergency telephone number staffed 24 hours a day: 020 271 2947, 0723 914 057 or 0721 289 733

Ethical Review Committee Chairperson: Professor A. N. Guantai, 020 2726300, Ext. 44102, 44355, can be contacted for questions about research subject rights

Researchers' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you information so you can decide if you want to be in the study. Please read the form carefully. You may ask questions about the purpose of the research and what we would ask you to do for the study. You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the research or this form. You may ask questions at any time (before, during, and after the study) about anything. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form. Please let us know if you would rather use the Kiswahili consent form.

Purpose of the Study

The reason we are doing this research project is to screen for disease which may lead to cervical cancer. Participation in this project lasts for up to 1 month. You were asked to participate in this project because you are:

- HIV-positive,
- currently receiving care at the Hope clinic,
- not pregnant,
- do not have a history of problems with bleeding,
- have not had a hysterectomy (an operation to remove the uterus),
- and have initiated sexual intercourse.

Cervical cancer is the most common cancer among young and middle-aged women in Kenya. More women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-infected women, cervical cancer is not common. However, in HIV-infected women, cervical disease that is not cancer is common. This disease is caused by a virus called the human papillomavirus (HPV). It is very important to find this disease and treat it before it becomes cancer. This study will screen you for cervical disease. If you screen positive for cervical disease, you may choose to enroll in a treatment study, or you will be referred elsewhere for treatment. The treatment study will be explained to you in detail before you decide. This screening study will have over 2,400 participants. By doing this study, we hope to provide free and comprehensive screening for HIV-positive women to prevent cervical cancer.

Procedures (see Appendix)

All participants will be asked to come for 1 to 3 visits over 1 month. All study visits will take from 20 to 40 minutes (Visit 1: consent process – 10 minutes, Pap smear – 20 minutes; Visit 2: review of Pap smear results – 10 minutes, colposcopy and biopsy – 30 minutes; Visit 3: review of biopsy results and discussion of treatment options – 30 minutes)

<u>Visit 1</u>:

If you agree, you will first undergo a pelvic exam with a Pap smear to see if you have a something like a wound (called a lesion). This lesion may possibly develop into cancer. A pelvic exam means that a doctor or nurse will examine your female parts. The Pap smear involves brushing the cervix with a small brush to collect material that can be looked at under a microscope (like a large magnifying glass).

Visit 2:

You will then return to this clinic 2 weeks later to find out the results of this test. Most of the time the results will show no disease or that we just have to repeat the Pap smear or visual inspection (VIA) every 6 months. If this is the case, then you will exit the study at this point and receive further follow-up at the Coptic Hope Cervical Cancer Screening Program (CCSP) or be asked to come back to the study clinic for a repeat Pap smear after 6 months. If we find lesions that need to be treated at these visits, we will discuss your treatment options with you in detail.

If you are screened and we find a lesion that needs to be looked at carefully, you will first have a pregnancy test. If you are pregnant, nothing more will be done until after you deliver. We will send you for special care at the Hope center to make sure you do not pass HIV to your baby (this care is called PMTCT), and you will exit the study and receive further follow-up at the CCSP. If you are not pregnant, we will look at your cervix with a type of magnifying lens called a colposcope. We will look closely at the cervix and take a piece out, about the size of a grain of rice. This is called a biopsy. We will look at this tissue biopsy under a microscope and share the results with you 4-6 weeks later. This test is very good and will help us decide whether you need to have treatment.

There are some cells found in the cervix and the lining of the uterus. These are called 'glandular cells.' When Pap smear results show that your glandular cells are abnormal, the doctor will perform a procedure referred to as 'Endocervical Curettage (ECC).' This is a procedure where a spoon-shaped instrument called a 'curette' is used to scrape abnormal material from the passageway between the cervix and the uterus. This procedure obtains a small sample, which is then sent to the lab to be examined for abnormal cells. ECC is performed during colposcopy and takes just a few minutes to perform. You can expect to feel mild cramping, much like menstrual cramps following the procedure. If you are found to have abnormal cells but the doctor cannot see them by means of a colposcope, you will undergo ECC as described above.

Visit 3: You will return to this clinic in 4-6 weeks for the biopsy results. If we find cervical disease that needs treatment, we will discuss your treatment options with you. You may choose to enroll in a further treatment study, which will be explained in detail at this time. If you prefer not to enroll in another study, you will be referred for treatment at Kenyatta National Hospital (KNH) and standard care at Coptic Hope Center. Whether you choose to accept study treatment or referral, you will be exited from this screening study at your third visit.

Contacting Participants

We will ask you to give us contact information like a phone number so we can call you if you do not come to a scheduled visit. We may ask about your health or where you are during these calls. It is important for you to come to all of your scheduled visits. If we cannot contact you by phone, we may try to visit you at your house. If this happens, we will not wear clothes that show we are health workers. You should tell us if you do not want to be contacted in this way. If you do not return for your Pap smear or biopsy results, we will also "flag" your Coptic Hope file so that you can be notified that you have available study results at your next clinic visit.

If study quality control procedures indicate that your Pap smear result is discordant from the original result you were given, we will ask you to return to the clinic to receive your new results and to discuss potential treatment options. At this point, you may be asked if you would like to re-enroll in the study.

Risks and discomforts of being in the study

This is an explanation of problems you may have through your participation in this study. Other problems not listed may happen as well.

Screening

Collection of samples through the pelvic exam may cause:

- mild discomfort as you are examined,
- a small amount of bleeding from the vagina for 1-2 days afterwards and
- mild to moderate cramping for around 5 minutes that is similar to mild period pain.

If you receive a biopsy, we ask that you do not have sex for 10 days. The reason is that if you are HIV-infected and your partner is not, then he may be at greater risk of becoming infected with HIV. If your partner is HIV positive, he may be at greater risk of getting re-infected with resistant HIV. Also, you need time to heal and will put yourself at higher risk of infection unless you give yourself this time. If you need help talking about these issues with your partner, a nurse, doctor or counselor can help you. We will give you free condoms to use if it is impossible for you to not have sex.

Another possible discomfort you may face is the worry or anxiety that you may have disease on your cervix. You may talk about this with a study nurse or doctor or if you would like talk to a counselor, we can help to arrange this.

We may find on screening that you have an infection. In this case we will give you a prescription for antibiotics. Side effects of these antibiotics may include: upset stomach, vomiting or diarrhea, sensitivity to light, rash, severe allergic reaction that could cause death, dizziness, headache, confusion, ringing in the ears or hearing loss, seizures (jerking of the body), heart problems, blood disorders, problems with blood sugar, liver disease, kidney disease and pain or numbness in your legs or arms. If you experience any of these problems, please report to study staff right away.

<u>Confidentiality</u>

The study staff will ask you for personal information that may be embarrassing to talk about like how many sexual partners you have had. You may choose not to answer any question. As part of the study, you may meet other patients from this clinic whom you know from outside the clinic. We have no plans to release your information to anyone other than the study researchers or appointed monitors. Sometimes committees that oversee research will examine study information to make sure nothing illegal or unethical is being done. Your personal information will be protected if this happens and will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or audit study activities. The reason for this would be to make sure that the study is being done the way it is supposed to be done. It would also make sure that your rights and health are protected. Your personal medical information will be kept confidential.

Alternative to taking part in this study

If you choose not to take part in this study, you will continue to receive medical care at the Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer screening at this clinic without having to enroll in this study.

Benefits of the study

Your participation will help us understand more about cervical disease. By participating in this study, you receive free screening for cervical disease. If you would like to know the results of the study you can contact the study office 6 months or 1 year after you leave the study.

Compensation for injury

There is no cost to you for participating in this study other than your time. The study will pay for all screening costs for tests provided at the study clinic. If any physical injuries happen to you as a result of study participation, the study will cover the costs of care. If you think you have an injury or illness related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or Dr. Nelly Mugo (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you or refer you for treatment.

Specimen and Data Storage and Use of your Samples for Future Studies

We would like to save your medical information and Pap smear, colposcopy and endocervical curettage samples in Kenya at the Coptic Hospital and Kenyatta National Hospital for future research. This research may be done by the University of Washington or by other researchers who are working with us on this study for ten years after the end of follow-up in the study. We will use these data and samples only for research related to cervical cancer and HIV. Before your samples leave the clinic, they will be assigned a code. Your name will not be on them. Your name will be linked to the code only for five years after the study is completed. After that time, the link between your name and the code on your samples and data will be destroyed. The Institutional Review Boards are committees that watch over the safety and rights of research participants at Kenyatta National Hospital and the University of Washington. They must approve any future research studies using your samples. If you do not want to have your samples saved for future research, you can still be in this study and your samples will be destroyed once testing for the study is completed. If you agree to store your samples now, but change your mind before the end of the study, let the study staff know and we will make sure that your samples do not get stored for future research. We will not sell your samples. Tests done on your samples may lead to a new invention or discovery. We have no plans to share any money or other benefits resulting from this invention or discovery with you.

Other information

Your medical information is confidential (or kept secret) and we will keep your records in a locked office. Your medical records and information about your participation in the research will be available to you and to the study team but not to anyone outside of the study without your agreement. If you agree, we will share the information from this study with your doctors at the Hope Center. This information may help them treat your HIV and give you better care. All of your records will be kept in locked areas and all computer information will be password protected.

University of Washington staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. You may refuse to participate or may leave from the study at any time without penalty or loss of benefit or help to which you have a right to. We will tell you if there is any new information about the treatments we are studying so you can decide if you want to leave the study. Your relationship with staff and services at Coptic Hope Center for Infectious Diseases will not be affected in any way if you do or do not participate or if you enter the program and leave later. Please inform study staff if you decide you would like to leave the study. You may be asked to give some final samples but you may refuse.

Study staff may decide to take you out the study if they find you may be harmed if you continue to participate. You may also be taken out of the study if the staff think you will not be able to follow study safety requirements.

Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr. Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

Signature of study staff_____ Date _____

Printed name of study staff_____

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I give permission to the researchers to use my medical records as described in this consent form. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Ethical Review Committee at Kenyatta National Hospital 726-300. I will receive a copy of this consent form if I would like one.

Please mark, initial and date one option:

Signature or thumbprint of participant _____ Date _____

Printed name of participant_____

Copies to: Investigator and Subject

STUDY WRITTEN CONSENT FORM

Cervical Treatment Study: Cryotherapy vs. LEEP

Full Title:

Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Investigators:

Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of Washington, 020 271-2947

Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology, Kenyatta National Hospital, 020 273-6744

Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

Hugo De Vuyst, MD, PhD, Epidemiologist, International Agency for Research on Cancer, World Health Organization, +33-472738521

Silvia Franceschi, MD, Epidemiologist, International Agency for Research on Cancer, World Health Organization, +33-4728404

Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington, +1-206-731-2425

Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-206-543-4278

Emergency telephone number staffed 24 hours a day: 020 271 2947, 0723 914 057 or 0721 289 733

Ethical Review Committee Chairperson: Professor A. N. Guantai, 020 2726300, Ext. 44102, 4435544355, can be contacted for questions about research subject rights

Researchers' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you information so you can decide if you want to be in the study. Please read the form carefully. You may ask questions about the purpose of the research and what we would ask you to do for the study. You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the research or this form. You may ask questions at any time (before, during, and after the study) about anything. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form. Please let us know if you would rather use the Kiswahili consent form.

Purpose of the Study

The reason we are doing this research project is to find the best treatment of disease which may lead to cervical cancer. Participation in this project lasts for 2 years. You were asked to participate in this project because you are:

- HIV-positive,
- currently receiving care at the Hope clinic,
- not pregnant,
- do not have a history of problems with bleeding,
- have not had a hysterectomy (an operation to remove the uterus),
- have initiated sexual intercourse
- have not received treatment for cervical disease in the past
- and have received a positive result for cervical disease from Pap smear and biopsy screening.

Cervical cancer is the most common cancer among young and middle-aged women in Kenya. More women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-infected women, cervical cancer is not common. However, in HIV-infected women, cervical disease that is not cancer is common. This disease is caused by a virus called the human papillomavirus (HPV). It is very important to find this disease and treat it before it becomes cancer. This study will compare two ways of treating cervical disease: cryotherapy and loop electrosurgical excision procedure (LEEP). Both treatments are commonly done for women around the world and are not new. We will explain these treatments for you. This study will have 400 participants. By doing this study, we hope to find the best way to treat HIV-positive women to prevent cervical cancer.

Procedures (see Appendix)

All participants will be asked for come for 5 to 8 visits over 2 years. All study visits will take from 15 to 40 minutes.

Randomization (Visit 1: review of biopsy results – 10 minutes, randomization and treatment– 30 minutes)

Based on your Pap smear and biopsy results, we have found cervical disease that needs treatment. If you decide to participate in this study, we will offer you one of two common and effective treatment methods. One method is called cryotherapy. It is a procedure which will freeze and remove the diseased part of your cervix. We freeze by touching your cervix with a small stick that is very cold. For cryotherapy, you will be offered an oral painkiller. The other method is called LEEP and uses a heated wire to do the same thing after the cervix is numbed by medication. The heated wire will scoop out the disease from the cervix.

You will be randomly assigned to one of these methods. Random assignment is like "flipping a coin." You have an equal chance of receiving either of these methods. We won't know which treatment you will receive until we open an envelope that has a sheet of paper telling us which treatment you will get. Neither of us will choose your treatment. We are randomly assigning one of

these methods because we do not know if one treatment is better than another for women who have HIV.

If we see that the diseased part of your cervix or 'lesion' is too large and cannot be treated well by cryotherapy, then we will not randomize you and will choose to treat you with LEEP. You will receive LEEP treatment free of charge and we will follow you every 6 months for 2 years. If the lesion cannot be treated well by either cryotherapy or LEEP, then we will refer you to Kenyatta National Hospital (KNH). At KNH you can receive different types of treatments at the lower cost of a government hospital. We will send copies of forms with you that will be important for your care. These forms will not show that you are part of a study. We will provide follow-up for you for 2 years after your care at KNH. If you agree to be treated by either cryotherapy or LEEP at the study clinic, 2 teaspoons (10 mls) of your blood will be taken with a needle from your arm. We will check a CD4 count and the levels of HIV in your blood. We will also brush your cervix and later test the sample for levels of HIV and for HPV. We would like to look at your medical records at the Hope Center. We want to gather a full picture of your prescribed medications and medical condition, the results of your laboratory tests, and your attendance in clinic.

Follow-up after Randomization (Visits 2-8: review results and cervical swab – 30 minutes)

If you are randomized to cryotherapy or LEEP, we will ask you to return again at the 1, 2, and 3-week visits after treatment. At these visits, we will draw 2 teaspoons (10mls) of blood and again brush your cervix to see how much HIV is there. We will want to see whether the level of virus is increased in your cervix after treatment and when it returns to usual levels.

If you are randomized or offered LEEP but not randomized, we will also ask you to return at 6, 12, 18, and 24 months after treatment for repeat Pap smears. This is to make sure that the diseased part of your cervix was completely removed and/or no new abnormal tissue has formed. We will also brush your cervix to test for HPV at this time and take 2 teaspoons (10 mls) of blood to measure your CD4 count and HIV viral levels. If we find more abnormal lesions at this time, we will treat you with LEEP or refer you for further care at KNH. The study will not pay for care you receive at KNH.

Contacting Participants

We will ask you to give us contact information like a phone number so we can call you if you do not come to a scheduled visit. We may ask about your health or where you are during these calls. It is important for you to come to all of your scheduled visits. We want to follow you carefully to find and treat any cervical disease you might have or develop later on. If we cannot contact you by phone, we may try to visit you at your house. If this happens, we will not wear clothes that show we are health workers. You should tell us if you do not want to be contacted in this way.

Risks and discomforts of being in the study

This is an explanation of problems you may have through your participation in this study. Other problems not listed may happen as well.

Treatment

There may be risks or discomforts from receiving treatment. If you have cryotherapy, then you may have:

- mild abdominal (or belly) cramps (usually last less than 10 minutes),

- fluid from the vagina for about 2 weeks (may last longer),

- bleeding,
- infection that we will need to treat here at the clinic or in rare cases, at the hospital. Infection may cause fevers, chills, night sweats, or white fluid from the vagina.

If you have LEEP, you may develop:

- bleeding during or after the procedure (you may have to return to the clinic if the bleeding starts and continues after the procedure is done)
- infection.

All of these complications can be treated with medications or treatments that will be provided free of charge by the clinic. Possible treatments may include:

- antibiotic medications to treat infection,
- packing the vagina with bandages to stop bleeding,
- putting stitches in the cervix to stop bleeding or
- hospitalization for severe infection or bleeding.

Please tell us if you have any of these problems after treatment. If you have received cryotherapy or LEEP, then we ask that you do not have sex for 4 weeks after it is performed. The reason is the same that your partner may be at greater risk of becoming infected with HIV. Also, you may be at greater risk of getting an infection. We can help you to discuss this with your partner.

All participants who have treatment (cryotherapy or LEEP) will get a prescription for antibiotics. These antibiotics include doxycline, metronidazole or norfloxacin.

Effects of these antibiotics may include upset stomach (must avoid alcohol for 2 days), vomiting or diarrhea, sensitivity to light, rash, dizziness, headache, confusion, seizures (jerking of the body), heart problems, blood disorders, problems with blood sugar, problems, liver disease and pain or numbness in your legs or arms. Any reaction to medications should be reported right away to study staff.

After having the treatment, there is a small chance that you may have problems later with pregnancy. After having LEEP, some women have problems when they are pregnant including infections, early contractions or problems with the cervix. Some women develop a tightened opening of their cervix that must be stretched. Other women have had their water break early or had babies born early possibly because of the operation on their cervix.

<u>Blood draw</u>

We will be collecting blood samples, 2 teaspoons (10 mls), from you using a new needle and syringe. The puncture of the needle may be uncomfortable and leave a bruise. It may also cause infection or fainting.

<u>Confidentiality</u>

The study staff will ask you for personal information that may be embarrassing to talk about like how many sexual partners you have had. You may choose not to answer any question. As part of the study, you

may meet other patients from this clinic whom you know from outside the clinic. We have no plans to release your information to anyone other than the study researchers or appointed monitors. Sometimes committees that oversee research will examine study information to make sure nothing illegal or unethical is being done. Your personal information will be protected if this happens and will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or audit study activities. The reason for this would be to make sure that the study is being done the way it is supposed to be done. It would also make sure that your rights and health are protected. Your personal medical information will be kept confidential.

Alternative to taking part in this study

If you choose not to take part in this study, you will continue to receive medical care at the Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer screening at this clinic without having to enroll in this study. The Coptic Hope Clinic can provide you with Cryotherapy treatment even if you do not enroll in this study. We can also refer you to Kenyatta National Hospital for different types of treatments at the lower cost of a government hospital.

Benefits of the study

Your participation will help us understand more about cervical disease. This may change the way cervical disease is found and treated in developing countries like Kenya. If you would like to know the results of the study you can contact the study office 6 months or 1 year after you leave the study.

Compensation for injury

There is no cost to you for participating in this study other than your time. The study will pay for all screening and treatment costs for tests and therapy provided at the study clinic. If any physical injuries happen to you as a result of study participation, the study will cover the costs of care. Treatment includes antibiotics, pain relief, and methods to stop bleeding. If you think you have an injury or illness related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or Dr. Nelly Mugo (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you or refer you for treatment.

Specimen and Data Storage and Use of your Samples for Future Studies

We would like to save your medical information and samples of your blood and cervix in Kenya at the Coptic Hospital and Kenyatta National Hospital for future research. This research may be done by the University of Washington or by other researchers who are working with us on this study for ten years after the end of follow-up in the study. We will use these data and samples only for research related to cervical cancer and HIV. Before your samples leave the clinic, they will be assigned a code. Your name will not be on them. Your name will be linked to the code only for five

years after the study is completed. After that time, the link between your name and the code on your samples and data will be destroyed. The Institutional Review Boards are committees that watch over the safety and rights of research participants at Kenyatta National Hospital and the University of Washington. They must approve any future research studies using your samples. If you do not want to have your samples saved for future research, you can still be in this study and your samples will be destroyed once testing for the study is completed. If you agree to store your samples now, but change your mind before the end of the study, let the study staff know and we will make sure that your samples do not get stored for future research. We will not sell your samples. Tests done on your samples may lead to a new invention or discovery. We have no plans to share any money or other benefits resulting from this invention or discovery with you.

Other information

Your medical information is confidential (or kept secret) and we will keep your records in a locked office. Your medical records and information about your participation in the research will be available to you and to the study team but not to anyone outside of the study without your agreement. If you agree, we will share the information from this study with your doctors at the Hope Center. This information may help them treat your HIV and give you better care. Some of your samples including blood and samples from the cervix may be sent to the USA or Europe for testing. Your information and samples will still be protected if this happens. All of your records will be kept in locked areas and all computer information will be password protected.

University of Washington staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined.

You may refuse to participate or may leave from the study at any time without penalty or loss of benefit or help to which you have a right to. We will tell you if there is any new information about the treatments we are studying so you can decide if you want to leave the study. Your relationship with staff and services at Coptic Hope Center for Infectious Diseases will not be affected in any way if you do or do not participate or if you enter the program and leave later. Please inform study staff if you decide you would like to leave the study. You may be asked to give some final samples but you may refuse.

Study staff may decide to take you out the study if they find you may be harmed if you continue to participate. You may also be taken out of the study if the staff think you will not be able to follow study safety requirements.

Transportation costs of Ksh 300 will be given to you when you return to the clinic for a study-related visit. You will receive transport money from the study receptionist.

Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr. Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

Signature of study staff_____ Date _____

Printed name of study staff_____

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I give permission to the researchers to use my medical records as described in this consent form. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Ethical Review Committee at Kenyatta National Hospital 726-300. I will receive a copy of this consent form if I would like one.

Please mark, initial and date one option:

_____I DO agree to store my samples and data for future research

_____I DO NOT agree to store my samples and data for future research

Signature or thumbprint of participant _____

Date _____

Printed name of participant_____

Copies to: Investigator and Subject

MAKUBALIANO YA PAMOJA

KISWAHILI CONSENT FORM

MATIBABU YA SARATANI YA MLANGO WA KIZAZI: UCHUNGUZI

IDHINI YA AWALI

WATAFITI

Michael H Chung, MD. MPH, Mkufunzi, Idara ya utabibu, Chuo Kikuu cha Washington 272-2710

Nelly Mugo, MBChB, MMed, MPH, Gainakolojia, Mhadhiri, Idara ya Ukunga na Gainakologia, Hospitali kuu ya Kenyatta, 020-273-6744

Sarah Sakr, MBChB, Msimamizi wa afya, Hospitali ya Coptic, Kenya 020-272-4737

Hugo De Vuyst, MD, PhD, Epidemiologisti, Idara ya Kimataifa ya Utafiti wa Saratani, Shirika la Afya la Dunia (WHO), +33-472738521

Silvia Franceschi, MD, Epidemiologisti, Idara ya Kimataifa ya Utafiti wa Saratani, Shirika la Afya la Dunia (WHO), +33-4728404

Barbara Richardson, PhD, Profesa Msaidizi katika Utafiti, Idara ya Biostatistiki, Chuo Kikuu cha Washington, +1-206-731-2425

Grace John Stewart, MD, PhD, Profesa, Kitivo Cha Utabibu, Chuo Kikuu Cha Washington, +1-206-543-4278

Nambari za simu ya dharura; 072-2710 au 0733-711-288

Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102, 44355unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.

Ujumbe wa Watafiti

Tunakuuliza kushiriki katika utafiti huu wa kitaalamu. Lengo la fomu hii ya idhini ni kukupa habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la. Tafathali soma maelezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote, haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usicho elewa kwenye fomu hii. Tukishajibu maswali yako yote, unapaswa kuamua kushiriki kwenye utafiti huu au la. Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadhia. Tafadhali tujulishe iwapo ungependa kutumia lugha ya Kingereza.

Lengo la Utafiti huu.

Mathumuni ya mradi huu wa utafiti ni kukupima njia yako ya uzazi kuthibitisha ikiwa una dalili inayoashiria kuwa unaweza kupata saratani ya mlango wa uzazi (cervical cancer). Umeulizwa kushiriki katika utafiti huu kwa sababu;

- Umeambukizwa maradhi ya UKIMWI
- Unapata matibabu katika kituo cha matibabu cha Hope
- Hauna Mimba
- Hauna historia ya shida ya kuvuja damu
- Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- Umewahi fanya ngono

Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamu nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma” (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya mlango wa kizazi.

Utafiti huu utakupima mlango wako wa uzazi. Iwapo wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, unaweza kujiunga na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza kutumwa upate matibabu kwingine.Tutakuelezea njia za matibabu kabla hujaamua kujiunga na utafiti huo. Katika utafiti huu, tutakuwa na washiriki takriban 2,400. Utafiti huu utatuwezesha kupima wanawake bila malipo ili kuwawezesha wale wanoishi na virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila saratani ya mlango wa kizazi.

Hatua ya kushiriki katika utafiti

Washirika wote watahitajika kutembelea kiliniki mara 1 au 2 au 3. Kila mara, mshirika atatumia dakika 20 hadi 40 katika kiliniki.

Uteuzi; (Kutembelea kiliniki Mara Ya 1;Makubaliano - dakika 10, Pap Smear-dakika 20; Kutembelea kiliniki Mara Ya 2; Marejeleo ya Matokeo ya Pap Smear- dakika 10, Colposcopy na Biopsy (ikihitajika)- dakika 30; Kutembelea kiliniki mara ya 3; Marejeo ya matokeo ya biopsy na kujadili juu ya njia za matibabu- dakika 30)

Kutembelea kiliniki mara ya 1:

Ukikubali kushiriki katika utafiti huu, kwanza utahitajika kuchunguzwa fupanyonga (Pelvic exam) kwa kupanguzwa sehemu yako ya siri kutumia burashi ili kuthibitisha ikiwa una dalili inayoashiria kuwa na virusi vinavyoweza kusababisha saratani ya mlango wa uzazi (Pap Smear). Kuchunguzwa fupanyonga, kunamaanisha kuwa muuguzi atakagua sehemu zako za siri (uke wako). Pap smear

itajumuisha utumiaji wa burashi ndogo iingizwayo kwenye kizazi ili kuchukua chembe chembe zitakazochunguzwa kwa kutumia "mikroskope". Kisha utahitajika kurudi katika kiliniki baada ya majuma mawili ili kuchukua matokeo ya uchunguzi huu.

Kutembelea kiliniki mara ya 2:

Utarejea kwenye kiliniki baada ya wiki mbili ili kupata matokeo ya pap smear. Mara nyingi, matokeo huwa ni sawa (hakuna kasoro) na mtu hahitaji matibabu ya ziada, ila kurudia "Pap smear" tena baada ya kila miezi sita au kufanyaukaguzi na asidi asetiki (VIA) baada ya miezi sita. Ikiwa hujambo utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic Hope Cervical Cancer Screening Program (CCSP)*] ampapo utapokea VIA, au utaulizwa kurudi katika kiliniki ya utafiti baada ya miezi sita ili kurudia "Pap smear".

Wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, watakuelezea juu ya matibabu.

Lakini watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri kwa makini. Kwanza utapimwa kama wewe ni mjamzito. Kama wewe ni mjamzito, Hakuna utafiti mwingine utaendelea hadi utakapojifungua mtoto. Watafiti watakutuma kupata matibabu ya dharura katika kituo cha Hope ili kuhakikisha hauambukizi mtoto wako virusi vinavyosababisha ukimwi (PMTCT). Kisha utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre,[*Coptic Hope Cervical Cancer Screening Program (CCSP)*].

Ikiwa wewe si mjamzito, watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri kwa makini wakitumia chombo kiitwacho "colposcope", ili kuchukua tishu, kiwango kama kipande kimoja cha mchele, utarabu huu unajulikana kama "Biopsy". Tishu iliyochukuliwa, itachunguzwa kwa mikroskope na utajulishwa matokeo baada ya wiki nne hadi sita. Mwenendo huu wa kupima ambao majibu yake huwa ni sahihi utatuwezesha kujua kana kwamba unahitaji matibabu.

Kuna chembe chembe za ndani ya njia ya kizazi katikati ya mlango wa kizazi na kizazi na pia zinaendelea mpaka ndani ya kizazi. Hizi chembe chembe zinaitwa 'glandular cells'. Ikiwa majibu ya pap smear itaonyesha 'glandular' cells si kawaida, daktari ata gwaruza kwa njia ya kizazi kutumia chombo chenye umbo cha kijiko ili sampuli ndogo ipatikane ya kukaguliwa. Utaratibu huu unaitwa 'Endocervical curettage (ECC)'. Kukwaruza inafanywa wakati 'colposcopy' na inachukuwa dakika chache. Unaweza pata maumivu ya tumbo kidogo kama wakati unapo pata damu ya mwezi. Pia, kama chembe chembe za mlango wa kizazi kwa pap smear inaonyesha si kawaida na mabadiliko ya ugonjwa kwa mlango wa kizazi wakati wa colposcopy haionekani, hii kukwaruza itafanywa kama vile imeelezwa hapo mbeleni.

Kutembelea kiliniki mara ya 3:

Utarejea kwenye kiliniki kati ya wiki nne na wiki sitaili kupata matokeo ya biopsy. Iwapo tutagundua maambukizi yanayohitaji matibabu, tutakujulisha matibabu ambayo unaweza pata. Unaweza kujiunga na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza chagua matibabu kwingine, au tunaweza kukutuma Hospitali Kuu ya Kenyatta (KNH) na uendelee kupokea

matibabu yako ya kawaida katika Coptic Hope Center.Ukichagua kuendelea na utafiti wa matibabu au la, katika kiwango hii, tutakuondoa katika utafiti wa kupimwa mlango wa kizazi.

Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kliniki.

Kuwasiliana na Washiriki

Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa. Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza kukutembelea kwako nyumbani. Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi yatakayoashiria kuwa sisi ni wahudumu katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii ya mawasiliano.Usiporejea kupokea matokeo yako ya pap smear au biospy, tutawasiliana na wafanyi kazi wa mapokezi ya Coptic waweke mawaidha kwa faili yako ili unaporejea kwa matibabu yako ya kawaidia, utakumbushwa kupitia kwenye kiliniki ya utafiti kupokea matokeo yako.

Kamataratibu zakudhibiti ubora wautafitizinaonyesha kuwaPapsmearyakomatokeonitofautinamatokeoya awali uliyo pewa,tutakuuliza urudiklinikikupokeamatokeo yakompya nakujadilimatibabu inayowezekana.Katika hatua hii,unaweza kuulizwakamaungependakujiandikisha tena katikautafiti.

Athari na usumbufu wa kushiriki kwenye utafiti huu.

Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu. Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

Kiingilio (Screening)

Kuchukua sampuli kutoka kwenye fupanyonga (pelvic) kwaweza sababisha;

- kukerwa kidogo wakati ukaguzi ukiendelea,
- kutokwa na damu kidogo kwenye uke wako baadaye kwa siku moja au mbili, na
- kupata uchungu mdogo wa tumbo kama ule wa damu ya mwezi kwa dakika tano hivi.

Ukifanyiwa uchunguzi wa “Biopsy” kwenye fupanyonga (Pelvic), tunakusihi usishiriki ngono kwa muda wa siku kumi. Hii ni kwa sababu ikiwa una virusi vinavyosababisha ukimwi na (HIV) ili hali mpenzio hana, atakuwa katika hatari kubwa zaidi ya kuambukizwa na virusi hivi vya ukimwi. Ikiwa mpenzi wako ana virusi vinavyosababisha ukimwi, atakuwa katika hatari kubwa ya kuambukizwa tena na virusi stahimilivu vinavyosababisha ukimwi. Pia, wewe unahitaji muda wa kupona na utajiweka katika hatari ya maambukizi usipojipatia muda huu. Iwapo unahitaji msaada wowote wa

kuongelea mambo haya na mpenzi wako, muuguzi, daktari au mshaurikatika hospital atakusaidia. Tutakupatia mipira ya kondomu bila malipo iwapo hutaweza kutoshiriki katika ngono.

Athari nyengine unayoweza kukumbana nayo ni wasiwasiya kuwa una ugonjwa katika mlango wako wa uzazi. Unaweza kuongea kuhusu jambo hili na muuguzi wa kitafiti, daktari, au ukitaka kuongea na mshaurikatika hospitali, tutakusaidia kupanga haya.

Tunaweza kugundua katika kiingilio kuwa una maambukizo. Iwapo utapatikana na maambukizo, tutakupa maagizo ya kupata dawa. Madhara ya dawa hizi yanaweza kuwa kuumwa na tumbo, kutapika na kuharisha, usikivu wa mwangaza, mwasho, mzio mkali mmenyuko unaoweza kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa, kupigapiga kwenyemasikio au kupoteza usikivu, mshtuko wa mwili (jerking of the body), maumivu ya moyo, machafuko ya damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au kuganda kwenye mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi katika utafiti huu mara moja.

Uwekaji wa siri

Wahudumu katika utafiti huu,watakusanya habari ya binafsi na waweza kuona aibu kuongea kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao umewajua mbeleni.Hatuna mpango wa kupeana habari yako ya kibinafsi kwamtu yeyote nje ya utafiti huuisipokuwa watafiti au wachunguzi walioteuliwa.Wakati mwingine kamati inayosimamia utafiti huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi huu.Kamamdhamini wautafiti, CDC wanaweza kufuatiliaaukukaguashughuli zautafiti.Sababu hiiitakuwakuhakikishakuwa utafitiunafanyika kwanjiainayotakiwa, napia kuhakikishakwamba hakiyakonaafya yako inalindwa.Matibabuyakotaarifa binafsiitakuwasiri.

Mbadala wa kujiunga na utafiti huu

Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata matibabu na dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi wa saratani ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika utafifi huu.

Manufaa kutokana na utafiti huu

Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa nyumba ya uzazi. Kwa kujiunga na utafiti huu, utapata kupimwa mlango wako wa uzazi bila malipo. Kama ungependa kujua matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita au mwaka mmoja baada ya kumaliza utafiti huu.

Gharama na Fidia ya Majeraha

Hakuna gharama yoyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu utalipia gharama ya uchanguzi wowote utakayopokea kwenye kiliniki ya utafiti. Ikiwa Utapata majereha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo ya utunzaji. Ikiwa unafikiri kuwa umepata jeraha ama maumivu kutokana na utafiti huu, wasiliana na wahudumu wa utafiti huu, (Daktari Michael Chung (020-272-2710) au Daktari Nelly Mugo (020-273-

6744) au Daktari Evans Malava (0721 289 733)) mara moja. Watakuhudumia kwa matibabu au kukupendekeza kwa matibabu.

Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye

Tungependa kuhifadhi habari yako ya matibabu na sampuli za pap smear na biopsy katika Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya utafiti wa baadaye. Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti wengine wanaofanya kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa kufuatiliwa katika utafiti. Tutatumia data na sampuli hizi kwa minajili ya utafiti unaoegemea na saratani ya mlango wa kizazi na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa kifichomaalumu Jina lako halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano pekee yake baada ya kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na kificho kilichoko katika sampuli na data kitaangamizwa. Bodi za taasisi ya mapitio ni kamati zinazoagalia usalama na haki za washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu cha Washington. Lazima ziidhinishe utafiti wowote wa baadaye utakaotumia sampuli na data yako. Ikiwa hupendi sampuli zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika utafiti huu na sampuli zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhufadhi wa sampuli zako leo, kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamishe watafiti ambao watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye. Hatutauza sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika uvumbuzi mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo zitakazotokana na uvumbuzi huu -

Maelezo ya ziada

Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na kikundi cha watafiti pekee wala si mtu mwengine yeyote nje ya utafiti huu bila idhini yako. Ikiwa utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza kuwasaidia kukupa matibabu na huduma bora ya UKIMWI.Rekodi zako zote zitahifadhiwa katika sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri la kuhakikisha ulinzi.

Wakati mwengine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika, rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious diseases, hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia kwenye mpangilio halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamishe wahudumu wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana sampuli za mwisho lakini waweza kukataa.

Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr (272-4737), au Daktari Nelly Mugo (273-6744).

Je, una maswali yeyote?

Sahihi ya mtafiti…… Tarehe……..

Jina la Mtafiti……

Muhusika

Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali kuhusu haki yangu kama mhusika kwenye utafiti , naweza piga simu kwa kamati ya uchunguzi wa maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa nakala ya fomu hii yangu binafsi.

Tafadhali tia alama , ufupi wa jina na anwani katika chaguo moja:

_____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

_____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

Sahihi au alama ya kidole cha gumba cha mshiriki _____

Tarehe_____

Jina la Mshiriki lililochapishwa_____

Nakala kwa Mtafiti na Mshiriki

MAKUBALIANO YA PAMOJA

KISWAHILI CONSENT FORM

MATIBABU YA SARATANI YA MLANGO WA KIZAZI: UCHUNGUZI

UANDIKISHAJI UPYA

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Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102, 44355unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.

Ujumbe wa Watafiti

Tunakuuliza kushiriki katika utafiti huu wa kitaalamu. Lengo la fomu hii ya idhini ni kukupa habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la. Tafathali soma maelezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote, haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usicho elewa kwenye fomu hii. Tukishajibu maswali yako yote, unapaswa kuamua kushiriki kwenye utafiti huu au la. Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadhia. Tafadhali tujulishe iwapo ungependa kutumia lugha ya Kingereza.

Lengo la Utafiti huu.

Mathumuni ya mradi huu wa utafiti ni kukupima njia yako ya uzazi kuthibitisha ikiwa una dalili inayoashiria kuwa unaweza kupata saratani ya mlango wa uzazi (cervical cancer). Umeulizwa kushiriki katika utafiti huu kwa sababu;

- Umeambukizwa maradhi ya UKIMWI
- Unapata matibabu katika kituo cha matibabu cha Hope
- Hauna Mimba
- Hauna historia ya shida ya kuvuja damu
- Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- Umewahi fanya ngono

Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamu nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma” (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya mlango wa kizazi.

Utafiti huu utakupima mlango wako wa uzazi. Iwapo wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, unaweza kujiunga na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza kutumwa upate matibabu kwingine.Tutakuelezea njia za matibabu kabla hujaamua kujiunga na utafiti huo. Katika utafiti huu, tutakuwa na washiriki takriban 2,400. Utafiti huu utatuwezesha kupima wanawake bila malipo ili kuwawezesha wale wanoishi na virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila saratani ya mlango wa kizazi.

Hatua ya kushiriki katika utafiti

Washirika wote watahitajika kutembelea kiliniki mara 1 au 2 au 3. Kila mara, mshirika atatumia dakika 20 hadi 40 katika kiliniki.

Uteuzi; (Kutembelea kiliniki Mara Ya 1;Makubaliano - dakika 10, Pap Smear-dakika 20; Kutembelea kiliniki Mara Ya 2; Marejeleo ya Matokeo ya Pap Smear- dakika 10, Colposcopy na Biopsy (ikihitajika)- dakika 30; Kutembelea kiliniki mara ya 3; Marejeo ya matokeo ya biopsy na kujadili juu ya njia za matibabu- dakika 30)

Kutembelea kiliniki mara ya 1:

Ukikubali kushiriki katika utafiti huu, kwanza utahitajika kuchunguzwa fupanyonga (Pelvic exam) kwa kupanguzwa sehemu yako ya siri kutumia burashi ili kuthibitisha ikiwa una dalili inayoashiria kuwa na virusi vinavyoweza kusababisha saratani ya mlango wa uzazi (Pap Smear). Kuchunguzwa fupanyonga, kunamaanisha kuwa muuguzi atakagua sehemu zako za siri (uke wako). Pap smear

itajumuisha utumiaji wa burashi ndogo iingizwayo kwenye kizazi ili kuchukua chembe chembe zitakazochunguzwa kwa kutumia "mikroskope". Kisha utahitajika kurudi katika kiliniki baada ya majuma mawili ili kuchukua matokeo ya uchunguzi huu.

Kutembelea kiliniki mara ya 2:

Utarejea kwenye kiliniki baada ya wiki mbili ili kupata matokeo ya pap smear. Mara nyingi, matokeo huwa ni sawa (hakuna kasoro) na mtu hahitaji matibabu ya ziada, ila kurudia "Pap smear" tena baada ya kila miezi sita au kufanyaukaguzi na asidi asetiki (VIA) baada ya miezi sita. Ikiwa hujambo utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic Hope Cervical Cancer Screening Program (CCSP)*] ampapo utapokea VIA, au utaulizwa kurudi katika kiliniki ya utafiti baada ya miezi sita ili kurudia "Pap smear".

Wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, watakuelezea juu ya matibabu.

Lakini watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri kwa makini. Kwanza utapimwa kama wewe ni mjamzito. Kama wewe ni mjamzito, Hakuna utafiti mwingine utaendelea hadi utakapojifungua mtoto. Watafiti watakutuma kupata matibabu ya dharura katika kituo cha Hope ili kuhakikisha hauambukizi mtoto wako virusi vinavyosababisha ukimwi (PMTCT). Kisha utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre,[*Coptic Hope Cervical Cancer Screening Program (CCSP)*].

Ikiwa wewe si mjamzito, watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri kwa makini wakitumia chombo kiitwacho "colposcope", ili kuchukua tishu, kiwango kama kipande kimoja cha mchele, utarabu huu unajulikana kama "Biopsy". Tishu iliyochukuliwa, itachunguzwa kwa mikroskope na utajulishwa matokeo baada ya wiki nne hadi sita. Mwenendo huu wa kupima ambao majibu yake huwa ni sahihi utatuwezesha kujua kana kwamba unahitaji matibabu.

Kuna chembe chembe za ndani ya njia ya kizazi katikati ya mlango wa kizazi na kizazi na pia zinaendelea mpaka ndani ya kizazi. Hizi chembe chembe zinaitwa 'glandular cells'. Ikiwa majibu ya pap smear itaonyesha 'glandular' cells si kawaida, daktari ata gwaruza kwa njia ya kizazi kutumia chombo chenye umbo cha kijiko ili sampuli ndogo ipatikane ya kukaguliwa. Utaratibu huu unaitwa 'Endocervical curettage (ECC)'. Kukwaruza inafanywa wakati 'colposcopy' na inachukuwa dakika chache. Unaweza pata maumivu ya tumbo kidogo kama wakati unapo pata damu ya mwezi. Pia, kama chembe chembe za mlango wa kizazi kwa pap smear inaonyesha si kawaida na mabadiliko ya ugonjwa kwa mlango wa kizazi wakati wa colposcopy haionekani, hii kukwaruza itafanywa kama vile imeelezwa hapo mbeleni.

Kutembelea kiliniki mara ya 3:

Utarejea kwenye kiliniki kati ya wiki nne na wiki sitaili kupata matokeo ya biopsy. Iwapo tutagundua maambukizi yanayohitaji matibabu, tutakujulisha matibabu ambayo unaweza pata. Unaweza kujiunga na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza chagua matibabu kwingine, au tunaweza kukutuma Hospitali Kuu ya Kenyatta (KNH) na uendelee kupokea

matibabu yako ya kawaida katika Coptic Hope Center.Ukichagua kuendelea na utafiti wa matibabu au la, katika kiwango hii, tutakuondoa katika utafiti wa kupimwa mlango wa kizazi.

Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kliniki.

Kuwasiliana na Washiriki

Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa. Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza kukutembelea kwako nyumbani. Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi yatakayoashiria kuwa sisi ni wahudumu katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii ya mawasiliano.Usiporejea kupokea matokeo yako ya pap smear au biospy, tutawasiliana na wafanyi kazi wa mapokezi ya Coptic waweke mawaidha kwa faili yako ili unaporejea kwa matibabu yako ya kawaidia, utakumbushwa kupitia kwenye kiliniki ya utafiti kupokea matokeo yako.

Kamataratibu zakudhibiti ubora wautafitizinaonyesha kuwaPapsmearyakomatokeonitofautinamatokeoya awali uliyo pewa,tutakuuliza urudiklinikikupokeamatokeo yakompya nakujadilimatibabu inayowezekana.Katika hatua hii,unaweza kuulizwakamaungependakujiandikisha tena katikautafiti.

Athari na usumbufu wa kushiriki kwenye utafiti huu.

Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu. Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

Kiingilio (Screening)

Kuchukua sampuli kutoka kwenye fupanyonga (pelvic) kwaweza sababisha;

- kukerwa kidogo wakati ukaguzi ukiendelea,
- kutokwa na damu kidogo kwenye uke wako baadaye kwa siku moja au mbili, na
- kupata uchungu mdogo wa tumbo kama ule wa damu ya mwezi kwa dakika tano hivi.

Ukifanyiwa uchunguzi wa “Biopsy” kwenye fupanyonga (Pelvic), tunakusihi usishiriki ngono kwa muda wa siku kumi. Hii ni kwa sababu ikiwa una virusi vinavyosababisha ukimwi na (HIV) ili hali mpenzio hana, atakuwa katika hatari kubwa zaidi ya kuambukizwa na virusi hivi vya ukimwi. Ikiwa mpenzi wako ana virusi vinavyosababisha ukimwi, atakuwa katika hatari kubwa ya kuambukizwa tena na virusi stahimilivu vinavyosababisha ukimwi. Pia, wewe unahitaji muda wa kupona na

utajiweka katika hatari ya maambukizi usipojipatia muda huu. Iwapo unahitaji msaada wowote wa kuongelea mambo haya na mpenzi wako, muuguzi, daktari au mshaurikatika hospital atakusaidia. Tutakupatia mipira ya kondomu bila malipo iwapo hutaweza kutoshiriki katika ngono.

Athari nyengine unayoweza kukumbana nayo ni wasiwasiya kuwa una ugonjwa katika mlango wako wa uzazi. Unaweza kuongea kuhusu jambo hili na muuguzi wa kitafiti, daktari, au ukitaka kuongea na mshaurikatika hospitali, tutakusaidia kupanga haya.

Tunaweza kugundua katika kiingilio kuwa una maambukizo. Iwapo utapatikana na maambukizo, tutakupa maagizo ya kupata dawa. Madhara ya dawa hizi yanaweza kuwa kuumwa na tumbo, kutapika na kuharisha, usikivu wa mwangaza, mwasho, mzio mkali mmenyuko unaoweza kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa, kupigapiga kwenyemasikio au kupoteza usikivu, mshtuko wa mwili (jerking of the body), maumivu ya moyo, machafuko ya damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au kuganda kwenye mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi katika utafiti huu mara moja.

Uwekaji wa siri

Wahudumu katika utafiti huu,watakusanya habari ya binafsi na waweza kuona aibu kuongea kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao umewajua mbeleni.Hatuna mpango wa kupeana habari yako ya kibinafsi kwamtu yeyote nje ya utafiti huuisipokuwa watafiti au wachunguzi walioteuliwa. Wakati mwingine kamati inayosimamia utafiti huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi huu.Kamamdhamini wautafiti, CDC wanaweza kufuatiliaaukukaguashughuli zautafiti.Sababu hiiitakuwakuhakikishakuwa utafitiunafanyika kwanjiainayotakiwa, napia kuhakikishakwamba hakiyakonaafya yako inalindwa.Matibabuyakotaarifa binafsiitakuwasiri.

Mbadala wa kujiunga na utafiti huu

Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata matibabu na dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi wa saratani ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika utafifi huu.

Manufaa kutokana na utafiti huu

Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa nyumba ya uzazi. Kwa kujiunga na utafiti huu, utapata kupimwa mlango wako wa uzazi bila malipo. Kama ungependa kujua matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita au mwaka mmoja baada ya kumaliza utafiti huu.

Gharama na Fidia ya Majeraha

Hakuna gharama yoyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu utalipia gharama ya uchanguzi wowote utakayopokea kwenye kiliniki ya utafiti. Ikiwa Utapata majereha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo ya utunzaji. Ikiwa unafikiri kuwa umepata jeraha ama maumivu kutokana na utafiti huu, wasiliana na

wahudumu wa utafiti huu, (Daktari Michael Chung (020-272-2710) au Daktari Nelly Mugo (020-273-6744) au Daktari Evans Malava (0721 289 733)) mara moja. Watakuhudumia kwa matibabu au kukupendekeza kwa matibabu.

Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye

Tungependa kuhifadhi habari yako ya matibabu na sampuli za pap smear na biopsy katika Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya utafiti wa baadaye. Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti wengine wanaofanya kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa kufuatiliwa katika utafiti. Tutatumia data na sampuli hizi kwa minajili ya utafiti unaoegemea na saratani ya mlango wa kizazi na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa kifichomaalumu Jina lako halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano pekee yake baada ya kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na kificho kilichoko katika sampuli na data kitaangamizwa. Bodi za taasisi ya mapitio ni kamati zinazoagalia usalama na haki za washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu cha Washington. Lazima ziidhinishe utafiti wowote wa baadaye utakaotumia sampuli na data yako. Ikiwa hupendi sampuli zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika utafiti huu na sampuli zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhufadhi wa sampuli zako leo, kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamishe watafiti ambao watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye. Hatutauza sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika uvumbuzi mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo zitakazotokana na uvumbuzi huu ..

<u>Maelezo ya ziada</u>

Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na kikundi cha watafiti pekee wala si mtu mwengine yeyote nje ya utafiti huu bila idhini yako. Ikiwa utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza kuwasaidia kukupa matibabu na huduma bora ya UKIMWI.Rekodi zako zote zitahifadhiwa katika sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri la kuhakikisha ulinzi.

Wakati mwengine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika, rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious diseases, hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia kwenye mpangilio halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamishe wahudumu wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana sampuli za mwisho lakini waweza kukataa.

Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr (272-4737), au Daktari Nelly Mugo (273-6744).

Je, una maswali yeyote?

Sahihi ya mtafiti…… Tarehe……..

Jina la Mtafiti……

Muhusika

Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali kuhusu haki yangu kama mhusika kwenye utafiti , naweza piga simu kwa kamati ya uchunguzi wa maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa nakala ya fomu hii yangu binafsi.

Tafadhali tia alama , ufupi wa jina na anwani katika chaguo moja:

_____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

_____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

Sahihi au alama ya kidole cha gumba cha mshiriki _____

Tarehe_____

Jina la Mshiriki lililochapishwa_____

Nakala kwa Mtafiti na Mshiriki

MAKUBALIANO YA PAMOJA

KISWAHILI CONSENT FORM

MATIBABU YA SARATANI YA MLANGO WA KIZAZI; CRYOTHERAPY AU LEEP

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Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102, 44355 unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.

Ujumbe wa Watafiti

Tunakuuliza kushiriki katika utafiti huu wa kitaalam. Lengo la fomu hii ya idhini ni kukupa habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la. Tafathali soma maelekezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote, haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usichoelewa kwenye fomu hii. Tukishajibu maswali yako yote, unapaswakuamua kushiriki kwenye utafiti huu au la. Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadhia. Tafadhalu tujulishe iwapo ungependa kutumia lugha ya Kingereza.

Lengo la Utafiti huu.

Mathumuni ya mradi huu wa utafiti, ni kutafuta njia iliyo bora ya kutibu ugonjwa unaosababisha saratani ya mlango wa kizazi (cervical cancer). Umeulizwa kushiriki katika utafiti huu kwa sababu;

- Umeambukizwa maradhi ya UKIMWI
- Unapata matibabu katika kituo cha matibabu cha Hope
- Hauna Mimba
- Hauna historia ya shida ya kuvuja damu
- Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- Umewahi fanya ngono
- Haujawahi kupata matibabu yoyote ya mlango wa kizazi hapo mbeleni
- Umepatikana kuwa na chembe chembe zisizo za kawaida kwa mlango wa uzazi kwenye pap smear ua biopsy.

Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamo nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma” (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya mlango wa kizazi.

Utafiti huu utalinganisha namna mbili za ukaguzi wa mlango wa kizazi; Cryotherapy na LEEP (loop electrosurgical excision procedure). Njia hizi mbili hutumika sana kwa wanawake wengi duniani na sio geni. Tutakuelezea njia hizi mbili za utabibu. Katika utafiti huu, tutakuwa na washiriki 400. Utafiti huu utatuwezesha kutambua matibabu bora itakayowawezesha wanawake wanaoishi na virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila saratani ya mlango wa kizazi.

Hatua ya kushiriki katika utafiti

Washirika wote watahitajika kutembelea kliniki mara 5 au 8 kwa muda usiozidi miaka 2. Kila mara, mushirika atatumia dakika 15 hadi 40 katika kiliniki.

Utaratibu wa kupeana matibabu bila mapendeleo (Randomization)

(Marejeleo ya Matokeo ya Biopsy – dakika 10, Utaratibu wa kupeana matibabu bila mapendeleo (ikihitajika) – dakika 30)

Matokeo ya pap smear na biopsy yameonyesha ya kuwa uko na maambukizo yanayohitaji matibabu. ukiamua kujiunga na utafiti huu, tutatumia mojawapo ya njia mbili ambazo ni za kutumainika. Njia moja inaitwa “Cryotherapy”. Njia hii inatia barafu sana (freeze) kwenye sehemu yako ya uzazi iliyoambukizwa na ugonjwa. Unaweza pewa dawa ya kumeza kupunguza maumivu baada ya Cryotherapy. Njia ya pili inajulikana kama, “LEEP”. Njia hii inatumia chuma kidogo kilichopashwajoto ili kutoa sehemu iliyoambukizwa baada ya kugandishwa kwa dawa. Utahudumiwa kwa njia mojawapo ya hizi bila mapendeleo ili kudhibitisha ni njia ipi iliyo bora kuliko nyengine.

Njia ya kuchagua matibabu bila mapendeleo ni kama “kuzungusha peni”, kila upande wa peni una uwezo uliyo sawa, kama ilivyo njia hizi mbili za matibabu. Hatujui kwa hakika ni njia gani ya matibabu utakayopata hadi tutakapofungua bahasha iliyo na kijikaratasi kitakachotujulisha ni njia gani ya matibabu utakayopata. Sio sisi wala wewe utakayechagua njia ya matibabu, bali ni bahasha iliyo na vijikaratasi vitakavyo tuelekeza ni njia ipi itakayotumika baada ya kufungua ile bahasha. Tutakuashiria kutumia mojawapo ya njia hizi mbili bila mapendeleo (kuegemea njia moja) kwa sababu hatujui ni njia ipi iliyo bora kutumiwa na wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV).

Tukigundua kuwa sehemu ya kizazi iliyoambukizwa ni kubwa mno, na haiwezi kutibika sawa sawa kwa “Cryotherapy”, tutakutibu tukitumia njia ya “LEEP”. Utapata matibabu ya LEEP bila malipo yoyote.

Ikiwa sehemu iliyoambukizwa haiwezi kutibika vizuri kwa “Cryotherapy” au “LEEP”, utaondoka kwenye utafiti huu na kuelekezwa kwenye hospitali kuu ya Kenyatta (KNH) utakapopata matibabu ya aina nyengine ya matibabu kwa bei nafuu katika hospitali ya serikali. Watafiti watakupatia fomu zako za matibabu ambazo ni muhimu kwa matibabu yako. Hizi fomu hazitaonyesha kuwa wewe ni mshirika wa utafiti huu. Baada ya matibabu utakayopokea kutoka KNH, tutakufuatilia kwa miaka 2 na kukupa matibabu.

Tukikupa njia mojawapo ya matibabu yaliyotajwa (Cryotherapy au LEEP), vijiko viwili vya chai (tea spoons [10mls]) vya damu vitatolewa ili kuhesabu chembe chembe za CD4 na kuthibitisha kiwango cha virusi vinavyosababisha ukimwi (HIV) katika damu yako kwa wakati huu. Kisha tutapanguza kwa burashi sehemu yako ya kizazi na kukagua kiwango cha virusi vinavyosababisha ukimwi. Mwisho, tutapangusa sehemu yako ya kizazi ili kukagua kiwango cha virusi vya “Papiloma” (HPV) ambavyo ni viini vinavyoambukiza sehemu ya kizazi na kusababisha saratani ya uzazi (Cervical cancer).

Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kiliniki.

<u>Mpangilio baada ya kupata matibabu bila mapendeleo</u>

(Kutembelea kiliniki Mara Ya 2-8;Marejeleo ya Matokeo na usufi wa mlango wa kizazi- dakika30)

Ukipata mojawapo ya matibabu (Cryotherapy au LEEP) bila mapendeleo, watafiti watakuuliza urudi kwenye kiliniki tena wiki ya kwanza (1), pili (2) na tatu (3) baada ya matibabu.

Kila mara utakaporudi kiliniki, vijiko viwili vidogo vya damu vitatolewa na kisha kupanguza sehemu yako ya kizazi ili kuthibitisha kiwango cha virusi vinavyosababisha ukimwi (HIV). Tungependa kujua kama kiwango hiki kimeongezeka baada ya matibabu na kitarudi katika hali yake ya kawaida lini?

Ukipata mojawapo ya matibabu (Cryotherapy au LEEP), tutakuuliza kurudi kiliniki ya utafiti mwezi wa sita (6), kumi na mbili (12), kumi na nane (18) na pia mwezi wa ishirini na nne (24) baada ya matibabu yako ya kwanza ili kurejelea “Pap smear” kudhibitisha Ikiwa sehemu yako ya kizazi iliyoambukizwa imeondolewa kabisa na hakuna tishu iliyojitenga au isiyo ya kawaida iliyojitengeza. Tutapanguza sehemu yako ya kizazi (cervix), ili kukagua virusi vya “Papiloma” (HPV) kwa wakati huu na kutoa vijiko viwilividogo vya damu ili kuhesabu chembe chembe za CD4 na kudhibitisha viwango vya virusi vinavyosababisha ukimwi (HIV). Tukigundua hali isiyo ya kawaida, tutakutibu kwa kutumia LEEP, kisha tutakuelekeza katika hospitali kuu ya Kenyatta (KNH) kwa matibabu ya ziada yaliyo nafuu.

Kuwasiliana na Washiriki

Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa. Tunataka kukufuatilia vyema na kwa makini ili kutibu ugonjwa wowote katika mlango wa kizazi ulio nao sasa au utakaoupata baadaye. Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza kukutembelea kwako nyumbani. Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi yatakayoashiria kuwa sisi ni wahudumu katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii ya mawasiliano.

Athari na usumbufu wa kushiriki kwenye utafiti huu.

Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu. Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

Matibabu

Kuna uwezekano wa madhara au maumivu u kipata matibabu haya. Ukishiriki katikautibabu wa “Cryotherapy”, waweza kuhisi;

- maumivu madogo ya tumbo kwa muda unaopungua dakika kumi,
- kutokwa na majimaji kwenye uke wako kwa muda wa wiki mbili (au zaidi).
- Kuvuja damu
- Maambukizo ambayo tunaweza kutibu hapa katika kiliniki au katika hospitali kwa nadra sana.

Maambukizo haya yanaweza kusababisha homa,baridi, kutokwa na jasho usiku, au majimaji meupe kutoka kwenye uke wako.

Ukitibiwa kwa LEEP, unaweza;

- kuvuja damu baada au wakati matibabu haya yanapoendelea. (Unashauriwa kurudi kiliniki Ikiwa uvujaji huu wa damu utaanza, kisha kuendelea baada ya matibabu kwa ukaguzi wa ziada.)
- Kuna uwezekano wa kuambukizwa kwenye eneo la matibabu.

Madhara haya yote yanaweza kutibiwa bila malipo yeyote katika kiliniki hii. Matibabu haya yanaweza kuwa;

- kupewa dawa ya kuuguza maambukizi.
- Kuingiza pamba kwenye uke wako kuzuia kuvuja damu,
- Kushona kwenye mlango wako wa uzazi ili kuzuia kuvuja kwa damu au
- Kulazwa hospitalini kwa makali ya maambukizo au uvujaji wa damu.

Tafadhali tufahamishe ikiwa una madhara haya baada ya matibabu.

Baada ya kupokea matibabu ya “Cryotherapy”, au LEEP tunakusihi usishiriki katika kitendo cha gono kwa muda wa juma nne, sababu ni kuwa waweza kumwambukiza mwenzio kwa urahisi. Pia kuna uwezekano wa wewe kupata maambukizo. Tunaweza kukusaidia kuongelea jambo hili na mpenzi wako.

Washiriki wote watakaopata matibabu ya “Cryotherapy” au “LEEP” watapata maagizo ya dawa ya “antibiotiki”. Dawa hii ya antibiotiki itashirikisha doxycline, metronidazole or norfloxacin.

Madhara ya dawa hizi yanaweza kuwa usumbufu wa tumbo (Lazima usikunywe tembo/pombe kwa siku 2) kutapika na kuharisha usikivu wa mwangaza, mwasho, mzio mkali mmenyuko unaoweza kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa, kupigapiga kwenyemasikio au kupoteza usikivu, mshutuko wa mwili (jerking of the body), maumivu ya moyo, machafuko ya damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au kuganda kwenye mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi katika utafiti huu mara moja.

Baada ya kupata matibabu haya, kuna uwezekano wa kupata matatizo utakapobeba mimba baadaye. Baada ya kupata matibabu ya “LEEP”, wanawake wengine wamepata matatizo wanapobeba mimba kama vile;maumivu ya mapema wakati wa kujifunguaau shida katika mlango wa mfuko wa uzazi.Katika Wanawake wachache, mlango wa mfuko wa uzazi huziba na inabidi ulegezwe. Wanawake wengine huvuja majimaji ya uzazi kabla ya muda ufaao wa kuzaa mtoto pengine kutokana na operesheni ya mlango wa mfuko wa uzazi (cervix).

Utoaji wa damu

Tutakusanya sampuli za damu, vijiko 2 (10 mls), kutoka kwako kwa kutumia shindano na “sirinji”. Kudungwa shindano kwaweza kuwa chungu na yaweza kuacha alama kidogo kwa muda mfupi. Yaweza kusababisha maambukizo au kuzirai.

Uwekaji wa siri

Wahudumu katika utafiti huu,watakusanya habari ya binafsi na waweza kuona aibu kuongea kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao umewajua mbeleni.Hatuna mpango wa kupeana habari yako ya kibinafsi kwamtu yeyote nje ya utafiti huuisipokuwa watafiti au wachunguzi walioteuliwa. Wakati mwingine kamati inayosimamia utafiti huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi huu.Kamamdhamini wautafiti, CDC wanaweza kufuatiliaaukukaguashughuli zautafiti.Sababu hiiitakuwakuhakikishakuwa utafitiunafanyika kwanjiainayotakiwa, napia kuhakikishakwamba hakiyakonaafya yako inalindwa.Matibabuyakotaarifa binafsiitakuwasiri.

Mbadala wa kujiunga na utafiti huu

Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata matibabu na dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi wa saratani ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika utafifi huu. Unaweza kutibiwa na Cryotherapi katika Hospitali ya kiliniki ya Hope hata ukichagua kutojiunga na utafiti huu. Pia, tunaweza kukutuma kupewa huduma katika hospitali kuu ya Kenyatta, ambapo malipo ni kama ya hospitali za serikali.

Manufaa kutokana na utafiti huu

Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa nyumba ya uzazi.Pia, kushiriki kwako katika utafiti huu kutachangia katika elimu ya nyanja hii ambayo yaweza kutoa mabadiliko katika jinsi ya ugonjwa wa saratani ya mlango wa uzazi unavyogunduliwa na kutibiwa. Kwenye nchi inayoendelea kama Kenya.Kama ungependa kujua matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita au mwaka mmoja baada ya kumalizika utafiti huu.

Gharama na Fidia ya Majeraha

Hakuna gharama yeyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu utalipia gharama ya uchaguzi na matibabu yoyote utakayopokea kwenye kiliniki ya utafiti. Ikiwa Utapata majereha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo ya utunzaji. Matibabu yatahusisha dawa zinazopambana na vidudu vilivyo hai (antibiotics), dawa zinazopunguza maumivu na njia zinazoachisha kuvuja damu. Ikiwa unafikiri kuwa umepata jeraha ama maumivu kutokana na utafiti huu, wasiliana na wahudumu wa utafiti huu, (Daktari Michael Chung (020-272-2710) au Daktari Nelly Mugo (020-273-6744) au Daktari Evans Malava (0721 289 733)) mara moja. Watakuhudumia kwa matibabu au kukupendekeza kwa matibabu.

Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye

Tungependa kuhifadhi habari yako ya matibabu na sampuli za damu yako na mlango mfuko wa uzazi, Kenya katika Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya utafiti wa baadaye. Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti wengine wanaofanya kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa kufuatiliwa katika utafiti. Tutatumia data na sampuli hizi kwa minajili ya utafiti unaoegemea na

saratani ya mlango wa kizazi na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa kifichomaalumu Jina lako halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano pekee yake baada ya kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na kificho kilichoko katika sampuli na data kitaangamizawa. Bodi za taasisi ya mapitio ni kamati zinazoangalia usalama na haki za washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu cha Washington. Lazima ziidhinishe utafiti wowote wa baadaye utakaotumia sampuli na data yako. Ikiwa hupendi sampuli zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika utafiti huu na sampuli zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhifadhi wa sampuli zako leo, kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamishe watafiti ambao watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye. Hatutauza sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika uvumbuzi mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo zitakazotokana na uvumbuzi huu ..

Maelezo ya ziada

Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na kikundi cha watafiti pekee wala si mtu mwengine yeyote nje ya utafiti huu bila idhini yako. Ikiwa utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza kuwasaidia kukupa matibabu na huduma bora ya UKIMWI. Baadhi ya sampuli zako ikiwa ni pamoja na sampuli za damu na sampuli kutoka kwenye mlango wa mfuko wa uzazi zaweza kutumwa USA au Uropa kwa uchunguzi. Habari yako na sampuli zako zitalindwa ikiwa haya yatatendeka. Rekodi zako zote zitahifadhiwa katika sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri la kuhakikisha ulinzi.

Wakati mwengine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika, rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious diseases, hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia kwenye programu halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamishe wahudumu wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana sampuli za mwisho lakini waweza kukataa.

Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

Utarejeshewa gharama ya usafiri ya Ksh 300 mara utakaporudi katika kiliniki kwa sababu zinazohusiana na utafiti huu. Utapata pesa za usafiri kutoka kwa mhudumu wa mapokezi.

Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr (272-4737), au Daktari Nelly Mugo (273-6744).

Je, una maswali yeyote?

Sahihi ya mtafiti…… Tarehe……..

Jina la Mtafiti……

Muhusika

Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali kuhusu haki yangu kama mhusika kwenye utafiti , naweza piga simu kwa kamati ya uchunguzi wa maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa nakala ya fomu hii yangu binafsi.Tafadhali tia alama , ufupi wa jina na anwani katika chaguo moja:

_____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

_____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

Sahihi au alama ya kidole cha gumba cha mshiriki _____

Tarehe_____

Jina la Mshiriki lililochapishwa_____

Nakala kwa Mtafiti na Mshiriki

ENROLLMENT

Study ID Number__ __ __ Hope ID Number __ __ __ __Interviewer Number_

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Agreed to store samples: Yes □ No □Don't know □ Other, specify

A: SOCIODEMOGRAPHIC

1. Date of birth (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Age _____ years
3. How many years of education did you complete? _____ years
4. What is highest education level you have completed? None □
   Primary □
   Secondary □
   Higher education/ University □
   Don't know □
   Refused □
   Other, specify
5. Marital status (tick one): Married (monogamous) □
   Married (polygamous) □
   Single □
   Divorced/Separated □
   Widowed □
   Refused □
   Cohabiting □
   Other, specify
6. Employment (tick one): Salaried job □
   Self-employed □

Housewife □

Unemployed □

Casual laborer □

Refused □

Other, specify

7. Household income per month (tick one): None □

< 5000 Ksh □

5001 – 10000 Ksh □

10001 – 15,000 Ksh □

>15,000 Ksh □

Don't know □

Refused □

B: SEXUAL HISTORY

8. How old were you when you first had vaginal intercourse? __ __ Don't know □refused □ never Other, specify

9. How many sex partners have you ever had? __ __ Don't know □refused □ Other, specify _____

10. How many different sex partners did you have in the last year? __ __ Don't know □ refused □ Other, specify

11. Have you had sex in the last month? (If no, don't know, refused, skip to 14)
Yes □ No □ Don't know □ Refused □ Other, specify

12. How often have you used condoms during sex in the last month?
Always (100%) □ Most of the time (75-99%) □
Half of the time (50%-74%) □ Sometimes (25-49%) □
Rarely (1-25%) □ Never (0%) □
□ Refused □
Don't know □ Other, specify

13. Do you think you may be currently pregnant? Yes □ No □ Don't know □ Refused □ Other, specify

C: CERVICAL CANCER SCREENING HISTORY

14. Have you been previously screened for cervical cancer? Yes □ No □
Don't know □ Refused □ Other, specify
If no,don't know or refused skip to 20.

15. What cervical cancer screening test did you undergo most recently (tick one)?

□ Pap smear

□ Visual inspection with Acetic acid

□ HPV

□ Other, specify: _____

□ Don't know

□Refused

16. Where was the most recent test performed?

□ Coptic

□ KNH

□ Refused

□ Don't know

□ Other, specify

17. When was the test performed?
Don't know □

18. What were the results?

□ Normal

□ Abnormal, specify _____

□ Don't know

□ Refused

19. Did you receive any cervical treatment or surgery as a result of this test?
Yes□ No□ Don't know □ Refused □ Other, specify _____

If yes, specify _____

20. Was Pap Smear performed today? Yes □ No □

If no, explain Refused □ Don't know

21. Comments.

PAP SMEAR

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Initial Visit □ Repeat □ Month 6 FU □ Month 12 FU □ Month 18 FU □ Month 24 □Other, specify _____

A: PHYSICAL EXAMINATION

1. Temperature __ __ __°C
2. Is there inguinal node enlargement Yes□ No □
3. Is there abdominal tenderness Yes□ No □
4. Are there any abdominal masses Yes□ No □
5. Were there any other abnormalities found on general physical exam Yes□ No □
   If yes, specify

B: PELVIC EXAMINATION

6. What was found on the external genital exam (tick all that apply)?
   - □ Abnormal visible discharge at introitus □ Ulcers
   - □ Excoriations □ Vesicles
   - □ Oedema □ Papules
   - □ Sores □ Normal
   - □ Other (Specify) _____

7. Were there any perineal warts on external genital exam? Yes□ No □
   If yes, specify
   a. Size __ __ mm
   b. Number of warts __ __
   c. Location of warts _____
8. Did the cervix appear abnormal on gross pelvic exam? Yes□ No □
   If yes, tick all that apply

□ Abnormal discharge □ Warts

□ Bleeds easily on touch □Cervicitis

□ Visible lesion □Condylomata

□ Bloody discharge □ Ulcers

□ Fungating mass

□ Leukoplakia □Cervical polyp

□Bartholian cysts □Blisters

□Overt cervical cancer □ Other abnormality, specify

9. Did you palpate the uterus? Yes□ No □
If yes, then specify

a. Estimated uterine size __ __ . __ cm
b. Was the uterus tender? Yes□ No □
c. Were there possible fibroids? Yes□ No □

10. Was there any adnexal tenderness? Yes□ No □
If yes, specify location Right Left □ Both □

C: Pap

11. Were you able to take an adequate Pap smear? Yes□ No □
a. If no, specify why
□Patient discomfort

□Excessive bleeding

□Excessive discharge or inflammation

□Other, specify

D: DIAGNOSIS

12. Normal exam Yes□ No □
13. Candidiasis Yes□ No □
14. Cervicitis Yes□ No □
15. Pelvic inflammatory disease Yes□ No □
16. Vulval warts Yes□ No □
17. Vaginal warts Yes□ No □
18. Genital ulcerations Yes□ No □
19. Lower genital tract infection Yes□ No □
20. Other Yes□ No □
If others, specify

E: OTHER

21. Did you give any treatment to the participant? Yes □ No □
If yes, specify (treatment

22. Did you give referal to the participant? Yes □ No □
If yes, specify (diagnosis and referral institution)

23. Comment.

COLPOSCOPY

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Initial Visit □ Month 6 FU □ Month 12 FU □ Month 18 FU

□ Month 24 FU □LSIL FU □CIN 1 FU □Other, specify _____

A: PAP SMEAR DIAGNOSIS

1. What date was the Pap smear performed?
2. What was the Pap smear diagnosis (tick all that apply)?

□ No dysplasia (NIL)

□ ASCUS

□ LSIL (CIN 1)

□ HSIL (CIN 2 & 3)

□ASC-H

□ Invasive carcinoma

□ ACG (Atypical Glandular Cells)

□ Cervicitis

□ Yeast infection

□ Indeterminate/insufficient sample

□ Other, specify

□ Unknown, specify reason

3. Is cervical biopsy with colposcopy indicated based on Pap smear cytology?

Yes□ No □

If no,skip to Q24 and fill exit form where necessary

If yes, and colposcopy had been done previously,skip to Q24.

If yes and colposcopy had not been done previously, do a pregnancy test

4. Result of pregnancy test: Pregnant □ Not Pregnant □

(If pregnant fill exit form, If not pregnant refer for colposcopy)

Not pregnant □

B: PHYSICAL EXAMINATION

5. Temperature __ __ __ °C
6. Is there inguinal node enlargement Yes□ No □
7. Is there abdominal tenderness Yes□ No □
8. Are there any abdominal masses Yes□ No □

9. Were there any other abnormalities found on general physical exam Yes□ No □
If yes, specify

C: PELVIC EXAMINATION

10. What was found on the external genital exam (tick all that apply)?

□ Abnormal visible discharge at introitus □ Ulcers

□ Excoriations □ Vesicles

□ Oedema □ Papules

□ Sores □ Normal

11. Were there any perennial warts on external genital exam? Yes□ No □
If yes, specify

d. Size __. __ __ mm
e. Number of warts __ __
f. Location of warts _____

12. Did the cervix appear abnormal on gross pelvic exam? Yes□ No □
If yes, tick all that apply

□ Abnormal discharge □ Warts

□ Bleeds easily on touch □Cervicitis

□ Visible lesion □Condylomata

□ Bloody discharge □ Ulcers

□ Fungating mass

□ Leukoplakia □Cervical polyp

□Blisters

4014 □Overt cervical cancer

4015 13. Did you palpate the uterus? Yes□ No □
4016 If yes, the specify

4017 a. Estimated uterine size __ __ . __ cm
4018 b. Was the uterus tender? Yes□ No □
4019 c. Were there possible fibroids? Yes□ No □
4020 d. Was there any adnexal tenderness? Yes□ No □
4021 d(i) If yes, specify location Right □ Left □ Both □

4022

4023 **D: COLPOSCOPIC BIOPSY**

4024 15. Did you see the entire squamocolumnar junction (SCJ)? Yes□ No □
4025 16. Was it a satisfactory colposcopy? Yes□ No □
4026 If no, specify

4027 17. Were there colposcopic findings within the transformation zone? Yes□ No □
4028 If yes, specify (tick all that apply)

4029 □ Flat acetowhite epithelium

4030 □ Micropapillary or microconvoluted acetowhite epithelium

4031 □ Leukoplakia

4032 □ Punctation

4033 □ Mosaic

4034 □ Atypical vessels

4035 □ Iodine-negative epithelium

4036 □ Lesion extended into endocervix

4037 18. Draw SCJ (acetowhite, punctation, mosaics, atypical vessels, and other lesions):
4038 19. Were there any other colposcopic findings? Yes□ No □
4039 If yes, specify (tick all that apply)

4040 □ Mucosal bleeding easily induced

4041 □ Purulent cervicitis

4042 □ Opaque discharge

4043 □ Yellow discharge

4044 □ Other, specify:

4045 20. Were there colposcopic findings consistent with invasive carcinoma?
4046 Yes□ No □

E: COLPOSCOPY DIAGNOSIS

21. Is patient eligible for cryotherapy if necessary? Yes□ No □
If no, indicate reason (tick all that apply)

□ Lesion >75% of cervix

□ Lesion is larger than cryoprobe tip

□ Lesion suspicious for cancer

□ Polyp or anatomic defect preventing access to cervix

□ Previous treatment with cryotherapy in this study

□ Other, specify

22. What was your diagnosis based on colposcopy examination (tick all that apply)?
□ Normal colposcopic findings

□ Unsatisfactory, specify:

□ Inflammation/infection, specify

□ Leukoplakia

□ Condyloma

□ LSIL (CIN 1)

□ HSIL (CIN 2 & 3)

□ Invasive cancer

□ Other, specify:

D: SPECIMEN COLLECTION

23. Was a biopsy taken? Yes□ No □
a. If yes, how many biopsies were taken __ __
b. Draw: (mark site(s) with an 'X' on colposcopy drawing)
c. If no, specify why biopsy was not taken

E: Treatment

24. Was any treatment given to the patient ? Yes □ No □
If yes, specify treatment

25. Was a referral given to the patient? Yes □ No □
If yes, specify diagnosis, and the referral institution

4079

4080 26.Comments:
4081

RANDOMIZATION

Study ID Number__ __ __ Hope ID Number __ __ __ __

Randomization Number_ _ Interviewer Number_

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

A: CURRENT MEDICAL HISTORY

1. Do you have pain when passing urine? Yes □ No □ Other, specify Refused □ Don't know
2. Do you have any lower abdominal pain?Yes □ No □ Other, specify Refused □ Don't know
3. Do you have any abnormal vaginal discharge? Yes □ No □ Other, specify Refused □ Don't know
4. Have you noticed any growths around your vagina? Yes □ No □ Don't know □ Other, specify Refused □ Don't know

B: REPRODUCTIVE HEALTH

5. How old were you when you had your first menstrual period? __ __ Don't know □ refused □ Other, specify
6. Date of last menstrual period (day/month/year) ___ ___/___ ___/___ ___ ___ ___ Don't know □ refused □ Other, specify
7. Do you have history of abnormal vaginal bleeding Yes □ No □ Don't know □ Refused □ Other, specify

If yes specify the type of bleeding

□ Irregular

□ Heavy

Menorrhagia □ Other, specify

□ Don't know

□ Refused

8. Have you ever used any form of family planning method? Yes □ No □
Don't know □
Refused □
Other, specify _____

If yes, specify (tick all that apply)

Injectable □ IUCD □ Natural □

Condoms □ OCP □ Norplant/ Implant □

BTL □ others, specify _____

9. Are you using any form of family planning method now?
Yes □ No □Don't know □Refused □
Other, specify □ _____

If yes, specify (tick all that apply)

Injectable □ IUCD □ Natural □

Condoms □ OCP □ Norplant/ Implant □

BTL □ others, specify _____

10. How many times have you been pregnant? __ __ Refused □ Don't know □
Other □
11. How many times have you had live births? __ __ Refused □ Don't know □
Other □
12. How many abortions, miscarriages, and/or stillbirths have you had? __ __
Refused □ Don't know □ Other □
13. Have you ever been admitted to the hospital with a gynecological problem?
Yes □ No □ Don't know □ Refused □ Other, specify

14. Have you ever had abdominal surgery? Yes □ No □ Refused □
Don't know □ Other, specify
15. Have you ever had vaginal surgery? Yes □ No □
Refused □ Don't know □ Other, specify
16. Do you currently smoke cigarettes Yes □ No □
Refused □ Don't know □ Other, specify

C: HIV HISTORY

17. When were you diagnosed as having HIV? (day/month/year) ___ ___/___
___/___ ___ ___ ___
18.1. How was HIV detected? (tick only one)

- At the occasion of a VCT: Yes ☐
- During pre-natal check-up: Yes ☐
- Because of a sickness, specify:_____Yes ☐
- Other, specify:_____ ☐
- Don't know: ☐
- Refused: ☐

19. Are you currently on antiretroviral medications? Yes ☐ No ☐
Don't know ☐

Refused ☐
Other, specify

If yes,

a) specify current medications: _____

b) original start date: ___ ___/___ ___/___ ___ ___ ___ Don't know ☐

c) Do you know why you were started on antiretroviral medication?

- because of sickness, specify: _____ Yes ☐

- because of low CD4 count: Yes ☐

- because of high viral load: Yes ☐
- Other, specify: _____ ☐
- Don't know: ☐
- Refused: ☐

20. Comment

TREATMENT

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Initial Visit □ Month 6 FU □ Month 12 FU □ Month 18 FU

□ Month 24 FU □ CIN 1 FU □Other, specify _____

Does the patient have any known allergies to medications or antibiotics?Yes □ No □

If yes, specify

A: DIAGNOSIS

1. What date was the cervical biopsy performed? ___ ___/___ ___/___ ___ ___ ___
2. What was the result of cervical biopsy histopathology (tick all that apply)?
   □No dysplasia (NIL)
   □CIN 1
   □CIN 2
   □ CIN 3
   □ CIS
   □ AGC (Atypical Glandular Cells)
   □ Invasive carcinoma
   □ Cervicits
   □ Unknown, specify reason
   □ Other, specify
3. Has patient previously received treatment as part of this study?
   Yes □ No □

If yes, skip to 7

B: RANDOMIZATION

4. Is patient indicated for LEEP or cryotherapy treatment based on histopathology?
Yes□ No □
If no, continue to 14

5. Is patient's lesion amenable to cryotherapy? Yes □ No □ (If yes, go to question 6)
5(i)If no, indicate reason (tick all that apply)

□ Lesion >75% of cervix

□ Lesion is larger than cryoprobe tip

□ Invasive cervical cancer on histology

□ Lesion suspicious for cancer

□ Polyp or anatomic defect preventing access to cervix

□ Patient declines procedure

□ Other, specify

5(ii)If no, is patient's lesions amenable to LEEP? Yes □ No □

If yes, skip to 7

If no, skip to 14

6. Was patient randomized to LEEP or cryotherapy today? Yes □ No □
If yes, to which treatment? LEEP □Cryotherapy □

If no, why?

□ Patient refuses

□ Patient not eligible for treatment, specify reason

□ Other, specify

C: TREATMENT

7. Did you perform LEEP or cryotherapy today? (tick one)
LEEP □ Cryotherapy □ Neither, explain □

(If neither, explain, skip to Q14)

8. Did you visualize the full extent of lesion? Yes□ No □
9. Was the squamocolumnar junction fully visualized? Yes□ No □
10. Draw position of lesion and treatment performed:
11. Did the patient experience any pain during the procedure? Yes□ No □
12. Was analgesia provided? Yes□ No □
13. Were there any complications? Yes□ No □

If yes, specify

14. Was any antibiotics given? Yes☐ No ☐
If yes, specify

D: OTHER

15. Was the patient referred for further treatment at another institution? Yes☐
No ☐
If yes, specify institution and reason
16. Was treatment or a referral given for something other than cervical disease? Yes ☐ No ☐
If yes, specify (give diagnosis and treatment)

17. Comments

ADDRESS AND INTAKE

Study ID number __ __ __ **Interviewer number ____ ____**

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Format(tick one) □**New** □**Update (fill only updated info)**

A. PERSONAL INFORMATION

1. What is your name?
   a. First name
   b. Middle name
   c. Last name
2. How are you called in your home area?
3. What is the current physical location where you live?
   a. District
   b. City
   c. Village
   d. Estate
   e. Plot number
   f. Door number
   g. Road name

4. Public Transportation to the house:

   4a. Type: ⊦ Bus ⊦ Boda boda ⊦ Matatu ⊦ Taxi ⊦ Other (specify)

   4b. Route number:

   4c. Stage Name

   4d. General Name of the Area

5. Walking directions to house from the stage?
6. Landmarks that aide in locating the household: (Names of schools, churches, businesses etc.)
7. Can you be reached by phone? Yes □ No □
   If yes,

   7 (i)What is the phone number 1?
   7 (ii)What is the phone number 2?

   7iii. Who carries the phone (tick one) □ self □ other, specify

B. SIGNIFICANT CONTACT

8. Is there another person who is ware of your HIV status that we can contact through phone if we are unable to reach you directly?
   If no, skip to 9.

9. What is the name of this contact person?
   a. First name
   b. Middle name
   c. Last name
10. What is the relationship of this person to you?
11. (a)What is the phone number 1?
    (b) What is the phone number 2?

C. UPCOUNTRY INFORMATION

12. Do you have an upcountry home? Yes □ No □
    If no, skip to 19

13. What is the physical location of your upcountry home?
    a. District
    b. City
    c. Village
    d. Estate
    e. Plot number
    f. Door number
14. Specific directions to residence
15. Is there person located in your upcountry home whom we can contact if we are unable to reach you directly? Yes □ No □
    If no, skip to 19

16. What is the name of this contact person?
    a. First name
    b. Middle name
    c. Last name
17. What is the relationship of this person to you?
18. Does this contact have a phone number? Yes □ No □
    If yes, specify: phone number 1, phone number 2

D. OTHER

Comment:

SHEDDING

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Week 1 FU □ Week 2 FU □ Week 3 FU□Other, specify _____

A: MEDICAL HISTORY

1. Has the patient experienced any lower abdominal pain since the last visit?
   Yes □ No □

If yes, indicate:

   a. Duration __ __ days
   b. Severity (scale from 1 to 5; 5 being most severe) __ __

2. Has the patient experienced any vaginal bleeding since the last visit?
   Yes □ No □

If yes, indicate:

   a. Duration __ __ days
   b. Volume
   □ Stain pants

   □ Requires sanitary pad

   □ Other, specify

3. Has the patient experienced any vaginal discharge since the last visit?
   Yes □ No □

If yes, indicate:

   c. Duration __ __ days
   d. Color
   □ Yellow

□ Brown

□ White

□ Clear

□ Other, specify

e. Smell
□ Malodorous

□ No odor

□ Other, specify

f. Volume
□ Stain pants

□ Requires sanitary pad

□ Other, specify

4. Has the patient experienced any fever after the last visit?
Yes □ No □

If yes, specify duration __ __ days

5. Did the patient seek medical care for these or other complaints?

Yes □ No □

If yes, specify what complaint prompted the participant to seek care:

□ Abdominal pain

□ Fever

□ Vaginal Bleeding

□ Vaginal discharge

a. Other, specify

If yes, specify where the participant sought care:

□ Study clinic

□ Hope Center

□ Coptic Hospital

□ KNH

b. Other, specify

6. Was the participant's condition possibly due to a study procedure? (Ask if any of questions 1-4 is yes)

Yes □ No □

If any question 1-4 is Yes and the condition is not expected as per study protocol, or is more severe than expected, fill an AE form.

7. Date of last menstrual cycle (dd/mm/yyyy)

8. Have you ever had vaginal sex since treatment? Yes □ No □ Refused □

Other (specify) □ _____

8 (a). If yes, how many times? __

8(b) If you have had vaginal sex since treatment, how often did you use condoms during sex?

Always (100%)□ Most of the time (75-99%) □
Half of the time (50%-74%) □ Sometimes (25-49%) □
Rarely (1-25%) □ Never (0%) □
Refused □ Don't know □ Other, specify_____

9. Do you think you may be currently pregnant? Yes □ No □

10. Are you currently on antiretroviral medications?

Yes □ Refused □ Other, specify □

No □ Don't know □

If No, Refused, or Don't Know, skip to Q14

If yes, specify current medications and original start date.

□ d4t, 3tc, nvp

□ d4t, 3tc, efv

□ azt, 3tc, nvp

□ azt, 3tc, efv

□ Other specify

Original ARV start date (dd/mm/yyyy)

11. During the last 7 days, how many antiretroviral pills did the patient MISS taking? □

12. During the last 30 days, how many antiretroviral pills did the patient MISS taking? □

(If Q11 and Q12 patient did not MISS taking any pills skip to Q14)

13. If the patient missed any doses, please specify reasons (check all that apply)

- Toxicity/ side effect
- Share with others
- Forgot
- c. Felt better
- Too ill
- Stigma, disclosure or privacy issues
- Drug out of stock
- Patient lost or ran out of pills
- Delivery /travel problem
- Inability to pay
- Alcohol
- Depression
- d. Other specify

B: DIAGNOSIS

14. Is there any new infection that was related to the procedure since the last visit?
Yes No

If yes, specify and fill an Adverse Event questionnaire:

15. Were there any new complications diagnosed today related to the treatment?
Yes No
If yes, specify and fill an Adverse Event questionnaire:

C: TREATMENT

16. Was any treatment provided today? Yes No
If yes, specify

17. Was the patient referred for further cervical treatment at another institution?
Yes No

17 (i)If yes, specify institution

17(ii)If yes, specify reason for referral

D: SPECIMEN COLLECTION

18. Did you collect cervical HIV swab? Yes □ No □
If no, specify reason:

19. Did you collect blood? Yes □ No □
If no, specify reason:

E: ACCEPTABILITY OF TREATMENT

20. Please complete the items listed below by placing a checkmark on the box next to each question that best indicates how the client feels about the treatment she received.

	Strongly Disagree	**Disagree,**	**Neutral,**	**Agree**	**strongly agree**
(i) I find this treatment an acceptable way of dealing with cervical lesions	□	□	□	□	□
(ii) I would be willing to use this procedure if I were to develop more lesions	□	□	□	□	□
(iii) I would recommend this procedure to someone with cervical lesions	□	□	□	□	□
(iv) overall, I have a positive reaction to this treatment	□	□	□	□	□

F: OTHER

22.
__

23.
24. Comments:

PATIENT CONTACT

Study ID Number __ __ __ **Interviewer Number** __ __

Date of contact (day/month/year) ___ ___/___ ___/___ ___ ___ ___

1. Date of last Hope clinic visit (day/month/year)
2. Date of last study clinic visit (day/ month/year)

3. Was patient or patient contact reached by phone or home visit?

Ⱶ Phone Ⱶ Home visit Ⱶ Other, specify

4. Did you talk to the patient or patient contact?

Ⱶ Yes, talked to patient (*Go to 6)*

Ⱶ Yes, talked to patient contact *(Go to 5)*

Ⱶ No *(Go to 4)*

5. If talked to patient contact, who was the source of information (tick one)

Ⱶ Clinician / clinic staff Ⱶ Mother or Father Ⱶ Neighbor

Ⱶ Spouse or Partner Ⱶ Employer Ⱶ Caregiver

Ⱶ Family member / Relative Ⱶ Friend Ⱶ Treatment supporter

Ⱶ Other (specify) ☐

5a. Did the source of information have credible knowledge for whether the patient was alive or dead?

Ⱶ Yes, credible and patient confirmed alive *(Go to 4)*

Ⱶ Yes, credible and patient confirmed dead *(Go to 7 and complete Verbal Autopsy form)*

Ⱶ Source did not know whether patient was dead or alive *(Go to 4)*

Ⱶ Source not credible *(Go to 7 and complete Verbal Autopsy form)*

6. Reasons for missed study appointment (tick all that apply)

☐ N/A, did not reach patient or patient contact ☐ Unable attend because health problem

☐ No longer willing to be in study ☐ Family problems

☐ Wait time too long in clinic ☐ Client will go to faith healer

☐ Conflict with work ☐ Unwilling to disclose

☐ Financial problems ☐ No longer willing attend Hope Clinic

☐ Client moved or relocated ☐ Other (specify) ☐

7. If talked to patient, did the patient wish to remain in the study?

☐ Yes *(Go to 7a)*

☐ No *(Go to 8 and complete Exit Form)*

☐ N/A, did not talk to patient *(Go to 9)*

7a. Did the patient schedule a study appointment? ☐ Yes ☐ No *(If Yes go to 7b, If No go to 7c)*

7b. If yes, date of scheduled appointment (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

7c. If no, why did the patient not schedule an appointment (tick all that apply)

☐ Unable to attend because of health problems

☐ Family problems

☐ Conflict with work

☐ Financial problems

☐ Client moved or relocated

☐ Client lives too far away

☐ Other (specify) ☐

8. If the patient does not wish to return to the study, specify why (tick all that apply)

4524 ⊦ Not willing to attend Hope Clinic

4525 ⊦ Not willing to be in study

4526 ⊦ Attend clinic closer to home

4527 ⊦ Wait time too long

4528 ⊦ Conflict with work

4529 ⊦ Financial problems

4530 ⊦ Unwilling to attend because of health problems

4531 ⊦ Family problems

4532 ⊦ Client will go to a faith healer

4533 ⊦ Not willing to disclose HIV status

4534 ⊦ Referred else where

4535 ⊦ Other (specify) [ ]

4536 ⊦ Unknown

4537

4538

4539 9. Comments

4540 [ ]

4541

4542

4543

VERBAL AUTOPSY

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

1. Age at death ☐☐☐ years

2. Date of death (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

3. Place of death

4. The information source for the cause of death was (tick all that apply)

☐ Partner/spouse ☐ Mother or Father ☐ Friend

☐ Hospital records/staff ☐ Other family member/relative ☐ Care giver

☐ Neighbor ☐ Unknown ☐ Other (specify) ☐

5. Was the deceased seeking other medical treatment (other than Hope Center) during the last 3 months before his/her death? ☐ Yes ☐ No ☐ Unknown *If yes go to 5a, if no go to 6*

5a. If yes, where specifically was the deceased receiving other medical care?

Name of facility:_____

5b. What type of care was the deceased receiving at the these other facilities? (Tick all that apply)

☐ General medical care ☐ TB ☐ STD

☐ HIV/AIDS ☐ Malaria ☐ Other infectious disease(s)

☐ Other care (specify all types of care received:_____)

6. Respondent's detailed account of the illness of the deceased:

7. Did a health care worker tell you the cause of death? ⊢ Yes ⊢ No ⊢ Unknown
If yes go to 7a, if no go to 8

7a. What did the health care worker say was the cause of death?_____

8. Did s/he have any operation for the illness? ⊢ Yes ⊢ No ⊢ Unknown
If yes go to 8a, if no go to 9

8a. How long before the death was the operation? _____days

8b. On what part of the body was the operation?

⊢ Abdomen ⊢ Chest ⊢Head ⊢ Other(Specify_____)

9. Has spouse or other sexual partner(s) of the deceased died in the past 5 years?

⊢ Yes ⊢ No ⊢ Unknown *If yes go to 9a, if no go to 10*

9a. If yes, what is the believed cause(s) of death of the partner(s)

9a1. Partner 1:_____

9a2. Partner 2:_____

Injury/accident/suicide

10. Did s/he suffer from any injury or accident that led to her death? ⊢ Yes ⊢ No ⊢ Unknown

If yes go to 10a, if no go to 11

10a. What kind of injury or accident did the deceased suffer?

☐ Road traffic accident ☐ Fall ☐ Drowning ☐ Poisoning

☐ Burns ☐ Violence/assault ☐ Other:_____

☐ Unknown

10b. Was the injury or accident intentionally inflicted by someone else? ☐ Yes ☐ No ☐ Unknown

10c. Do you think that s/he committed suicide? ☐ Yes ☐ No ☐ Unknown

Skip to Q.12

11. Did s/he suffer from any animal/insect bite that led to her/his death? ☐ Yes ☐ No ☐ Unknown

11a. If yes, what type of animal/insect?_____

History of previously known medical conditions

12. Did the deceased suffer from any of the following conditions?

a. High blood pressure ☐ Yes ☐ No ☐ Unknown

b. Diabetes ☐ Yes ☐ No ☐ Unknown

c. Asthma ☐ Yes ☐ No ☐ Unknown

d. Epilepsy ☐ Yes ☐ No ☐ Unknown

e. Malnutrition ☐ Yes ☐ No ☐ Unknown

f. Cancer ☐ Yes ☐ No ☐ Unknown

f1. If yes, specify type of cancer or site:_____

g. Tuberculosis ☐ Yes ☐ No ☐ Unknown

h. Any other medically diagnosed illness? ☐ Yes ☐ No ☐ Unknown

h1. If yes, specify:_____

4635

4636 **13. Signs, symptoms, and their severity during the last illness:**

Symptom/ Signs	**Symptom present?**	**If present, duration of symptom**
a. Fever	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
b. Loss of weight	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
c. Diarrhea	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
d. Vomiting/associated abdominal pain	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
e. Constipation/associated abdominal pain	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
f. Cough	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
g. Cough followed by vomiting	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
h. Breathing trouble (chest indrawing/difficult/rapid/wheezing)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
i. Neck stiffness	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
j. Unconscious episodes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
k. Fits	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
l. Jerking of individual limbs	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
m. History of epileptic illness in earlier years	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
n. Paralysis of limbs	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
o. Rigid body stiffness, unable to open mouth	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
p. Red and sore eyes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
q. Skin rash and itching	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
r. Herpes Zoster (at any time in life)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
s. Abscesses/body sores	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
t. White patches on the inside of mouth and tongue	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
u. Oedema	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
v. Hair changes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
w. Yellowing of eyes or passing of brown urine	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
x. Chest pain	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
y. Other (Specify:)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown

4637

Unexpected vaginal bleeding or discharge	☐No ☐ Yes	≤2 weeks ☐ >2 weeks ☐ Unknown
Pelvic or vaginal pain	☐No ☐ Yes	≤2 weeks ☐ >2 weeks ☐ Unknown

4638

14. Records available in home, e.g., death certificate (extract findings):

15. Comment

EXIT

Study ID Number: ___ ___ ___ **Interviewer Number:** ____ ____

Date of visit (day/month/year) ___ ___ / ___ ___ / ___ ___ ___ ___

1. Is the patient exiting the study because she has completed the study protocol and qualifies as per study guidelines to exit the study at this time? ☐ Yes ☐ No *(If Yes, go to 9, If No go to 2)*

2. Date of last study visit (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

3. Date last seen by study staff (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

4. Has the patient accessed care at the Hope Clinic in the past year? ☐ Yes ☐ No

5. Did you talk to the patient? ☐ Yes ☐ No *(If Yes go to 6, If No go to 5a)*

5a. If no, who was the source of information (tick one)

☐ Clinician / clinic staff ☐ Employer ☐ Treatment supporter

☐ Spouse or Partner ☐ Friend ☐ Other (specify)

☐ Family member / Relative ☐ Neighbor

☐ Mother or Father ☐ Caregiver

6. Has the patient transferred HIV care to another program? ☐ Yes ☐ No *(If Yes go to 6a, If No go to 7)*

6a. If yes, where is the patient transferring care to (tick one)

☐ Transferred to another non-Hope clinic, specify

☐ Transferred to Industrial area clinic

☐ Transferred to Maseno clinic

7. Has Hope Clinic asked the patient to Exit or leave the program? ⊦ Yes ⊦ No *(If Yes go to 7a, If No go to 8)*

7a. Reasons for being Exited from the program (tick all that apply)

⊦ Client has not returned to clinic for 1 year

⊦ Poor Adherence

⊦ Poor Clinic Attendance

⊦ Not willing to disclose HIV status

⊦ Referred else where

⊦ Tested Negative

⊦ Other (specify) _____

⊦ Unknown

8. Has the patient asked to be Unenrolled from the study? ⊦ Yes ⊦ No *(If Yes go to 8a, If No go to 9)*

8a. Reasons patient is asking to Unenroll from the study (tick all that apply)

⊦ Not willing to attend

⊦ Waiting time too long

⊦ Conflict with work

⊦ Financial problems

⊦ Unwilling to attend because of health problems

⊦ Family Problems

⊦ Client will go to a faith healer

⊦ Not willing to disclose HIV status

⊦ Referred else where

⊦ Other (specify) _____

⊦ Unknown

9. At what point was the patient exited? ⊦ After Pap smear ⊦After Biopsy ⊦ Mortality ⊦ Withdrawn from study ⊦Other (If other specify)

10. Comment

CYTOLOGY REPORT

☐First read ☐Re-read 1 ☐Consensus reading

Study ID Number__ __ __

Test/ Visit code___ ___ ___ ___Hope ID Number ___ ___ ___ ___

Visit (tick one) ☐ Initial Visit ☐ Repeat ☐ Month 6 FU ☐ Month 12FU ☐ Month 18 FU

☐ Month 24 FU ☐Other, specify

Interviewer number __ __ __

Patient Age

1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Time sample was collected in clinic
3. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___ ___ ___ ___
4. Time sample was received in laboratory
5. When was the Pap smear preparation processed? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
6. When was the Pap smear preparation reported? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
7. Quality of specimen: ☐ Satisfactory ☐ Unsatisfactory

(If unsatisfactory, fill Q8 and skip to Q13)

8. Quality limitations in sample? Yes No

If "Yes", specify limitations:

- No endocervical components ☐☐
- Not enough cellular material ☐☐
- Air dried ☐☐
- Bad fixation ☐☐
- Too much blood ☐☐
- Too much pus ☐☐
- Other specify……

9. Any microbiological findings? □ Yes □ No
If "Yes", specify findings:

Lactobacilli □□

Mixed flora □□

Bacterial vaginosis □ □

Candida □ □

Trichomonas vaginalis □□

Actinomyces □□

Schistosoma □□

Herpes simplex □□

Other, specify……

10. Any reactive changes observed? □ Yes □ No
If "Yes", specify findings

Metaplasia □□

Inflammatory changes □□

Follicular cervicitis □□

Parakeratosis □□

Atrophy □□

Other reactive changes □□

If "Yes", specify……

11. Squamous epithelium: □ Normal □ Abnormal
If "Yes", specify findings

ASC-US □ Yes □ No

ASC-H □ Yes □ No

Low grade SIL □ Yes □ No

- With koilocytosis □ Yes □ No

High grade SIL □ Yes □ No

HSIL invasion not ruled out □ Yes □ No

Squamous cell carcinoma □ Yes □ No

Others, specify _____

12. Glandular epithelium: □ Normal □ abnormal

If "Yes", specify findings

Abnormal presence of endometrial cells □ Yes □ No

Atypical glandular cells, pref. neoplastic □ Yes □ No

Adenocarcinoma in situ □ Yes □ No

Adenocarcinoma □ Yes □ No

- Endometrial □ Yes □ No

- Endocervical □ Yes □ No

Others, specify _____

13. Other remarks.....

Interviewer number of pathologist □

Date: _____

COLPOSCOPIC BIOPSY HISTOLOGY REPORT

☐First read ☐Re-read 1 ☐Consensus reading☐ Tie-break

Study ID Number__ __ __ **Hope ID Number** ___ ___ ___ ___

Test/ Visit code_____

Visit (tick one) ☐ Initial Visit ☐ Month 6 FU ☐ Month 12 FU ☐ Month 18 FU

☐ Month 24 FU ☐Other, specify

Interviewer number --- ----**Patient Age _____**

1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Time sample was collected in clinic
3. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___ ___ ___ ___
4. Time sample was received in laboratory
5. When was the biopsy processed? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
6. When was the biopsy reported? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
7. Was the amount of sample adequate for reading? ☐ Yes ☐ No ☐Other, specify
8. What was the histology result of the cervical biopsy (tick one)?

☐No dysplasia (NIL)

☐CIN 1

☐CIN 2

☐CIN 3

☐Invasive carcinoma

☐Indeterminate/

☐CIS

☐Other, specify

9. Was there evidence of cervicitis? ☐ Yes ☐ No ☐Other, specify
10. Who read the biopsy and gave this histology result?

Pathologist Interviewer number ___

11. Comments:

ENDOCERVICAL CURETTAGEHISTOLOGY REPORT

☐First read ☐Re-read 1 ☐Consensus reading☐Tie-break

Study ID Number__ __ __ **Hope ID Number** ___ ___ ___ ___

Test/ Visit code_____

Visit (tick one) ☐ Initial Visit ☐ Month 6 FU ☐ Month 12 FU ☐ Month 18 FU

☐ Month 24 FU ☐Other, specify

Interviewer number --- ----**Patient Age _____**

1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Time sample was collected in clinic
3. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___ ___ ___ ___
4. Time sample was received in laboratory
5. When was the biopsy processed? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
6. When was the biopsy reported? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
7. Was the amount of sample adequate for reading? ☐ Yes ☐ No ☐Other, specify
8. What was the histology result of the Endocervical Curettage biopsy (tick one)?

☐No dysplasia (NIL)

☐CIN 1

☐CIN 2

☐CIN 3

☐Invasive carcinoma

☐Indeterminate/

☐CIS

☐Other, specify

9. Was there evidence of cervicitis? ☐ Yes ☐ No ☐Other, specify
10. Who read the biopsy and gave this histology result?

Pathologist Interviewer number ___

11. Comments:

LEEP BIOPSY HISTOLOGY REPORT

☐First read ☐Re-read 1 ☐Consensus reading☐ Tie-break

Study ID Number__ __ __ **Hope ID Number** ___ ___ ___ ___

Test/ Visit code_____

Visit (tick one) ☐ Initial Visit ☐ Month 6 FU ☐ Month 12 FU ☐ Month 18 FU

☐ Month 24 FU ☐Other, specify

Patient Age _____ Interviewer number --- ----

1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Time sample was collected in clinic
3. Notes:
4. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___ ___ ___ ___
5. Time sample was received in laboratory

6. When was the LEEP specimen processed? (day/month/year) ___ ___/___ ___/___ ___ __

7. When was the LEEP specimen reported? (day/month/year) ___ ___/___ ___/___ ___ ___

8. Was the amount of sample adequate for reading? ☐ Yes ☐ No ☐Other, specify

9. What was the histology result of the LEEPcervical biopsy (tick one)?

☐No dysplasia (NIL)

☐CIN 1

☐CIN 2

☐CIN 3

☐Invasive carcinoma

☐Indeterminate/

☐CIS

☐Other, specify

10. Was there evidence of cervicitis? ☐ Yes ☐ No ☐Other, specify
11. Who read the biopsy and gave this histology result?

Pathologist Interviewer number ___

12. Comments:

CD4 REPORT

Study ID Number__ __ __ **Hope ID Number ___ ___ ___ ___**

Visit (tick one) □ Randomization/LEEP Visit □ Month 6FU □ Month 12FU □ Month 18 FU □ Month 24 FU □Other, specify

Patient Age **Interviewer number**

1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___ ___
2. Time sample was collected in clinic
3. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___ ___ ___ ___
4. Time sample was received in laboratory
5. When was the CD4 count run? (day/month/year) ___ ___/___ ___/___ ___ ___ ___
6. What was the result of the CD4 count? ___ ___ ____ ____
7. Who ran the CD4 count and gave this CD4 result? Coptic lab H Other, specify

8. Comments:

FOLLOW-UP FORM

Study ID Number__ __ __ Hope ID Number __ __ __ __Interviewer Number_

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Month 6 FU □ Month 12 FU □ Month 18 FU

□ Month 24 FU □Other, specify

A: MEDICAL HISTORY

1. Did you consult a doctor or clinical officer between today and your previous study visit?

Yes	□	
No	□	(go to question 2)
Don't know	□	(go to question 2)
Refused	□	(go to question 2)

If yes:

1.1. How many consultations?

___ ___

Don't know	□	(go to question 2)
Refused	□	(go to question 2)

1.2. Why did you consult?

1.2.1. Visit 1:

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

1.2.2. Visit 2:

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

1.2.3. Visit 3:

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

1.2.4 Visit 4

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

1.2.5 Visit 5

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

1.2.6 Visit 6

Reason for consultation		
Routine check-up visit not study related	|__|	yes
Sickness…….…….	|__|	yes
Other, specify …….	|__|	yes
Do not recall the reason	|__|	yes
Refused	|__|	yes

(For those previously not on ARVs- please refer to enrollment form)

2. Have you initiated anti-retroviral medication since the last visit?

Yes □
No □
Don't know □
Refused □

If yes:

2.1. Which date did you initiate ARV's --/ --/ ----

2.2. Specify current regimen

3. Are you still on ARVs? (For those previously on ARVs-please refer to enrollment form)

Yes □
No □
NA □
(If NA go to Q4)

3.1 If no, reasons for not being on ARVs

- Poor adherence
- Side effect
- Stigma
-Concurrent illness
- Other (specify)

3.2 If yes, has your anti-retroviral medication changed since last cervical treatment visit?

Yes ☐
No ☐ (go to question 4)
Don't know ☐ (go to question 4)
Refused ☐ (go to question 4)

If yes:
3.2.1. On which date was it changed: ___ ___/___ ___/___ ___ ___ ___
3.2.2. What was the reason for changing your antiretroviral medication? (Check all that apply)

a) Because of low CD4 counts: Yes ☐
b) Because of high viral load: Yes ☐
c) Because of clinical symptoms: Yes ☐
f) Other, specifiy: ___ ___ ___ ___ ___ ___ Yes ☐
e) Don't know: Yes ☐
d) Refused: Yes ☐

3.2.3 Specify current medications: _____

4. Did you receive any cervical treatment other than what we offered?

Yes ☐
No ☐ (go to part B)
Don't know ☐ (go to part B)
Refused ☐ (go to part B)

If yes:
4.1. On which date was this: ___ ___/___ ___/___ ___ ___ ___
4.2. Which treatment did you receive?

a) Cryotherapy: Yes ☐
b) LEEP: Yes ☐
c) Cold knife exconisation: Yes ☐
d) Hysterectomy: Yes ☐
f) Other, specifiy: ___ ___ ___ ___ ___ ___ Yes ☐
e) Don't know: Yes ☐
d) Refused: Yes ☐

B. SEXUAL HISTORY

5. Have you had sex in the last 6 months?

Yes ☐
No ☐ (go to Q6)
Don't know ☐ (go to Q6)
Refused ☐ (go to Q6)

If yes:
5.1. With your regular partner? Yes ☐
No ☐ (go to Q5.2)
If yes,
5.1.1. How often have you used condoms during sex with your regular partner in the last 6 months?
Always (100%) ☐
Most of the time (75-99%) ☐

Half of the time (50%-74%) ☐
Sometimes (25-49%) ☐
Rarely (1-25%) ☐
Never (0%) ☐
Don't know ☐
Refused to answer ☐

5.1.2. Do you suspect that your partner has had other sexual partnersduring the last 6 months?

Yes ☐
No ☐
Don't know ☐
Refused ☐

5.2. Did you have sex with any other partner(s) than your regular partner during the last 6 months?

Yes ☐
No ☐ (Go to Q6)
Don't know ☐ (Go to Q6)
Refused ☐ (Go to Q6)

If yes:

5.2.1. How many other different sexual partners besides your regular partner did you have in the last 6 months? ___ ___

Don't know ☐
Refused ☐

5.2.2. How often have you used condoms during sex with these other partner(s) in the last 6 months?

Always (100%) ☐
Most of the time (75-99%) ☐
Half of the time (50%-74%) ☐
Sometimes (25-49%) ☐
Rarely (1-25%) ☐
Never (0%) ☐
Don't know ☐

6. Refused to answer
7. Comment

5054

ADVERSE EVENTS

Study ID Number __ __ __ **Interviewer Number**__ __

Date of visit (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ **Shedding1** □ **Shedding2** □ **Shedding3**

□ **Month 6 FU** □ **Month 12 FU** □ **Month 18 FU** □ **Month 24 FU**

□**Other, specify _____**

	Adverse Event	**Start Date**(DD/MM/YYYY)	**End Date** (DD/MM/YYYY)	**Severity** 1= Mild 2= Moderate 3= Severe 4= Life Threatening	**Relationship to Study procedures** 1= Related 2= Notrelated	**Outcome** 1= Resolved without sequelae 2= Resolved with sequelae 3= Ongoing 4= Death 5= Unknown	**Serious** 0= No 1= Yes**
1							
2							
3							
4							

Comments: _____
_____

** If Serious Adverse Event, contact a PI immediately after filling this form.**

PI Contacts: Dr. Michael Chung – 020-271-2947, 0722-579-963, Dr. Nelly Mugo – 020-273-6744

UANDIKISHAJI

Study ID Number__ __ __ Hope ID Number __ __ __ __Interviewer Number_

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Ulikubali kuhifadhi sampuli : Ndio □ La □Sijui □ Nyingine, eleza

A: SOCIODEMOGRAPHICS

1. Tarehe ya kuzaliwa (siku/mwezi/mwaka) ___ ___/___ ___/___ ___ ___ ___
2. Miaka _____ years
3. Ulikamilisha miaka ngapi ya elimu? _____ years
4. Elimu ya juu zaidi uliyokamilisha? Hakuna □
   Msingi □
   Sekondari □
   Elimu ya juu/ Chuo Kikuu □
   Sijui □
   Amekataa □
   Nyingine, eleza
5. Hali ya ndoa (jibu moja) Ndoa (mke mmoja) □
   Ndoa (wake wengi) □
   Pekee □
   Talaka/Tenganishwa □
   Mjane □
   Amekataa □
   Kuishi pamoja □
   Nyingine eleza □
6. Ajira (jibu moga): Kazi inayokupa mshahara □
   Kujiajiri □

Mama wa nyumbani □

Hujaajiriwa □

Mfanyikazi wa kawaida □

Amekataa □

Nyingine, eleza □

7. Kipato cha kaya kwa mwezi (jibu moja): Hakuna □
< 5000 Ksh □

5001 – 10000 Ksh □

10001 – 15,000 Ksh □

>15,000 Ksh □

Sijui □

Amekataa □

B: HISTORIA YA KUFANYA MAPENZI

8. Ulikuwa na miaka mingapi ulipofanya ngono ya uke mara ya kwanza?__ __
Sijui□Amekataa □ Hujawahi □ Nyingine, eleza

9. Umewahi kuwa na wapenzi wangapi wa ngono? __ __ Sijui □Amekataa □
Nyingine,eleza □ _____

10. Umekuwa na wapenzi wangapi tofauti wa ngono mwaka wa mwisho? __
__ Sijui □ Amekataa □ Nyingine, eleza

11. Umefanya ngono katika mwezi wa mwisho? (If no, don't know, refused, skip to 14) Ndio □ La □ Sijui □ Amekataa □ Nyingine, eleza

12. Ni mara ngapi umetumia mpira wakati wa ngono katika mwezi uliopita?
Kila wakati (100%) □ Wengi wa wakati huo (75-99%) □
Nusu ya mudu (50%-74%) □ Wakati mwingine (25-49%) □
Mara chache (1-25%) □ Kamwe (0%) □
Amekataa □ Sijui □
Nyingine, eleza

13. Je, unafikiri unaweza kuwa ma mimba sasa? Ndio □ La □ Sijui □
Amekataa □ Nyingine, eleza

C: SARATANI YA UZAZI HISTORIA YA UCHUNGUZI

14. Hapo awali, umewahi kupimwa saratani ya uzazi? Ndio □ La □
Sijui □ Alikataa □ Nyingine, eleza

If no,don't know or refused skip to 20.

15. Uchunguzi gani wa saratani ya uzazi uliofanyiwa hivi karibuni? (jibu moja)

□ Pap smear

□ Ukaguzi na asetiki aside

□ HPV

□ Nyingine, eleza : _____

□ Sijui

□Amekataa

16. Uchunguzi huu wa hivi karibuni ulifanyiwa wapi?

□ Coptic
□ KNH

□ AmekataaSijui

□ Nyingine, eleza

17. Uchunguzi huu ulifanyiwa wapi?
sijui □

18. Majibu yalikuwa nini?

□ Kawaida

□ Usiokuwa ya kawaida, eleza _____

□ Sijui

□ Amekataa

19. Ulipokea matibabu yoyote ya kizazi au upasuaji kwasababu ya majibu ya hii uchunguzi?
Ndio□ La□ Sijui □ Amekataa □ Nyingine, eleza _____

Kama ni ndio, eleza _____

20. Pap Smear ilifanywa leo? Ndio □ La □Amekataa □ Sijui
Kama ni la, fafanua
21. Maoni

UBAHATISHAJI

Study ID Number__ __ __ Hope ID Number __ __ __ __

Randomization Number_ _ Interviewer Number_

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

A: HISTORIA YA SASA YA MATIBABU

1. Je, unauchungu unapopitisha mkojo? Ndio □ La □ Nyingine, eleza Amekataa □ Sijui

2. Je, una uchungu sehemu ya chini ya tumbo? Ndio □ La □ Nyingine, eleza Amekataa □ Sijui

3. Je, unatokwa na uchafu yasiyo ya kawaida katika uzazi wako wa kike? Ndio □ La □ Nyingine, eleza□ Amekataa □ Sijui

4.Je, umeona uvimbe yoyote katika uzazi wako wa kike? Ndio □ La □ Nyingine, eleza □ Amekataa □ Sijui

B: AFYA YA UZAZI

5. Ulikuwa na miaka mingapi ulipopata damu ya mwezi? __ Amekataa□ Sijui □ Nyingine, eleza

6. Tarehe ya mwisho ya kupata damu yako ya mwezi ? (dd/mm/yy) ___ ___/___ ___/___ ___ ___ ___ Sijui □ Amekataa □ Nyingine eleza

7. Je, una historia ya kutokwa na damu isiyo ya kawaida sehemu ya uke?Ndio □ La □ Sijui □Amekataa □ Nyingine, eleza

Kama ndio, eleza aina ya damu

□ Isiyo mara kwa mara

□ Nzito

□Kutokwa na damu nzito sana wakati wako wa mwezi

□ Nyingine, eleza

□ Sijui

□ Amekataa

8. Je, umewahi kutumia njia yoyote ya kupanga uzazi? Ndio □ La □
Sijui □
Amekataa □
Nyingine, eleza _____

Kama ndio, eleza (chagua yote yanayotumuka)

Sindano □ IUCD □ Asili □

Mpira □ Tembe □ Norplant/Implant □

BTL □ Nyingine, eleza _____

9. Je, sasa hivi unatumia njia yoyote ya kupanga uzazi?
ndio □ la □Sijui □Amekataa □
Nyingine, eleza□ _____

Kama ndio, eleza (chagua yote yanayotumika)

Sindano □ IUCD □ Asili □

Mpira □ Tembe □ Norplant/Implant □

BTL □ Nyingine, eleza _____

10. Je, umekuwa na mimba mara ngapi? __ __ Amekataa □ Sijui □ Nyingine □

11. Je, umekuwa na watoto walioishi mara ngapi? __ __ Amekataa □ Sijui □ Nyingine □

12. Je, umetoa mimba ngapi au kupoteza mimba au mtoto kufia kabla kuzaliwa ?
__ __ Amekataa □ Sijui □ Nyingine □

13. Je, umewahi kulazwa hospitalini na tatizo yoyote ya gynecologia?
Ndio □ La □ Sijui □ Amekataa □ Nyingine, eleza

14.Je, umewahi kupasuliwa tumbo? Ndio □ La □ Amekataa □ Sijui □ Nyingine, eleza

15. Je, umewahi kupasuliwa uke? Ndio □ La □ Amekataa □ Sijui □ Nyingine, eleza

16. Sasa hivi, unavuta sigara? Ndio □ La □ Amekataa □ Sijui □ Nyingine, eleza

C: HISTORIA YA HIV

17. Ulijulikana uko na HIV lini? (dd/mm/yyyy) ___ ___/___ ___/___ ___ ___ ___

18.1. HIV ilitambuliwa aje? (jibu moja pekee)

- Ulipotembelea kituo cha VCT: Ndio □
- Kwa kliniki ya wajawazito : Ndio □
- Kwasababu ya ugonjwa , eleza:_____ Ndio □
- Nyingine, eleza:_____ □
- Sijui: □
- Amekataa: □

19. Je, sasa hivi unatumia madawa ya kurefusha maisha? Ndio □ La □
Sijui □
Amekataa □
Nyingine, elezaKama ndio,

a) Eleza madawa unayotumia sasa : _____

b) tarehe ya awali uliyoanza ___ ___/___ ___/___ ___ ___ ___ sijui □

c) Je, unajua sababu ulioanzishwa madawa ya kurefusha maisha?

- Kwasababu ya ugonjwa, eleza: _____ Ndio □
- Kwasababu ya CD4 kuwa chini : Ndio □
- Kwasababu ya viwango vya virusi kuwa juu: Ndio □
- Nyingine, eleza: _____ □
- Sijui: □
- Amekataa □

20. Maoni

ANUANI NA ULAJI

Study ID number __ __ __ __ __ __ **Interviewer number ____ ____**

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Format(tick one) □**New** □**Update (fill only updated info)**

A. YA KIBINAFSI

19. Jina Lako Nani?
    a. Jina la kwanza
    b. Jina la katikati
    c. Jina la mwisho

20. Wajulikana kwa jina lipi eneo unako ishi?
21. Jina kamili ya eneo unako ishi.
    a. Wilaya
    b. Mji
    c. Kijiji
    d. Mtaa
    e. Nambari ya ploti
    f. Nambari ya mlango
    g. Jina la barabara

22. Usafiri wa umma hadi kwako nyumbani:

    4a. Aina: Ⱶ Bus Ⱶ Boda boda Ⱶ Matatu Ⱶ Taxi Ⱶ Mengine(Fafanua)

    4b. Numbari ya gari iendako eneo unakoishi:

    4c. Jina la kituo cha kuabiria magari?

    4d. Jina inalojulikana eneo unakoishi.

23. Maelezo ya njia kutoka kwako hadi kituo cha kuabiria magari?
24. Alama ya kuwa msaidizi katika kuuweka kaya: (Majina ya shule, makanisa, biashara nk)
25. Je, unaweza kufikiwa kwa njia ya simu? Ndiyo □ La □
    Kama ndiyo,

    (i) Nambari ya simu yako 1?
    (ii)) Nambari ya simu yako 2?

    iii. Nani anaye beba simu hiyo (Weka alama kwa moja) □ Mimi □ Mwingine, fafanua

B. <u>MAWASILIANO MUHIMU</u>

26. Je, kuna mtu mwingine ambaye anjua hali yako ya HIV ambaye tunaweza kuwasiliana kwa njia ya simu kama hatuwezi kufikia wewe moja kwa moja? If no skip to 9.

27. Jina lake ni nani?
    a. Jina la kwanza
    b. Jina la katikati
    c. Jina la mwisho
28. Uhusiano gani upo kati yako na mtu huyu ?
29. (a)Nambari yake ya simu1?
    (b) Nambari yake ya simu2?

C. MAWASILIANO KUHUSU KWAKO MASHAMBANI

30. Je, una nyumbani bara? Ndiyo □ La□
    If no, skip to 19

31. Ni wapi kwako Bara?
    a. Wilaya
    b. Mji
    c. Kijiji
    d. Mtaa
    e. Nambari ya ploti
    f. Nambari ya mlango
32. Maelekezo maalum kwa makazi
33. Je, kuna mtu u ko bara ambaye tunaweza kuwasiliana kama hatuwezi kufikia wewe moja kwa moja? Ndiyo □ La □
    If no, skip to 19

34. Jina lake huyu mtu ni nani?
    a. Jina la kwanza
    b. Jina la katikati
    c. Jina la mwisho
35. Uhusiano gani upo kati yako na mtu huyu ?
36. Je huyu mtu ako na simu? Ndiyo □ La□
    Iwapo ndiyo , fafanua

    (a)Nambari yake ya simu1?
    (b) Nambari yake ya simu2?

D. ANDRA

Maoni

SHEDDING

Study ID Number __ __ __ **Interviewer Number** __ __

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

Visit (tick one) □ Week 1 FU □ Week 2 FU □ Week 3 FU □Other, specify _____

A: MEDICAL HISTORY

1. Unasikia maumivu ya tumbo ya chini?

ndio□ la □

(Ndio,fafanua)

a. muda wa __ __ (siku)
b. Ukali(kidogo 1-5, 5 kuwakali zaidi)

9. Umekuwa na historia ya kutokwa na damu ambaye si yakawaida? Fafanua

Ndio □ La □

(Ndio,fafanua)

g. muda wa__ __ siku
h. kiasi
□doasuruali)

□Inahitajipediya usafi

□Mwingine,eleza

Unatokwa na majimaji ya uke yasiyo ya kawaida?

10.

□Ndio □la

(Ndio,fafanua)

i. muda wa __ __ siku)
j. rangi ya
 Majano

hudurungi

 nyeupe

wazi

 Nyingine ,fafanua

k. harufu
 Harufu mbaya

Hakunaharufu

Mengine,eleza

l. kiasi
 inadoasuruali

Inahitajipediya usafi

Mengine,eleza

11. Mgonjwa amekuwa nahoma yoyotebaada ya ziara yamwisho?
Ndio la

kama ndio, fafanua muda….siku

12. Je,mgonjwaametafutahuduma zamatibabu kwa ajili yahaya aumalalamiko mengine?

Ndio La

If yes, specify what complaint prompted the participant to seek care:

 Uchungu wa tumbo ya chini

 Homa

 Damu kutoka uzazi wa kike

 Uchafu unaotoka katika uzazi wa kike

e. Mengine, fafanua

If yes, specify where the participant sought care:

 Study clinic

 Hope Center

□ Coptic Hospital

□ KNH

f. Other, specify

13. Was the participant's condition possibly due to a study procedure? (Ask if any of questions 1-4 is yes)

Yes □ No □

If yes, fill out a Complications questionnaire.

14. Damu yako ya mwezi ya mwisho ilikuwa lini? (dd/mm/yyyy)

15. Umewahi fanya ngono uke tangu utibiwe? □ Ndio □la □Kataa

Nyingine fafanua_____

8 (a). Ndio, mara ngapi?__

8(b) Kamawamefanya mapenziuketangumatibabu,je,ni mara ngapikutumia kondomuwakati wa ngono?

Kila wakati (100%) □ Wengi wa wakati huo (75-99%) □
Nusu ya mudu (50%-74%) □ Wakati mwingine (25-49%) □
Mara chache (1-25%) □ Kamwe (0%) □
Amekataa □ Sijui □
Nyingine, eleza

9. Unafikiri unaweza kuwa mjamzito

□Ndio □la

10. Kwa sasa unatumia madawa ya kupungua makali ya virusi

□ Ndio □Kataa □Nyingine,fafanua

□La □Sijui

Ndio, fafanua madawa unayo tumia sasa na tarehe uliyo yaanza

- d4t, 3tc, nvp
- d4t, 3tc, efv
- azt, 3tc, nvp
- azt, 3tc, efv
- zingine, fafanua

Tarehe ya kuanzaARV awali (dd /mm /yyyy)

11 Katika siku7 ya mwisho , mgojwa alikosa kumeza tembe ngapi za dawaza kurefusha maisha?

12 Katika siku 30 ya mwisho30, mgonjwa alikosa kumeza tembe ngapi za dawaza kurefusha maisha?

(If Q11 and Q12 patient did not MISS taking any pills skip to Q14)

13. If the patient missed any doses, please specify reasons (check all that apply)

- Toxicity/ side effect
- Share with others
- Forgot

g. Felt better

- Too ill
- Stigma, disclosure or privacy issues
- Drug out of stock
- Patient lost or ran out of pills
- Delivery /travel problem
- Inability to pay
- Alcohol
- Depression

h. Other specify

B: DIAGNOSIS

14. Is there any new infection that was related to the procedure since the last visit?

Yes □ No □

If yes, specify and fill a Complications and/or Adverse Event questionnaire:

15. Were there any new complications diagnosed today related to the treatment?
Yes □ No □
If yes, specify and fill a Complications and/or Adverse Event questionnaire:

C: TREATMENT

16. Was any treatment provided today? Yes □ No □
If yes, specify

17. Was the patient referred for further cervical treatment at another institution?
Yes□ No □

17 (i)If yes, specify institution

17(ii)If yes, specify reason for referral

D: SPECIMEN COLLECTION

18. Did you collect cervical HIV swab? Yes □ No □
If no, specify reason:

19. Did you collect blood? Yes □ No □
If no, specify reason:

E: ACCEPTABILITY OF TREATMENT

20. Please complete the items listed below by placing a checkmark on the box next to each question that best indicates how the client feels about the treatment she received.

	SIKUBALI KAMWE	haukubaliani	kadri,	kukubaliana	sanakukubaliana
(i) Naona hii njia ni mwafaka kwa kukabiliana na magonjwa ya njia ya uzazi)	□	□	□	□	□
(ii) Naweza tumia haya ya matibabu nikipatamagonjwa kama haya siku ya mbeli	□	□	□	□	□
(iii) ningependekeza haya matibabu kwa mtu mwingine	□	□	□	□	□
(iv) kwa jumla nakubaliana na haya matibabu)	□	□	□	□	□

F: OTHER

24. Comments:

VERBAL AUTOPSY

Study ID Number __ __ __ **Interviewer Number** __
__

Date of interview (day/month/year) ___ ___/___ ___/___ ___ ___ ___

1. Umriwakati was kifo I- years

2. Tarehe yakifo I-I-/I-I-/I-I-I-

3. Mahaliya kifo

4. The information souce for the cause of death was (tick all that apply)

I- Partner/spouse I- Mother or Father I- Friend

I- Hospital records/staff I- Other family member/relative I- Care giver

I- Neighbor I- Unknown I- Other (specify)

5. Was the deceased seeking other medical treatment (other than Hope Center) during the last 3 months before his/her death? I- Yes I- No I- Unknown *If yes go to 5a, if no go to 6*

5a. If yes, where specifically was the deceased receiving other medical care?

Name of facility:_____

5b. What type of care was the deceased receiving at the these other facilities? (Tick all that apply)

I- General medical care I- TB I- STD

I- HIV/AIDS I- Malaria I- Other infectious disease(s)

I- Other care (specify all types of care received:_____)

6. Respondent's detailed account of the illness of the deceased:

7. Je,mfanyakazi wahuduma za afya alikuambiasababu ya kifo? Ndio☐ la ☐ sijui☐ *If yes go to 7a, if no go to 8*

7a. Ninimfanyakazi wahuduma za afyawanasemakilichosababisha kifo?

8. Alifanyiwa upasuaji wowote kwa sababu ya ugonjwa? Ndio☐ La☐ sijui☐ *If yes go to 8a, if no go to 9*

8a. Upasuaji ulikuwa muda ganikabla ya kifo?_____siku

8b. Sehemu gani ya mwili alifanyiwa upasuahi?

☐ tumbo ☐ Kifua ☐kichwa) ☐ Mengine(fafanua) _____)

9. Mpenzi(wapenzi)wa marehemu wowote wamekufakatikakipindi cha miaka 5 iliyopita?

Ndio☐ La ☐ Haijulikani ☐ *If yes go to 9a, if no go to 10*

9a. Kama ndiyo, ni nini waliamini kilichosababisha kifo champenzi(s)

9a1. Partner 1:_____

9a2. Partner 2:_____

Injury/accident/suicide

10. Je alikabiliwa namajerahayoyoteauajaliambayo imesababishakifo chake? Ndio☐ La☐ sijui☐

If yes go to 10a, if no go to 11

10a. Ni aina gani yamajerahaauajalimarehemualiteseka nayo?

☐ Barabara yaajaliza barabaranii ☐ kuanguka ☐ kuzama ☐sumu

☐ kuungua ☐ magombano ☐ Mengine ☐ Haijulikani

10b. Majeruhi au ajali ilikuwa ya makusudi au ilifanywa na mtu mwingine) ndio☐ La☐ sijui☐

10c. Je, unafikirikwambayeye alijiua?) ndio⊢ La⊢ sijui⊢

11. Je,yeye aliumwa na mnyama/mdudu yeyote iliyosababishakifo chake? Ndio⊢ La⊢ Siju⊢

11a. Kama ndiyo, niaina yamnyama/mdudu?

History of previously known medical conditions

12. Did the deceased suffer from any of the following conditions?

a. High blood pressure ⊢ Yes ⊢ No ⊢ Unknown

b. Diabetes ⊢ Yes ⊢ No ⊢ Unknown

c. Asthma ⊢ Yes ⊢ No ⊢ Unknown

d. Epilepsy ⊢ Yes ⊢ No ⊢ Unknown

e. Malnutrition ⊢ Yes ⊢ No ⊢ Unknown

f. Cancer ⊢ Yes ⊢ No ⊢ Unknown

f1. If yes, specify type of cancer or site:_____

g. Tuberculosis ⊢ Yes ⊢ No ⊢ Unknown

h. Any other medically diagnosed illness? ⊢ Yes ⊢ No ⊢ Unknown

h1. If yes, specify:_____

13. Signs, symptoms, and their severity during the last illness:

Symptom/ Signs	**Symptom present?**	**If present, duration of symptom**
a. Fever	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown
b. Loss of weight	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown
c. Diarrhea	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown
d. Vomiting/associated abdominal pain	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown
e. Constipation/associated abdominal pain	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown
f. Cough	⊢No ⊢ Yes	⊢ ≤2 weeks ⊢ >2 weeks ⊢ Unknown

g. Cough followed by vomiting	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
h. Breathing trouble (chest indrawing/difficult/rapid/wheezing)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
i. Neck stiffness	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
j. Unconscious episodes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
k. Fits	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
l. Jerking of individual limbs	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
m. History of epileptic illness in earlier years	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
n. Paralysis of limbs	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
o. Rigid body stiffness, unable to open mouth	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
p. Red and sore eyes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
q. Skin rash and itching	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
r. Herpes Zoster (at any time in life)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
s. Abscesses/body sores	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
t. White patches on the inside of mouth and tongue	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
u. Oedema	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
v. Hair changes	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
w. Yellowing of eyes or passing of brown urine	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
x. Chest pain	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown
y. Other (Specify:)	☐No ☐ Yes	☐ ≤2 weeks ☐ >2 weeks ☐ Unknown

Unexpected vaginal bleeding or discharge	☐No ☐ Yes	2 weeks ☐ >2 weeks ☐ Unknown
Pelvic or vaginal pain	☐No ☐ Yes	2 weeks ☐ >2 weeks ☐ Unknown

14. Records available in home, e.g., death certificate (extract findings):

15. Comment

EXIT

Study ID Number: ___ ___ ___ **Interviewer Number:** ____ ____

Date of visit (day/month/year) ___ ___ / ___ ___ / ___ ___ ___ ___

1. Is the patient exiting the study because she has completed the study protocol and qualifies as per study guidelines to exit the study at this time? ⊢ Yes ⊢ No *(If Yes, go to 9, If No go to 2)*

2. Date of last study visit (DD/MM/YYYY) ⊢⊢/⊢⊢/⊢⊢⊢⊢

3. Date last seen by study staff (DD/MM/YYYY) ⊢⊢/⊢⊢/⊢⊢⊢⊢

4. Has the patient accessed care at the Hope Clinic in the past year? ⊢ Yes ⊢ No

5. Did you talk to the patient? ⊢ Yes ⊢ No *(If Yes go to 6, If No go to 5a)*

5a. If no, who was the source of information (tick one)

⊢ Clinician / clinic staff ⊢ Employer ⊢ Treatment supporter

⊢ Spouse or Partner ⊢ Friend ⊢ Other (specify)

⊢ Family member / Relative ⊢ Neighbor

⊢ Mother or Father ⊢ Caregiver

6. Je, mgonjwa anahamisha huduma ya HIV kwa mpangilio mwingine? ⊢ Ndiyo ⊢ La *(If Yes go to 6a, If No go to 7)*

6a. If yes, where is the patient transferring care to (tick one)

⊢ Kuhamishiwa kliniki ingine ambayo siya HOPE, elezea

⊢ Kuhamishiwa kliniki ya Industrial area

⊢ Kuhamishiwa kliniki yaMaseno

7. Has Hope Clinic asked the patient to Exit or leave the program? ☐ Yes ☐ No *(If Yes go to 7a, If No go to 8)*

7a. Reasons for being Exited from the program (tick all that apply)

☐ Client has not returned to clinic for 1 year

☐ Poor Adherence

☐ Poor Clinic Attendance

☐ Not willing to disclose HIV status

☐ Referred else where

☐ Tested Negative

☐ Other (specify) _____

☐ Unknown

8. Has the patient asked to be Unenrolled from the study? ☐ Yes ☐ No *(If Yes go to 8a, If No go to 9)*

8a. Reasons patient is asking to Unenroll from the study (tick all that apply)

☐ Kutokuwa na nia ya kuhudhuria

☐ Muda wa kusubiri kuwa mrefu sana

☐ Kutoambana na kazi

☐ Matatizo ya fedha

☐ Kukosa nia ya kuhudhuria kwa sababu ya matatizo ya kiafya

☐ Matatizo ya familia

☐ Mteja kwenda kwa mganga waimani

☐ Kutokuwa tayari kusema hali yake ya Ukimwi

☐ Kutumwa kwingine

☐ Nyingine (taja) _____

☐ Haijulikani

9. At what point was the patient exited? ☐ After Pap smear ☐After Biopsy

☐Mortality ☐Withdrawn from study☐Other (If other specify)

10. Comment

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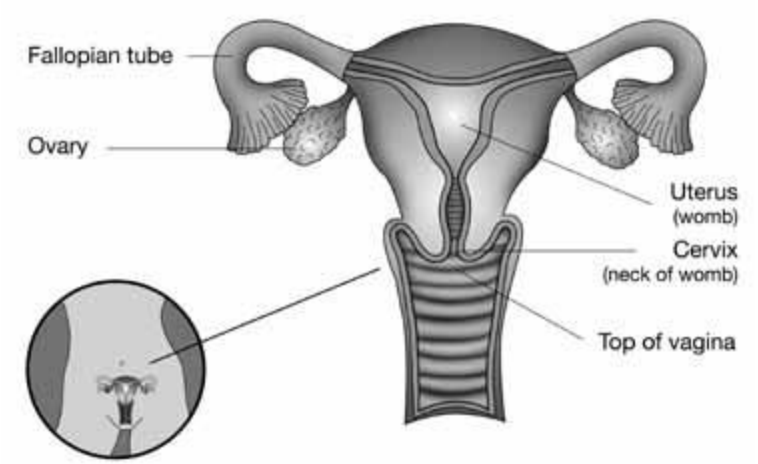
CERVICAL TREATMENT STUDY

What is a Pap smear?

A Pap smear is a simple test to check your cervix to make sure it is healthy. Your cervix is the opening of the uterus, and is at the top of your vagina (see the diagram below). A Pap smear takes only a few minutes and is not painful. Having a Pap smear every two years is the best way to prevent cancer of the cervix.



Why have a Pap smear?

A Pap smear can show the early warning signs of cancer of the cervix. Sometimes the cells of the cervix change from healthy to unhealthy (abnormal). A Pap smear can find abnormal cells before cancer develops.

What causes cervical cancer?

An infection with a virus called HPV (human Papillomavirus) is the cause of almost all cervical cancers. There are over 100 different types of HPV. Two of these types are known to cause most of the cervical cancer cases. HPV is very common. Most people (four out of five) will have HPV at some time in their lives. Anyone who has ever had sex can have HPV.

In most cases, HPV clears up by itself in a few years. Sometimes the virus can stay in your body longer, and can lead to cervical cancer. This usually takes a long time – about 10 years. A Pap smear every two years can find cell changes caused by HPV before they turn into cancer. Your doctor, nurse or health worker can then make sure your health is monitored and that you get treatment if you need it, so you can stay healthy.

How is a Pap smear done?

First the doctor or nurse asks you to undress from the waist down and to lie on your back for the examination. You can ask for a female doctor or nurse. Next the doctor or nurse will use a speculum (medical instrument) to open your vagina so your cervix can be seen more clearly. Some cells are gently wiped from your cervix with a small brush or spatula (a small plastic or wooden stick). The cells are placed on a glass slide and sent to a laboratory where they are looked at under a microscope.

What does it feel like?

Sometimes having a Pap smear can be a little embarrassing. Remember, for the person doing the smear, this is just part of their everyday work and they are not embarrassed. The

procedure might be a bit uncomfortable, but it shouldn't hurt. If it hurts, tell your doctor, nurse or health worker straight away.

What if my results are not normal?

If your results are not normal this does not mean you have cancer. Very often it will be that you have something simple like an infection that will clear up naturally. Sometimes a woman may need to have a Pap smear more often. Some types of abnormal cells may need to be treated by a specialist. Make sure you talk to your doctor, nurse or health worker about what is best for you.

HIV and cervical cancer

HIV-positive women are more likely to be infected with human Papillomavirus (HPV), the primary cause of cervical cancer, and progress to invasive, life-threatening disease than those who are HIV-negative.

Note: Being on HIV medication does NOT reduce your risk of cervical cancer.

Cervical Treatment Study

Researchers from the University of Washington in the USA, Kenyatta National Hospital, WHO and Coptic Hospital are conducting a study to see how treatment can prevent abnormal cells from becoming cancer, and how treatment might affect HIV. Those patients who enroll in the study will be given free screening for cervical disease that may develop into cancer and will also receive free treatment if they are found to have abnormal cells.

For more information about the study, contact:

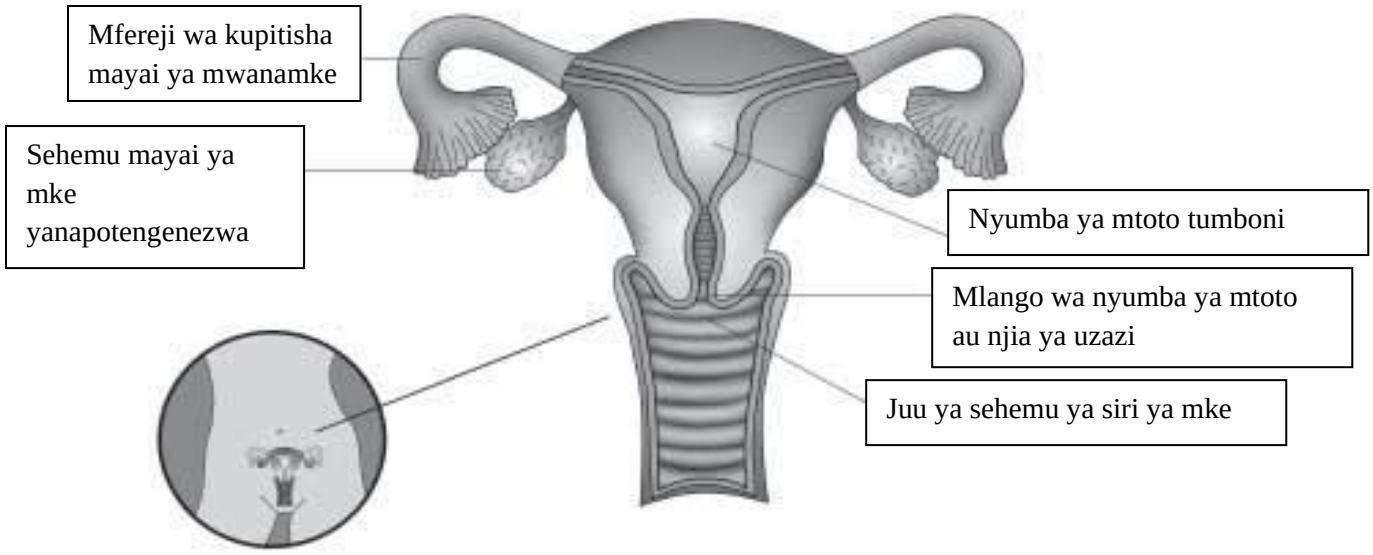
1. Peter Juma: 0721-898-785
2. Elizabeth Makena: 0728-456-540
3. Dr. Evans Malava: 0721-289-733

CERVICAL TREATMENT STUDY

Je Pap Smear ni nini?

Pap Smear ni kupimwa njia yako ya uzazi kwa njia rahisi kuhakikisha ni salama. Njia ya uzazi ni mlango wa nyumba ya mototo tumboni na iko kwa ndani juu ya sehemu yako ya siri (angalia mchoro hapo chini). Kupimwa njia ya uzazi huchukuwa dakika chache tu na si uchungu.

Kupimwa njia ya uzazi kila baada ya miaka miwili ndio njia bora zaidi ya kuzuia saratani ya njia ya uzazi.



Kwa nini upimwe njia ya uzazi?

Kupimwa njia ya uzazi kunaweza kuonyesha dalili za saratani ya njia ya uzazi. Wakati mwingine hali ya njia ya uzazi hubadilika, na kuwa na hitilafu. Ukipimwa njia ya uzazi inaweza kujulikana kama ina hitilafu kabla haijabadilika kuwa saratani.

Nini kinachosababisha Saratani wa njia ya uzazi?

Kuambukizwa kwa virusi vinavyoitwa HPV (humanpapillomavirus) kunasababisha karibu saratani zote za njia ya uzazi. Kuna zaidi ya aina 100 tofauti za HPV. Aina mbili za HPV zinajulikana kusababisha saratani kwa karibu wote wanaougua njia za uzazi. Virusi vya HPV vinapatikana kwa wingi. Watu wengi (wanne kwa watano) watakuwa na HPV wakati mmoja maishani mwao. Yeyote ambaye ashawahi kufanya ngono anaweza kuwa na HPV.

Mara nyingi, virusi vya HPV hutoweka vyenyewe baada ya miaka michache. Mara nyingine hivi virusi vinaweza vikakaa mwilini na vinaweza kusababisha saratani ya njia ya uzazi. Hii huchukuwa mda mrefu – kama miaka 10. Kupimwa njia ya uzazi kila baada ya miaka miwili kunaweza kufanya mabadiliko ya njia ya uzazi yajulikane kabla hayajasababisha saratani. Daktari wako, muuguzi au mfanya kazi kutoka kituo cha afya anaweza kuhakikisha kuwa afya yako inafuatiliwa na unapata matibabu kama unayahitaji ili uwe na afya bora.

Je mtu hupimwaje njia ya uzazi?

Kwanza daktari au muuguzi anakuuliza uvue nguo kutoka kiunoni kwenda chini na ulale chali ili akupime. Unaweza kuuliza upimwe na daktari au muuguzi wa kike. Halafu daktari au

muuguzi atatumia chombo cha kupimia kufungua sehemu yako ya siri ili njia ya uzazi ionekane vyema zaidi. Atapangusa ukuta katika njia yako ya uzazi na brashi ndogo au chombo cha kupima (kijiti kidogo ama kipande cha mpira kidogo). Kilichopanguswa kutoka njia ya uzazi, wataweka kwenye kioo kidogo na kupelekwa maabara (lebu) watakakotazama wakitumia darubini.

Je mtu husikiaje?

Wakati mwingine kupimwa njia ya uzazi ni jambo la kutahayari au kuonea aibu. Kumbuka, kuwa
anayekupima njia ya uzazi, hii ni kazi yake ya kawaida na hatahayari au kuona aibu. Unapopimwa, unaweza kusikia ovyo, lakini haina uchungu. Ukisikia uchungu, mwambie daktari wako, muuguzi au mfanyakazi kwenye kituo cha afya hapohapo.

Je kama majibu yangu sio sawa au salama?

Kama majibu yako sio sawa, haimaanishi uko na saratani. Mara nyingi itakuwa una jambo dogo kama kuambukizwa ambako huisha kwenyewe bila kutibiwa. Mara nyingine mwanamke anahitaji kupimwa njia ya uzazi mara kwa mara. Hali nyingine zisizo za kawaida zahitaji matibabu maalum. Hakikisha umeshauriana na daktari wako, muuguzi au mfanya kazi wa kituo cha afya ili akufahamishe kilicho bora kwako.

Uhusiano wa UKIMWI na saratani ya njia ya uzazi

Wanawake wanaougua ugonjwa wa UKIMWI wanauwezekano mkubwa kuliko wale ambao hawana UKIMWI kuambukizwa virusi vya human Papillomavirus (HPV), vinavyosababisha saratani ya njia ya uzazi, na iendelee hadi ivaamie mwili na iwe, kitisho kwa maisha. **Kumbuka: Kutumia dawa ya UKIMWI haiwezi kupunguza hatari ya saratani ya njia ya kizazi.**

Utafiti wa matibabu ya njia ya kizazi (Cervical Treatment Study)

Watafiti kutoka Chuo Kikuu cha Washington huko Marekani, Hospitali Kuu ya Kenyatta, Shirika la Afya Duniani na Hospitali ya Coptic wanafanya utafiti kuona jinsi gani tiba inaweza kuzuia chembe chembe zisizo za kawaida isiwe saratani ya njia ya kizazi, na jinsi tiba inaweza kuathiri ugonjwa wa UKIWMI. Wagonjwa ambao watahusika katika utafiti huu watapewa uchunguzi (Pap smear) wa bure na pia watapata matibabu ya bure wakipatikana na chembe chembe zisizo za kawaida.

Kwa habari zaidi kuhusu utafitii huu, wasiliana na:

1. Peter Juma: 0721-898-785
2. Elizabeth Makena: 0728-456-540
3. Dr. Evans Malava: 0721-289-733

COPTIC HOPE MEDICAL RECORD FORMS

HOPE CLINIC
ADDRESS AND INTAKE

Page 1

HOPE ID Number

Site Code **Today's Date (DD.MM.YYYY)** **Interviewer number**

Name (First, Middle,Last)

1. Gender ☐ Male ☐ Female

2. Age (Years) ☐☐☐ Month ☐☐ 3. Date Of Birth (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

4. In which region does the client reside(stay)?

☐ Nairobi province (see 4a) ☐ Rift Valley Province

☐ Nyanza Province (see 4b) ☐ North Eastern Province

☐ Western Province (see 4b) ☐ Eastern Province

☐ Central Province ☐ Coast Province

☐ Other country (specify)

4a. If Nairobi province, specify area: (tick one)

☐ Langata/Kibera ☐ Westlands

☐ Starehe ☐ Kasarani

☐ Dagoretti ☐ Kamukunji

☐ Makadara ☐ Eastland/ Industrial Area

☐ Embakasi ☐ Other (specify)

4b. If western or Nyanza, specify area: (tick one)

☐ Kisumu Rural ☐ Maseno

☐ Siaya ☐ Chulaimbo

☐ Vihiga ☐ Lela

☐ Kakamega ☐ Other (Specify)

☐ Luanda

5. Email

6. Physical Address

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HOPE CLINIC
ADDRESS AND INTAKE

7. How long has the client stayed at this residence?

☐ Less than a year ☐ Greater than a year

8. How long does the client plan to stay at this residence?

☐ Less than a year ☐ Greater than a year

9. Phone number (Cell) | | | | | | | | | | | | |

9a. Relationship to phone owner (tick one)

☐ Self ☐ Employer

☐ Relative ☐ Other (specify) _____

☐ Friend

10. Phone number (Landline) | | | | | | | | | | | | |

10a. Relationship to phone owner (tick one)

☐ Self ☐ Employer

☐ Relative ☐ Other (specify) _____

☐ Friend

Emergency contact (in case we cannot reach the patient)

11. Name (Last, First, Middle) _____

11a. Relationship to client (tick one)

☐ Self ☐ Employer

☐ Relative ☐ Other (specify) _____

☐ Friend

☐ Husband/Wife

11b. Phone No. | | | | | | | | | | | | |

Clients transferring from Pediatric Clinic

12. Pediatric Hopeid | | | | | |

For the data use only (tick after scanning the form)

Scanned ☐ *Date* ___ / ___ / _____ *Name of data person* _____

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HOPE CLINIC
COUNSELING ADHERENCE #1

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

Checklist	Tick
Explain about HIV and how it affects the body	◯
Explain about CD4 cells and why it is necessary to measure the CD4 count	◯
Explain the difference between HIV and AIDS.	◯
Explain about ARV.	◯
Explain ARV is not a cure.	◯
Explain the cause of resistance.	◯
Explain treatment failure	◯
Explain importance of adherence.	◯
Explain problem of side effects.	◯
Have patient think about life long commitment of therapy.	◯
Have patient think about ability to follow up care	◯
Explore patient support system	◯
Discuss adherence promotion strategies e.g. treatment buddy, pill diary e.t.c	◯

2. Identify barriers to adherence (tick all that apply)

◯ Poor Communication
◯ Inadequate understanding about HIV/AIDS
◯ Failure to disclose status
◯ Mental State
◯ Stigma
◯ Low literacy
◯ Lack of social support
◯ Alcohol/ Drug use
◯ None
◯ Others (specify)

3. Does the patient need to move forward with the protocol or to repeat counselling adherence #1 ?

◯ Move forward ◯ Repeat Counselling Adherence # 1

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person***

Modified December 2009 *Coptic Hope Clinic* *Version 5.0*

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HOPE CLINIC
COUNSELING ADHERENCE #2

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

Score scale: **1-Poor 2-Fair 3-Good**

Section A: Knowledge Assessment

Question	Rationale	Score
1. What do you know about ARVs?	Assess whether information given in Counseling Adherence#1 has been understood.	☐
2. What are the names of any ARVs?	Assess the client knows that AZT, NVP, etc. are ARVs, but septrin is not	☐
3. How do ARVs work?	Assess the client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection.)	☐
4 What side effects are associated with ARVs? What do you know about them?	Assess client's knowledge of side effects related to his/her ARV regimen and the appropriate response to deal with side effects.	☐
5. How long should you normally take ARVs?	Assess whether client knows ARV is life long treatment.	☐
6. What happens if you dont take ARVs consistently?	Assess whether client understands the problem of resistance given ARV interruptions.	☐
7. What is the purpose of CD4 counts?	Assess whether client knows that CD4 count is a laboratory indicator for monitoring the effect of ARV	☐
8. What are your expectations from ARVs?	Assess whether client has realistic expectations, e.g., prolonging life, keeping them well enough from their family, e.t.c. Assess for false expectations, e.g., a cure for HIV, e.t.c	☐
9. Can someone still transmit HIV while taking ARVs?	Assess/review need for continued prevention e.g. condom use.	☐
If total score is less than 18, patient has failed section A If total score is 18 or above, the patient passes section A	**Total Score:**	☐☐

Section B: Counselor Assessment

Question	Rationale	Score
10. Assess for barriers that help determine capability for followup	Assess whether client can attend HIV clinic for follow up medical and counselling care	☐
11. Ask the client whether s/he has a relative/friend whom s/he can rely on to support her/him taking ARV	Assess availability of support from home	☐
12. On a scale of 1 to 5 (5 being most ready, 1 being least), please rate the client's ability to adhere to medications	Score 1: Patient will adhere to the ARVs very poorly (Misses more than half the doses) Score 2: Patient will likely miss doses of ARVs ona regular basis (misses up to 50% of doses) Score 3: Patient will only miss some doses of ARVs (1 dose a month at most) Score 4: Patient will rarely miss a dose of ARVs (1 dose every 6 months at most) Score 5: Patient will almost never miss any doses (1 dose every year at most)	☐
If total score is 2 or below on question 12, patient fails section B If total score is 3 or above question 12, patient passes section B		

HOPE CLINIC

COUNSELING ADHERENCE #2

Section C: Participant Assessment

Question	Rationale	Score
13.Ask the client if s/he can come to HIV clinic for regular follow-up?	YES or NO answer	☐ Yes ☐ No
14. Do you want to start ARV treatment now?	YES or NO answer	☐ Yes ☐ No
	If any answers in this section are "NO" then patient fails Section C	

Section D: Final Assessment

15. a) Did the patient pass section A, B and C?

☐ Yes (Patient moves forward) ☐ No

b) If NO, is the patient scheduled to repeat counseling?

☐ Yes ☐ No

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person*** _____

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HOPE CLINIC

COUNSELING ADHERENCE #3

To be performed 1 month after starting ARVs

HOPE ID Number

Site Code	**Today's date (DD.MM.YYYY)**	**Interviewer number**
	/ /	

Score scale: 1- poor 2-Fair 3-Good

Section A: Knowledge Assessment

Question	Rationale	Score
1. What do you know about ARVs?	Assess whether information given in Counseling Adherence#1 has been understood.	
2. What are the names of your medications and dosage?	Assess whether the client knows his/her medication and dosage.	
3. How do ARVs work?	Assess the client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection.)	
4. What side effects are assosiated with ARVs and what do you do if you have side effects?	Assess client's knowledge of side effects related to his/her ARV regimen and the appropriate response to deal with side effects.	
5. How long should you normally take ARVs?	Assess whether client knows ARV is life long treatment.	
6. What happens if you don't take your ARVs consistently?	Assess whether client understands the problem of resistance given ARV interruptions.	
7. What is the purpose of CD4 counts?	Assess whether client knows that CD4 count is a laboratory indicator for monitoring the effect of ARV	
8. What are your expectations from ARVs?	Assess whether client has realistic expectations, e.g. prolonged life, keeping them well enough from thier family, etc. Assess for false expectations, e.g., a cure for HIV, etc.	
9. How can someone still transmit HIV while taking ARVs?	Assess review need for continued prevention e.g. condom use	
	Total Score	

Section B: Counselor Assessment

Question	Rationale	Score
10. During the last 7 days how many pills did the patient MISS taking?	Get exact number of pills missed	
11. On a scale of 1 to 5 (5 being most ready, 1 being least), please rate the client's ability to adhere to medications?	Score 1: Patient will adhere to the ARVs very poorly (Misses more than half the doses) Score 2: Patient will likely miss doses of ARVs ona regular basis (Misses up to 50% of doses) Score 3: Patient will only miss some doses of ARVs (1 dose a month at most) Score 4: Patient will rarely miss a dose of ARV (1 dose every 6 months at most) Score 5: Patient will almost never miss any doses (1 dose every year at most)	

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person***

Modified December 2009 *Hope Clinic* *Version 5.0*

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HOPE CLINIC

PHONE NUMBER AND ADDRESS UPDATE FORM

Page 1

HOPE ID Number

Site Code **Today's Date (DD.MM.YYYY)** **Interviewer number**

Name (First, Middle,last)

1. Has the client's phone number changed? ☐ Yes ☐ No *(If Yes go to 2, If No go to 4)*
2. Phone number (Cell)

2a. Relationship to phone owner (tick one)

☐ Self ☐ Friend
☐ Husband or wife ☐ Employer
☐ Relative ☐ Other (specify)

3. Phone number (Landline)

3a. Relationship to phone owner (tick one)

☐ Self ☐ Friend
☐ Husband or wife ☐ Employer
☐ Relative ☐ Other (specify)

4. Has the client moved? ☐ Yes ☐ No *(If Yes go to 5, If No go to 7)*

5. Physical Address

6. In which region does the client now reside (stay) *(For Maseno, check 2nd, 3rd and where applicable 4th column)*

☐ Nairobi province (See 6a) ☐ Central province ☐ Eastern province
☐ Nyanza province (See 6b) ☐ Rift Valley province ☐ Coast province
☐ Western province (See 6b) ☐ North Eastern province

6a. If Nairobi province, specify area: (tick one)

☐ Langata/Kibera ☐ Westlands
☐ Starehe ☐ Kasarani
☐ Dagoretti ☐ Kamukunji
☐ Makadara ☐ Eastlands/Industrial Area
☐ Embakasi ☐ Other(Specify)

6b. If western or Nyanza, specify area: (tick one)

☐ Kisumu Rural ☐ Maseno
☐ Siaya ☐ Chulaimbo
☐ Vihiga ☐ Lela
☐ Kakamega ☐ Other(specify)
☐ Luanda

HOPE CLINIC

PHONE NUMBER AND ADDRESS UPDATE FORM

7. Has the client's email changed? ☐ Yes ☐ No ***(If Yes go to 8, If No go to 9)***

8. Email ☐

Emergency contact (in case we cannot reach the patient)

9. Has the client's emergency contact changed? ☐ Yes ☐ No ***(If Yes go to 10)***

10. Name (Last, First, Middle) ☐

10a. Relationship to client (tick one)

☐ Self ☐ Employer

☐ Relative ☐ Other (specify) ☐

☐ Friend

☐ Husband/Wife

10b. Phone No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

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Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person*** ☐

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HOPE CLINIC
PATIENT PHONE CONTACT FORM

HOPE ID Number

Site Code **Today's Date (DD.MM.YYYY)** **Interviewer number**

1. Date of phone contact (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

2. Did you talk to the patient or patient's contact?
   - ☐ Yes, talked to patient *(Go to 4)*
   - ☐ Yes, talked to patient's contact *(Go to 3)*
   - ☐ No *(Go to 4)*

3. If talked to patient's contact, who was the source of information *(tick one)*
   - ☐ Clinician/clinic staff
   - ☐ Employer
   - ☐ Caregiver
   - ☐ Spouse or partner
   - ☐ Friend
   - ☐ Treatment supporter
   - ☐ Family member/Relative
   - ☐ Neighbour
   - ☐ Other (specify) ☐
   - ☐ Mother/Father

   3a. Did the source of information have credible knowledge for whether the patient was alive or dead?
   - ☐ Yes, credible and patient confirmed alive *(Go to 4)*
   - ☐ Yes, credile and patient confirmed dead *(Go to 9 and complete Mortality form)*
   - ☐ Source did not know whether patient was dead or alive *(Go to 4)*

4. What was the reason for calling or contacting the patient or patient's contact?
   - ☐ Patient missed clinic appointment *(Go to 5)*
   - ☐ Patient missed pharmacy pickup *(Go to 6)*
   - ☐ Other (specify) ☐ *(Go to 7)*

5. Reasons for missed clinic appointment *(tick all that apply)*
   - ☐ N/A, did not reach patient or patient's contact
   - ☐ No longer willing to attend
   - ☐ Wait time too long
   - ☐ Conflict with work
   - ☐ Financial problems
   - ☐ Client moved or relocated
   - ☐ Unable to attend because of health problems
   - ☐ Family problems
   - ☐ Client will go to faith healer
   - ☐ Unwilling to disclose
   - ☐ Other (specify) ☐

6. Reasons for missed pharmacy pick up *(tick all that apply)*
   - ☐ Unable to attend because of health problems
   - ☐ Family problems
   - ☐ Conflict with work
   - ☐ Financial problems
   - ☐ Client moved or relocated
   - ☐ Got medication somewhere else
   - ☐ Client will go to faith healer
   - ☐ Unwilling to disclose
   - ☐ N/A, did not reach patient
   - ☐ Other (specify) ☐

7. If talked to patient, did the patient wish to remain in the clinic?

☐ Yes *(Go to 7a)*

☐ No *(Go to 8 and complete Exit form)*

☐ N/A, did not talk to patient *(Go to 9)*

7a. Did the patient schedule a clinic appointment? ☐ Yes ☐ No *(If YES go to 7b, If NO go to 7d)*

7b. If YES, date of scheduled appointment (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

7d. If NO, why did the patient not schedule an appointment (tick all that apply)

☐ Unable to attend because of health problems
☐ Family problems
☐ Conflict with work
☐ Financial problems
☐ Client moved or relocated
☐ Client lives too far away
☐ Other (specify) ☐

8. If the patient does not wish to return to the clinic, specify why (tick all that apply)

☐ Not willing to attend
☐ Attend clinic closer to home
☐ Wait time too long
☐ Conflict with work
☐ Financial problems
☐ Unwilling to attend because of health problems
☐ Family problems
☐ Client will go to faith healer
☐ Not willing to disclose HIV status
☐ Referred elsewhere
☐ Unknown
☐ Other (specify) ☐

9.Did you refer the client to any of the following (*tick all that apply*)

☐ Clinic ☐ Counselor ☐ Nutritionist ☐ HBC ☐ None

Comments

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person*** ☐

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HOPE CLINIC

Counseling General Session

HOPE ID Number

Site Code	Today's Date (DD/MM/YYYY)	Interviewer number
☐☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐☐

Notes

What was the focus of the session? (tick all that apply)

- ☐ Pretest
- ☐ Hygiene
- ☐ Family planning
- ☐ Crisis
- ☐ Discordance
- ☐ Sex and sexuality
- ☐ Post-test
- ☐ PMTCT
- ☐ Child(ren)
- ☐ Opportunistic infection
- ☐ Welfare
- ☐ Drug therapy
- ☐ HIV/STD Prevention
- ☐ Nutrition
- ☐ Bereavement
- ☐ Spirituality
- ☐ Disclosure
- ☐ Child transfer to Adult Clinic
- ☐ Other (specify) ☐

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HOPE CLINIC

COUNSELOR SCREENING

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

1. How many children do you have or care for? ☐☐ *If = 0 go to 2*

1a. Describe HIV test results and HIV care for each child.

	Test Result	Receiving HIV care?	Receiving HAART?	Recieving HAART and/or HIV care at Hope Clinic?
1	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A
2	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A
3	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A
4	☐ Positive ☐ Negative ☐ Unknown ☐ not tested	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A	☐ Yes ☐ Unknown ☐ No ☐ N/A

2. Have you revealed your serostatus to:

a. Spouse(s) or steady partner(s) ◯ All ◯ Some ◯ None ◯ Has no spouse

b. Casual or non-casual partner(s) ◯ All ◯ Some ◯ None ◯ Has no partner

c. Parents ◯ All ◯ Some ◯ None ◯ Has no parents

d. Siblings ◯ All ◯ Some ◯ None ◯ Has no siblings

e. Children ◯ All ◯ Some ◯ None ◯ Has no children

f. Friends ◯ All ◯ Some ◯ None ◯ Has no friends

g. Others ◯ All ◯ Some ◯ No one else ◯ Specify

3. Who forms your closest social support (tick one)

☐ Spouse/steady partner ☐ Sibling

☐ Mother ☐ Other (specify)

☐ Father ☐ No social supporter

☐ Friend

3a. Have you informed this person of your serostatus?

☐ Yes ☐ No ☐ N/A

4. Have you ever had sex? ☐ Yes ☐ No *(If YES, go to 5, If NO go to 13)*

5. How many spouse(s) or steady partner(s) do you have? ☐☐ *(If = 0 go to 6)*

5a. Describe HIV test results and HIV care for each spouse(s) or steady partner(s)

	Relationship	Test Result	Receiving HIV care?	Receiving HAART?	Recieving HAART and/or HIV care at Hope Clinic?
1	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
2	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
3	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
4	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
5	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
6	☐ Spouse ☐ Steady partner	☐ Positive ☐ Negative ☐ Unknown ☐ Not tested	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A

6. How many diffrerent casual or non-steady partner(s) did you have in the past year? ☐☐

7. In the past year, how many different sexual partners have you had, including your spouse(s) and steady partner(s)? ☐☐☐

8. During your lifetime have you had sex with

☐ Men Only ☐ Women Only ☐ Both ☐ None ☐ Refused to answer

9. Describe your condom use in the past 12 months todate:-

a.Spouse(s) or steady partiners *(Tick one)*

☐ Never ☐ Sometimes ☐ Always ☐ No sex in past 12 months ☐ No spouse/steady partner

b.Non- steady partiners. *(Tick one)*

☐ Never ☐ Sometimes ☐ Always ☐ No sex in past 12 months ☐ No Non-steady partner

10. Did you use a condom during your last sexual encounter

☐ No ☐ Yes ☐ Refused to answer

11. Are you able to talk about using condoms with your spouse(s) or steady partner(s)?

☐ No ☐ Yes ☐ Refused to answer ☐ No spouse/steady partner ☐ Dont know

11a. Are you able to say NO to sex if your spouse or steady partner will not use a condom?

☐ No ☐ Yes ☐ No spouse/steady partner ☐ Refused to answer ☐ Don't know

12. Are you able to talk about condoms with your casual or non-steady partner(s)?

☐ Yes ☐ No ☐ No non-steady partner(s) ☐ Refused to answer ☐ Don't know

12a. Are you able to say NO to sex if your casual or non-steady partner(s) will not use a condom?

☐ No ☐ Yes ☐ No non-steady partner(s) ☐ Refused to answer ☐ Don't know

13. Are you Circumcised ? ***(Ask Male client only)***

☐ Yes ☐ No ☐ Refused to answer ☐ Female client

14. Do you feel neglected by anyone *(tick all that apply)*

☐ Family ☐ Friends ☐ Health care workers ☐ None ☐ Others (specify) ☐

15. Counselor, does the client need a treatment supporter? ☐ Yes ☐ No *(If yes go to 15a, if no go 16)*

15a. If YES why? specify (Tick all that apply)

☐ Client requests treatment supporter
☐ Physically disabled
☐ Mentally disabled
☐ Other (specify) ☐

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16. Counselor is this client recommended for homecare? ☐ Yes ☐ No

16a. If YES, specify why? (Tick all that apply)

- ☐ Physically or mentally disabled adult
- ☐ Adult dependent on care-giver
- ☐ Client requests a home visit
- ☐ Disclosure (patient would like help disclosing status to family members)
- ☐ Family testing (client would like other family members to be tested)
- ☐ Other (specify) ☐

17. Have you explained/discussed or checked the following with the Client?

Checklist	Tick (if Yes)	Tick (if No)
1. Overview of HOPE Center Program and Services	○	○
2. Importance of commitment to the program	○	○
3. Policy for adherence and clinic attendance	○	○
4. Patients enrollment status in other programs or facilities	○	○
5. Patients long term goals for health management at our program	○	○

Notes / Assessment

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Scanned ☐ *Date* ___ / ___ / _____ *Name of data person* ☐

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HOPE CLINIC
ADULT LOCATOR FORM

HOPE ID Number

Site Code **Today's Date (DD/MM/YYYY)** **Interviewer number**

1. Name (Last, First, Middle)

2. Gender ☐ Male ☐ Female

3. Age (Years)

CLIENT'S RESIDENTIAL AND TELEPHONE CONTACT INFORMATION

4. Public Transportation to the house:

4a. Type

☐ Bus ☐ Citi Hoppa ☐ Matatu ☐ Taxi ☐ Other(specify)

4b. Number

4c. Stage Name

4d. General name of the area

5. Walking directions to house from the stage?

6. Landmarks that aide in locating the household: (Schools, churches, businesses etc.)

7. How is the Client or Caregiver called or refered to in home area:

8. Primary Telephone Contact:

☐ Mobile ☐ Landline ☐ Unknown

8a. Line belongs to:

☐ Client ☐ Friend
☐ Parent ☐ Neighbour
☐ Caregiver ☐ Nerby Simu ya Jamii
☐ Other household member ☐ Guardian Institution or organisation
☐ Relative ☐ Other(specify) ____

8b. If the phone is not the client's does the owner know of the client's status?

☐ Yes ☐ No ☐ Unknown

9. Secondary Telephone Contact:

☐☐☐☐☐☐☐☐☐☐☐ ☐ Mobile ☐ Landline ☐ Unknown

9a. Line belongs to:

☐ Client ☐ Friend
☐ Parent ☐ Neighbour
☐ Caregiver ☐ Nearby Simu ya Jamii
☐ Other household member ☐ Guardian Institution or organisation
☐ Relative
☐ Other(specify) ____

9b. If the phone is not the client's does the owner know of the client's status?

☐ Yes ☐ No ☐ Unknown

10. How long has the client been living at this residence: ☐☐ Years ☐☐ Months

10a. This residence is:

☐ Permenent ☐ Temporary ☐ Unknown

For the data use only (tick after scanning the form)

Scanned ☐ *Date* ___ / ___ / _____ *Name of data person* ____

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HOPE CLINIC

ADULT MEDICAL FOLLOW-UP

HOPE ID Number

	Site Code	**Today's Date (DD.MM.YYYY)**	**Interviewer number**
	☐☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐☐

HISTORY OF PRESENT ILLNESS

MEDICAL REVIEW

1. Does the patient currently have Extra pulmonary TB? ☐ Yes ☐ No

2.Does the Patient have Pulmonary TB? ☐ Yes ☐ No *(If YES go to 2a, If NO go to 4)*

2a. If YES, what was the diagnosis based on (tick all that apply)

- ☐ Chest X-ray
- ☐ Sypmtoms (persistent cough >2 weeks, fever, night sweats, etc)
- ☐ Failure to respond to empirical antibiotics
- ☐ Sputum
- ☐ Other (specify)
- ☐ Unknown

3. Is the patient currently on treatment for TB(PTB & ETB) *(If YES go to 3a, If NO or Unknown go to 4)*
☐ Yes ☐ No ☐ Unknown

3a. If yes, specify treatment start date (DD.MM.YYYY) ☐☐ / ☐☐ / ☐☐☐☐

3b. If YES, specify treatment

- ☐ EH ☐ SHRZE
- ☐ RHZ ☐ unknown
- ☐ RHZE ☐ Other (specify)
- ☐ RH

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

3c. Is the patient currently being treated for TB at coptic? ☐ Yes ☐ No *(If YES go to 4, If NO go to 3d)*

3d. If NO, specify where:

- ☐ Private hospital
- ☐ Public hospital
- ☐ Other government facility
- ☐ Other (specify)

4. In the past month, has the patient experienced any of the following? (tick all that apply)

- ☐ Dysparenuia
- ☐ Genital sores or ulcers
- ☐ Lower Abdominal pain
- ☐ Painful micturation(Dysuria)
- ☐ None
- ☐ Testicular pain or swelling
- ☐ Urethral discharge
- ☐ Vaginal discharge
- ☐ Vaginal itching/burning

MEDICATIONS

5. Is the patient currently taking HAART or ARVs, excluding PMTCT & PEP? ☐ Yes ☐ No *(If YES go to 5a, If NO go to 7)*

5a. If yes, specify (tick one)

☐ AZT-3TC-EFV
☐ AZT-3TC-NVP
☐ AZT-3TC-LPV/rit
☐ d4T(30mg)-3TC-EFV
☐ d4T(30mg)-3TC-NVP
☐ d4T(30mg)-DDI-LPV/rit
☐ d4T(40mg)-DDI-LPV/rit
☐ TDF 3TC EFV
☐ TDF 3TC NVP
☐ TDF-ABC-LPV/rit
☐ Unknown
☐ Other (specify) _____

5b. Has the patient had any recent side effects due to HAART or ARV medications? ☐ Yes ☐ No ***(If Yes go to 5c, If NO go to 6)***

5c. If YES, describe the symptoms and severity of possible side effects (Tick for each symptom)

Symptom	**Frequency of Symptom**	**If YES, severity of symptom**
a. Nausea or vomiting	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
b. Rash	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
c. Fat changes	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
d. Diarrhea	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
e. Anemia	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
f. Cough	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
g. Fatigue	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
h. Abdominal pain	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
i. CNS - dizziniess, anxiety, nightmares	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
j. Headache	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
k. Jaundice	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
l. Difficulty breathing	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
m. Burning/numbness/tingling	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
n. Fever	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
o. Heartburn	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe
p. Other (specify) _____	☐ Sometimes ☐ Often	☐ Mild ☐ Moderate ☐ Severe

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6. During the last 7 days how many ARV pills did the patient MISS taking? (tick one)

☐ None ☐ Very Few ☐ Half ☐ Most ☐ All

6a. If patient MISSED doses, please specify reasons (tick all that apply).

☐ Alcohol ☐ Forgot ☐ Too ill

☐ Depression ☐ Inability to pay ☐ Toxicity/side effect

☐ Drug stock out - dispensary ☐ Patient lost or ran out of pills ☐ Other (specify) ☐

☐ Delivery/travel problems ☐ Stigma, disclosure or privacy issues

☐ Felt better ☐ Share with others

7. Is patient taking any of the following medications? (tick all that apply)

☐ Cotrimoxazole ☐ Antimalarial medications ☐ None of the above

☐ Dapsone ☐ Herbal traditional medications

☐ Fluconazole ☐ Multivitamin supplements

8. What other medications is patient currently taking?

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				

9. PHYSICAL EXAMINATION

Nurse number ☐☐☐

Temp (F) ☐☐☐.☐ HR ☐☐☐ BP ☐☐☐/☐☐☐ RR ☐☐ Wt (Kg) ☐☐☐.☐ HGT ☐☐☐.☐ Sa O2 ☐☐☐

BMI ☐ BMI>18.5 ☐ BMI<18.5 ☐ BMI Unknown **Gender** ☐ MALE ☐ Female

10.

System (tick one)	**Normal**	**Abnormal**	**Not done**	**Findings (if abnormal)**
General	☐	☐	☐	
Skin	☐	☐	☐	
Lymph nodes	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Abdomen	☐	☐	☐	
Genitourinary	☐	☐	☐	
Extremities	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Psychological	☐	☐	☐	

ASSESSMENT AND PLAN

11. What diagnoses does the patient have on today's visit (tick all that apply)?

☐ Anaemia	☐ Dermatitis	☐ Myalgia	☐ URTI
☐ Asthma	☐ Extra Pulmonary TB	☐ Neuropathy	☐ UTI
☐ Candidiasis (thrush) - oral	☐ Gonorrhea	☐ Peptic Ulcer disease	☐ Zoster
☐ Candidiasis (thrush) - vaginal	☐ Genital Ulcer disease	☐ Pneumonia	☐ None
☐ Chancroid	☐ Hypertension	☐ Side effects due to ARV	☐ Other (specify)
☐ Conjuctivitis	☐ HSV - genital	☐ Soft tissue infection	
☐ Diarrhea	☐ IRIS	☐ Syphilis	
☐ Dementia	☐ Malaria	☐ Ulcers - oral	

12. What is the patients current Pulmonary TB diagnosis?

☐ Pulmonary TB suspected *(If suspected go to 13)*

☐ Pulmonary TB diagnosed today *(If diagnosed go to 14)*

☐ Currently on pulmonaryTB treatment *(If currently on TB treatment go to 15)*

☐ Previously diagnosed with TB, not on Treatment *(skip to 14a)*

☐ No Pulmonary TB *(If NO TB go to 15)*

☐ Other(specify) ☐

13. If pulmonary TB suspected, what is the suspected pulmonary TB based on (tick all that apply)?

☐ Abnormal X-ray

☐ Symptoms (persistent cough >2 weeks, fever, night sweats, etc)

☐ Failure to respond to empirical antibiotics

☐ Recent contact with people with Pulmonary TB

☐ Other (specify) ☐

13a. Will the patient be sent for pulmonary TB testing? ☐ Yes ☐ NO *(If yes, go to 13b, if no go to 15)*

13b. If YES, which of the following tests will the patient be sent for:

☐ Sent for sputum

☐ Sent for X-ray

☐ Other (specify) ☐

(Go to 15)

14. If Pulmonary TB is diagnosed today, what is it based on(tick all that apply)?

☐ Abnormal X-ray ☐ Failure to respond to empirical antibiotics

☐ Symptoms (persistent cough >2 weeks, fever, night sweats, etc) ☐ Sputum

☐ Other (specify) ☐

14a. Specify treatment to be started:

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

☐ RHZE ☐ SHRZE

☐ RHZ ☐ EH

☐ Other (specify) ☐

Section B: Female Patients Only (If Male go to 19)

15. Is the patient currently pregnant?

☐ Yes ☐ No ☐ Unknown *(If YES, complete Pregnancy Monitoring Form)*

16. Is the patient currently breastfeeding? ☐ Yes ☐ No *(If YES,go to 16a,if no go to 17)*

16a. If yes, specify what type of breastfeeding (tick one)

◯ Exclusive breastfeeding *(Child given ONLY mother's milk and NO water, tea, formula, cow's milk or food of any kind)*

◯ Mixed feeding *(Child given mother's milk and water, tea formula, cow's milk or food)*

16b. If YES, has she had a session with the nutritionist since she started breast feeding?

☐ Yes ☐ No ***(If NO,refer patient to Nutritionist)***

17.Has the patient delivered in the past 18 Months? ☐ Yes ☐ No *(If yes go to 17a,If No go to 18)*

17a.If yes, is this the first time the patient has returned to the Hope Center since delivery?

☐ Yes ***(If yes, compelete pregnancy Close -Out form)***

☐ No

17b.Age of the child ☐☐ Months ☐☐ Days ☐ Child not Alive

17c. If not currently breastfeeding,at what age did the child stop breastfeeding?

☐☐ Months ☐☐ Days ☐ Unknown ☐ NA,Child never breastfed

17d.Has the child ever had a PCR test? ☐ Yes ☐ No

17e.If Yes, what was the result of the last PCR test?

☐ HIV Positive *(Go to 18)*

☐ HIV Negative

☐ Indeterminate

☐ Result not yet available

(Complete Infant PCR form;If Q17e is HIV Negative,Indeterminate or Result not yet available)

17f. Will an Infant PCR test be ordered today? ☐ Yes ☐ No

18.Is the patient being referred for Cervical Cancer screening at Hope? ☐ Yes ☐ No *(If yes go to 19, If NO go to 18a)*

18a. If NO, reasons why patient NOT referred for Cervical Cancer Screening *(tick all that apply)*

☐ Patient is younger than 18 years

☐ Patient has had total hysterectomy, LEEP or cryotherapy

☐ Patient is currently pregnant

☐ Patient has had a screening test in the last year

☐ No service available at this time

☐ Patient wishes to defer until a later time Specify reason

☐ Patient does not accept screening Specify reason

☐ Other(specify)

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19. Is the Client currently on HAART, excluding PMTCT and PEP? ☐ Yes ☐ No *(If YES go to 19a, If No go to 19b)*

19a. If yes, did you continue current HAART? ☐ Yes ☐ No *(If YES go to 20 ,If No go to 19a1)*

19a1. If no, did you change or stop HAART today? ☐ Changed ☐ Stopped

19a2. Specify why HAART was changed or stopped *(Tick all that apply)*

- ☐ Toxicity / Side effects
- ☐ Pregnancy
- ☐ Risk of pregnancy
- ☐ Newly diagnosed TB
- ☐ New drug available
- ☐ Drug not available
- ☐ Patient lacks finances
- ☐ Clinical treatment failure
- ☐ Immunologic treatment failure
- ☐ Virologic treatment failure
- ☐ Poor adherence
- ☐ Illness, hospitalization
- ☐ Other (specify) _____

(Skip to 20)

19b. If no, is patient ELIGIBLE for therapy? ◯ Yes ◯ No ◯ Not yet determined *(If Eligible go to 19b1; if NOT eligible or NYD go to 22)*

19b1. If ELIGIBLE for therapy then by what criteria (*tick all that apply)?*

◯ CD4 count ☐☐☐☐ CD4 % ☐☐ Date (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

◯ WHO Clinical Stage ◯ 1 ◯ 2 ◯ 3 ◯ 4 ☐ Viral Load ☐☐☐☐☐☐☐

◯ Patient on HAART/ARV in past

19c. Did you initiate HAART/ARV treatment at this clinic visit, excluding PMTCT and PEP? *(If YES go to 19c1 If No go to 19c2*

☐ Yes ☐ No

19c1.If yes,what was the WHO stage ◯ 1 ◯ 2 ◯ 3 ◯ 4

19c2. If NO, specify:

- ☐ Patient has not completed HAART protocol
- ☐ Patient currently on drugs which may interact with HAART/ARV
- ☐ Other (specify) _____
- ☐ Patient preference
- ☐ Patient too ill to begin HAART today

20. Has the patient completed HAART protocol? ☐ Yes ☐ No

21. What ARV medications were prescribed or continued today

- ☐ AZT-3TC-EFV
- ☐ AZT-3TC-NVP
- ☐ AZT-3TC- LPV/rit
- ☐ d4T(30mg)-3TC-EFV
- ☐ d4T(30mg)-DDI-LPV/rit
- ☐ d4T(30mg)-3TC-NVP
- ☐ TDF-ABC -LPV/rit
- ☐ TDF 3TC EFV
- ☐ TDF 3TC NVP
- ☐ None
- ☐ Other (specify) _____

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22. Did you initiate or continue Cotrimoxazole today? ☐ Yes ☐ No *(If YES go to 23, If NO go to 22a)*

22a. If no, why?

◯ Side effects/ toxicity ◯ Patient preference

◯ Stockout/drug supply interruption ◯ Other (Specify) _____

23. Did you initiate or continue any of the following medications today (tick all that apply)?

◯ Dapsone ◯ Fluconazole ◯ Multivitamin supplement ◯ None of the above

24. Other medications prescribed during this visit

Medication	Dose (mg)	Frequency (per day)	Start date	
1.				
2.				
3.				
4.				

25. What laboratory tests were ordered today (tick all that apply)

☐ ALT ☐ Hgb ☐ Viral Load

☐ cd4 ☐ HIV ELISA Confirmatory test ☐ Widal Test

☐ Chest X-ray ☐ LFT ☐ None

☐ Creatinine ☐ Lactic Test ☐ Other (specify) _____

☐ Complete Blood Count ☐ Urinalysis

Comments

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person*** _____

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HOPE CLINIC
ADULT MEDICAL SCREENING

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

HISTORY OF PRESENT ILLNESS

PAST MEDICAL HISTORY

1. Has the patient ever had pulmonary TB in the past? ◯ Yes ◯ No ◯ Unknown *(If YES go to 1a, If NO or unknown go to 2)?*

1a. If YES, what was the diagnosis based on *(tick all that apply)*

- ☐ Chest X-ray
- ☐ Sypmtoms (persistent cough >2 weeks, fever, night sweats, etc)
- ☐ Failure to respond to empirical antibiotics
- ☐ Sputum
- ☐ Other (specify)
- ☐ Unknown

1b. Was the patient treated ☐ Yes ☐ No ☐ Unknown *(If YES go to 1c, If NO or unknown go to 2)*

1c. If YES, specify treatment

- ☐ EH
- ☐ SHRZE
- ☐ RHZ
- ☐ unknown
- ☐ RHZE
- ☐ Other (specify)
- ☐ RH

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

1d. If YES, did the patient (tick one)?

- ◯ Never completed full treatment
- ◯ Doesn't know if received full treatment
- ◯ Completed Full Treatment

Date started (DD/MM/YYYY) / /

Date stopped (DD/MM/YYYY) / /

2. Does the patient currently have Extra pulmonary TB? ☐ Yes ☐ No

3.Does the Patient have Pulmonary TB? ☐ Yes ☐ No *(If YES go to 3a, If NO go to 4)*

3a. If YES, what was the diagnosis based on (tick all that apply)

- ☐ Chest X-ray
- ☐ Sypmtoms (persistent cough >2 weeks, fever, night sweats, etc)
- ☐ Failure to respond to empirical antibiotics
- ☐ Sputum
- ☐ Other (specify) _____
- ☐ Unknown

4. Is the patient currently on treatment for TB (either PTB or EPTB) *(If YES go to 4a If NO or Unknown go to 5)*

☐ Yes ☐ No ☐ Unknown

4a. If yes, specify treatment start date (DD.MM.YYYY) ☐☐ / ☐☐ / ☐☐☐☐

4b. If YES, specify treatment

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

- ☐ EH ☐ SHRZE
- ☐ RHZ ☐ unknown
- ☐ RHZE ☐ Other (specify) _____
- ☐ RH

4c. Is the patient currently being treated for TB at coptic? ☐ Yes ☐ No *(If YES go to 5, If NO go to 4d)*

4d. If NO, specify where:

- ☐ Private hospital
- ☐ Public hospital
- ☐ Other government facility
- ☐ Other (specify) _____

5. In the past month, has the patient experienced any of the following? (tick all that apply)

- ☐ Dysparenuia
- ☐ Genital sores or ulcers
- ☐ Lower Abdominal pain
- ☐ Painful micturation(Dysuria)
- ☐ Testicular pain or swelling
- ☐ Vaginal itching/burning
- ☐ Vaginal discharge
- ☐ Urethral discharge
- ☐ None

6. Has the patient ever had or been told he/she had a sexually transmitted infection? ◯ Yes ◯ No ◯ Unknown

6a. If yes, specify (tick all that apply)

- ☐ Chlamydia
- ☐ Chancroid
- ☐ Herpes
- ☐ Neisseria gonorrhea
- ☐ Trichomonas vaginalis
- ☐ Syphilis
- ☐ Unknown
- ☐ Other specify _____

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7. Does the patient currently have, or has the patient ever had, any of the following conditions (tick all that apply)

WHO stage 1	
Asymptomatic HIV infection	☐
Persistent generalized lymphadenopathy (PGL)	☐
WHO stage 2	
Herpes Zoster (within last 5 years)	☐
Minor Mucocutaneous Manifestations	☐
Recurrent Upper Resiratory Infections	☐
Weight loss < 10% of Body weight	☐
WHO stage 3	
Severe Bacterial infections (i.e Pneumonia, pyomysitis)	☐
Oral Candidiasis (Thrush)	☐
Unexplained chronic diarrhea (> 1 month)	☐
Unexplained Prolonged Fever (intermittent or constant, > 1 month)	☐
Oral Hairy Leukoplakia	☐
Tuberculosis, Pulmonary (within last 12 months from today)	☐
Weight loss > 10% of body weight	☐
WHO stage 4	
Candidiasis (Esophageal, Bronchi, Trachea, or lungs)	☐
Cryptococcosis, Extrapulmonary	☐
Cryptosporidosis with Diarrhea (> 1 month duration)	☐
Herpes Simplex (mucocutaneous > 1 months, or visceral or any duration)	☐
HIV Encephalopathy	☐
HIV Wasting Syndrom	☐
Kaposi's Sarcoma (KS)	☐
Lymphoma	☐
Atypical Mycobacteriosis, Disseminated	☐
Tuberculosis, Extrapulmonary	☐
Progressive Multifocal Leukoencephalopathy (PML)	☐
Mycosis, disseminated endemic (i.e., histoplasmosis, cocciodiomycosis)	☐
Pneumocystis Carinii Pneumonia (PCP)	☐
Salmonella Septicemia, Non-typhoid	☐
Toxoplasmosis, CNS	☐

8. What is the WHO Clinical Stage of the patient? (tick one) ◯ 1 ◯ 2 ◯ 3 ◯ 4

9. Last CD4 count ☐☐☐☐ ◯ Unknown ◯ Not tested

9a. Last CD4 count date (DD.MM.YYYY) ☐☐ / ☐☐ / ☐☐☐☐ ◯ Unknown

9b. Last Viral load ☐☐☐☐☐☐☐☐ ◯ undetectable ◯ Unknown ◯ Not tested

9c. Last viral load date (DD.MM.YYYY) ☐☐ / ☐☐ / ☐☐☐☐ ◯ Unknown

MEDICATIONS

10. Has the patient ever taken or is the patient presently on HAART excluding for the purpose of PMTCT and PEP?

☐ Yes ☐ No ***(If YES go to 10a, if NO go to 11)***

10a. If YES, specify history below

	Medication (tick all that apply)										
	d4T	**3TC**	**AZT**	**DDI**	**ABC**	**NVP**	**EFV**	**LPV/ rit**	**TDF**	**Truvada**	**Other (Specify)**
First regimen	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Second regimen	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Third regimen	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

	Generic or brand (tick one)	**CD4 count at time of regimen initiation (if known)**	**Adherence (1=V. poor, 2=poor, 3=Fair, 4= Good, 5=Excellent)**	**Date started (DD/MM/YYYY)**	**Did patient stop?**	**If yes, Date stopped (DD/MM/YYYY)**
First regimen	☐ Generic ☐ Brand ☐ Unknown	☐☐☐☐ ☐ Unknown	☐	☐☐ / ☐☐ / ☐☐☐☐	☐ Yes ☐ No	☐☐ / ☐☐ / ☐☐☐☐
Second regimen	☐ Generic ☐ Brand ☐ Unknown	☐☐☐☐ ☐ Unknown	☐	☐☐ / ☐☐ / ☐☐☐☐	☐ Yes ☐ No	☐☐ / ☐☐ / ☐☐☐☐
Third regimen	☐ Generic ☐ Brand ☐ Unknown	☐☐☐☐ ☐ Unknown	☐	☐☐ / ☐☐ / ☐☐☐☐	☐ Yes ☐ No	☐☐ / ☐☐ / ☐☐☐☐

If stopped why? (tick all that apply)								
	Costs	**Side effects**	**Failure of therapy**	**New diagnosis TB**	**Drug out of stock**	**Doctor orders**	**Unknown**	**Other (Specify)**
First regimen	☐	☐	☐	☐	☐	☐	☐	
Second regimen	☐	☐	☐	☐	☐	☐	☐	
Third regimen	☐	☐	☐	☐	☐	☐	☐	

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11. Is patient taking any of the following medications? (tick all that apply)

☐ Antimalarial medications ☐ Dapsone ☐ Herbal traditional medications ☐ None of the above

☐ Cotrimoxazole ☐ Fluconazole ☐ Multivitamin supplements

12. What other medications is patient currently taking?

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				

13. PHYSICAL EXAMINATION

Nurse number ☐☐☐

Temp (F) ☐☐☐.☐ HR ☐☐☐ BP ☐☐☐/☐☐☐ RR ☐☐ Wt (Kg) ☐☐☐.☐ Height (cm) ☐☐☐ Sa O2 ☐☐☐

BMI ☐ BMI>18.5 ☐ BMI<18.5 ☐ BMI Unknown **Gender** ☐ MALE ☐ Female

14.

System (tick one)	**Normal**	**Abnormal**	**Not done**	**Findings (if abnormal)**
General	☐	☐	☐	
Skin	☐	☐	☐	
Lymph nodes	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Abdomen	☐	☐	☐	
Genitourinary	☐	☐	☐	
Extremities	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Psychological	☐	☐	☐	

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ASSESSMENT AND PLAN

15. What new diagnoses does the patient have on today's visit (tick all that apply)?

- ☐ Anaemia
- ☐ Asthma
- ☐ Candidiasis (thrush) - oral
- ☐ Candidiasis (thrush) - vaginal
- ☐ Chancroid
- ☐ Conjuctivitis
- ☐ Diarrhea
- ☐ Dementia
- ☐ Dermatitis
- ☐ Extra Pulmonary TB
- ☐ Gonorrhea
- ☐ Genital Ulcer disease
- ☐ Hypertension
- ☐ HSV - genital
- ☐ IRIS
- ☐ Malaria
- ☐ Myalgia
- ☐ Neuropathy
- ☐ Peptic Ulcer disease
- ☐ Pneumonia
- ☐ Side effects due to ARV
- ☐ Soft tissue infection
- ☐ Syphilis
- ☐ Ulcers genital
- ☐ Ulcers - oral
- ☐ URTI
- ☐ UTI
- ☐ Zoster
- ☐ None
- ☐ Other (specify) ____

16. What is the patients current TB diagnosis?

- ☐ TB suspected *(If suspected go to 17)*
- ☐ TB diagnosed today *(If diagnosed go to 18)*
- ☐ Currently on pulmonaryTB treatment *(If currently on TB treatment go to 19)*
- ☐ No TB *(If NO TB go to 19)*
- ☐ Other(specify) ____

17. If TB suspected, what is the suspected TB based on (tick all that apply)?

- ☐ Abnormal X-ray
- ☐ Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- ☐ Failure to respond to empirical antibiotics
- ☐ Recent contact with people with TB
- ☐ Other (specify) ____

17a. Will the patient be sent for TB testing? ☐ Yes ☐ NO *(If YES, go to 17b, If NO go to 19)*

17b. If YES, which of the following tests will the patient be sent for:

- ☐ Sent for sputum
- ☐ Sent for X-ray
- ☐ Other (specify) ____

(Go to 19)

18. If TB is diagnosed today, what is it based on(tick all that apply)?

- ☐ Abnormal X-ray
- ☐ Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- ☐ Failure to respond to empirical antibiotics
- ☐ Sputum
- ☐ Other (specify) ____

18a. Specify treatment to be started:

- ☐ EH
- ☐ RHZE
- ☐ RHZ
- ☐ SHRZE
- ☐ Other (specify) ____

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SECTION B: FEMALE PATIENTS ONLY

19. In the past, has the patient ever taken any antiretroviral drugs for PMTCT?

☐ Yes ☐ No ☐ Unknown *(If YES go to 19a, If NO or Unknown go to 20)*

19a. If YES, how many times did the patient take PMTCT? ☐☐

19b. Specify history for each pregnancy in which the patient had PMTCT, beginning with the youngest child:

	Date of delivery (DD/MM/YYYY)	Regimen	Specify when the drug was taken (Tick all that apply	Location of delivery	Mode of delivery
1.	☐☐ / ☐☐ / ☐☐☐☐	☐ AZT	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum	☐ Hospital ☐ Home ☐ Other (specify) ☐	☐ C-section ☐ Unassisted vaginal ☐ Assisted vaginal (use of forceps or vacuum)
		☐ 3TC	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ NVP	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ HAART	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Other (Specify) ☐	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Unknown			
2.	☐☐ / ☐☐ / ☐☐☐☐	☐ AZT	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum	☐ Hospital ☐ Home ☐ Other (specify) ☐	☐ C-section ☐ Unassisted vaginal ☐ Assisted vaginal (use of forceps or vacuum)
		☐ 3TC	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ NVP	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ HAART	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Other (Specify) ☐	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Unknown			

	Date of delivery (DD/MM/YYYY)	Regimen	Specify when the drug was taken (Tick all that apply	Location of delivery	Mode of delivery
3.	☐☐ / ☐☐ / ☐☐☐☐	☐ AZT	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum	☐ Hospital ☐ Home ☐ Other (specify)	☐ C-section ☐ Unassisted vaginal ☐ Assisted vaginal (use of forceps or vacuum)
		☐ 3TC	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ NVP	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ HAART	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Other (Specify)	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Unknown			
4.	☐☐ / ☐☐ / ☐☐☐☐	☐ AZT	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum	☐ Hospital ☐ Home ☐ Other (specify)	☐ C-section ☐ Unassisted vaginal ☐ Assisted vaginal (use of forceps or vacuum)
		☐ 3TC	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ NVP	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ HAART	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Other (Specify)	☐ Antepartum ☐ Labor & Delivery ☐ Postpartum		
		☐ Unknown			

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20. Is the patient currently pregnant?
☐ Yes ☐ No ☐ Unknown *(If YES also complete Pregnancy Monitoring Form)*

21. Is the patient currently breastfeeding? ☐ Yes ☐ No *(If YES go to 21a, if NO go to 22)*

21a. If yes, specify what type of breastfeeding (tick one)
◯ Exclusive breastfeeding *(Child given ONLY mother's milk and NO water, tea, formula, cow's milk or food of any kind)*
◯ Mixed feeding *(Child given mother's milk and water, tea formula, cow's milk or food)*

21b. If YES, has she had a sesson with the nutritionist since she started breastfeeding.
☐ Yes ☐ No ***(If NO refer to Nutritionist)***

22. Is the patient currently on HAART, excluding PMTCT and PEP? ☐ Yes ☐ No *(If YES, go to 22a, If NO go to 22b)*

22a. If yes, did you continue current HAART today? ☐ Yes ☐ No *(If YES, go to 23, If NO go to 22a1)*

22a1. If no, did you change or stop HAART today? ☐ Changed ☐ Stopped

22a2. Specify why HAART was changed or stopped (Tick all that apply) :

☐ Toxicity / Side effects	☐ Clinical treatment failure
☐ Pregnancy	☐ Immunologic treatment failure
☐ Risk of pregnancy	☐ Virologic treatment failure
☐ Newly diagnosed TB	☐ Poor adherence
☐ New drug available	☐ Planned treatment interruption
☐ Drug not available	☐ Illness, hospitalization
☐ Patient lacks finances ***(Go To 23)***	☐ Other (specify) ☐☐☐☐☐☐☐☐☐☐

22b. If NO, is patient ELIGIBLE for therapy? ◯ Yes ◯ No ◯ Not yet determined *(If Eligible=NO or NYD >>24)*

22b1. If ELIGIBLE for therapy then by what criteria (tick all that apply)?

◯ CD4 count ☐☐☐☐ Date (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐
◯ WHO Clinical Stage ◯ 1 ◯ 2 ◯ 3 ◯ 4 ☐ Viral Load ☐☐☐☐☐☐☐ copies
◯ Patient on HAART/ARV in past

22c. Did you initiate HAART/ARV treatment at this clinic visit, excluding PMTCT and PEP? ☐ Yes ☐ No

(If YES go to 23, If NO go to 22c1)

22c1. If NO, specify:

☐ Patient has not completed HAART protocol	☐ Patient preference
☐ Patient currently on drugs which may interact with HAART/ARV	☐ Patient pregnant
☐ Patient too ill to begin HAART today	☐ Other (specify) ☐☐☐☐☐☐☐☐☐☐

23. What ARV medications were prescribed or continued today

☐ AZT-3TC-EFV	☐ TDF-ABC -LPV/rit
☐ AZT-3TC-NVP	☐ TDF 3TC EFV
☐ AZT-3TC- LPV/rit	☐ TDF 3TC NVP
☐ d4T(30mg)-3TC-EFV	☐ None
☐ d4T(30mg)-DDL-LPV/rit	☐ Other (specify) ☐☐☐☐☐☐☐☐☐☐
☐ d4T(30mg)-3TC-NVP	

24. Did you initiate or continue Cotrimoxalzole today? ☐ Yes ☐ No *(If yes go to 25, if no go to 24a)*

24a. If no, why?

◯ Side effects/ toxicity ◯ Patient preference

◯ Stockout/drug supply interruption ◯ Other (Specify)

25. Did you initiate or continue any of the following medications today (tick all that apply)?

◯ Dapsone ◯ Fluconazole ◯ Multivitamin supplement ◯ None of the above

26. Other medications prescribed during this visit

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				
4.				
5.				

27. What laboratory tests were ordered today (tick all that apply)

☐ ALT ☐ Hgb ☐ Viral Load

☐ cd4 ☐ HIV ELISA Confirmatory test ☐ Widal Test

☐ Chest X-ray ☐ LFT ☐ None

☐ Creatinine ☐ Lactic Test ☐ Other (specify)

☐ Complete Blood Count ☐ Urinalysis

Additional Comments

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person***

5894

HOPE CLINIC
VERBAL AUTOPSY FORM

HOPE ID Number

Site Code **Today's Date (DD.MM.YYYY)** **Interviewer number**

1. Gender ☐ Female ☐ Male

2. Age at death ☐☐☐ Years

3. Date of death (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

4. The information source for the cause of death was (Tick all that apply)

- ☐ Hospital records/Staff
- ☐ Mother or Father
- ☐ Partner/Spouse
- ☐ Other family member/relative
- ☐ Neighbour
- ☐ Caregiver
- ☐ Friend
- ☐ Unknown
- ☐ Other (Specify)

5. Was the deceased seeking other medical treatment (other than Hope Center) during that last 3 months before his/her death?

☐ Yes ☐ No ☐ Unknown *(If YES go to 5a, If NO go to 6)*

5a. If YES, where specifically was the deceased receiving other medical care?

Name of facility:

5b. What type of care was the deceased receiving at these other facilities? (Tick all that apply)

- ☐ General medical care
- ☐ TB
- ☐ STD
- ☐ HIV/AIDS
- ☐ Malaria
- ☐ Other infectious disease(s)
- ☐ Other (Specify)

6. Respondent's detailed account of the illness of the deceased:

7. Did a health care worker tell you the cause of death? *(If YES go to 7a, If NO go to 8)*

☐ Yes ☐ No ☐ Unknown

7a. What did the health care worker say was the cause of death?

8. Did s/he have any operation for the illness? *(If YES go to 8a, If NO go to 9)*

☐ Yes ☐ No ☐ Unknown

8a.How long before the death was the operation? : ☐☐ Months

8b. On what part of the body was the operation?

☐ Abdomen ☐ Chest ☐ Head

☐ Other(specify)

9. Has the deceased's spouse or partner died in the past in the past 5 years? *(If YES go to 9a, If NO go to 10)*

☐ Yes ☐ No ☐ Unknown ☐ Had no spouse

9a. If YES, what is the percieved cause(s) of death of the partner(s)

9a1. Partner 1:

9a2. Partner 2:

Injury/accident/suicide

10. Did s/he suffer from any injury or accident that led to her/his death? *(If YES go to 10a, If NO go to 11)*

☐ Yes ☐ No ☐ Unknown

10a. What kind of injury or accident did the deceased suffer?

☐ Road traffic accident ☐ Fall

☐ Burns ☐ Violence/assault

☐ Unknown ☐ Poisoning

☐ Drowning ☐ Other:

10b. Was the injury or accident intentionally inflicted by someone else?

☐ Yes ☐ No ☐ Unknown

10c. Do you think that s/he committed suicide?

☐ Yes ☐ No ☐ Unknown

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History of previously known conditions

11. Did the deceased suffer from any of the following conditions?

a. High blood pressure	☐ Yes	☐ No	☐ Unknown
b.Diabetes	☐ Yes	☐ No	☐ Unknown
c. Asthma	☐ Yes	☐ No	☐ Unknown
d. Epilepsy	☐ Yes	☐ No	☐ Unknown
e. Malnutrition	☐ Yes	☐ No	☐ Unknown
f. Cancer	☐ Yes	☐ No	☐ Unknown

f1. If YES, specify type or site

g. Tuberculosis	☐ Yes	☐ No	☐ Unknown
h. Any other medically diagnosed illness?	☐ Yes	☐ No	☐ Unknown

h1. If YES, specify

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12. Signs, symptoms and their severity during the last illness:

Symptom	Symptom present?	If present, duration of symptom
a. Fever	☐ Yes ☐ No ☐ unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
b. Loss of weight	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
c. Diarrhea	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
d. Vomiting/associated abdominal pain	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
e. Constipation/associate abdominal pain	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
f. Cough	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
g. Cough followed by vomiting	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
h. Breathing trouble (chest indrawing/difficult /rapid/wheezing)	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
i. Neck stiffness	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
j. Unconscious episodes	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
k. Fits	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
l. Jerking of individual limbs	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
m. History of epileptic illness in earlier years	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
n. Paralysis of limbs	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
o. Rigid body stiffness, unable to open mouth	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
p. Red and sore eyes	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
q. Skin rash and itching	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
r. Herpes zoster (at any time in life)	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
s. Abscesses/body sores	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
t. White patches on the inside of mouth and tongue	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
u. Oedema	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
v. Hair changes	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
w. Yellowing of eyes or passing of brown urine	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
x. Chest pain	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
y. Other (specify) ☐	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown

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Women only:

z. unexpected vaginal bleeding or discharge	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown
aa.Pelvic or vaginal pain	☐ Yes ☐ No ☐ Unknown	☐ =<2 weeks ☐ >2 weeks ☐ Unknown

14. Records available in home e.g. death certificate (extract findings):

Comments (if the form is incomplete or any other comments)

For the data use only (tick after scanning the form)

Scanned ☐ *Date* ___ / ___ / _____ *Name of data person*

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HOPE CLINIC
ADULT NURSING SCREENING

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

Section A: All Patients

1. Who referred patient here? (tick one)

- ◯ Hope VCT
- ◯ Other VCT
- ◯ PMTCT
- ◯ CCC Clinic or HIV Clinic
- ◯ Hope TB clinic
- ◯ Other TB clinic
- ◯ Self-referral
- ◯ Child welfare Clinic
- ◯ Family member, spouse or friend
- ◯ Other patients
- ◯ NGO
- ◯ Coptic ward
- ◯ Other hospital ward (specify)
- ◯ Coptic Pharmacy
- ◯ Private doctor
- ◯ Other (specify)

2. Does the client have a NASCOP referral number? ◯ Yes ◯ No *(If YES go to 2a, If NO go to 3)*

2a. If Yes, specify the client's NASCOP referral number with date

NASCOP Referral Number

Refferal Date (DD/MM/YYYY) / /

◯ NASCOP referral number unknown

3. Has client ever been on antiretroviral drugs, excluding for PMTCT and PEP? ◯ Yes ◯ No *(If YES go to 3a, If NO go to 4)*

3a. If YES, where did the client receive antiretroviral drugs ?

- ◯ CCC Clinic or HIV Clinic
- ◯ Private Doctor
- ◯ Hospital ward
- ◯ NGO
- ◯ Other (specify)

3b. What is the reason for transfer of care (tick all that apply)

- ◯ Financial
- ◯ Client's preference
- ◯ Distance to clinic
- ◯ Doctors advice
- ◯ Poor management
- ◯ Client was asked to leave
- ◯ Facility unable to
- ◯ Other (specify)

4. In the past, has the patient ever taken any antiretroviral drugs for PMTCT?

☐ Yes ☐ No ☐ Unknown ☐ N/A,Male Client

4a. If YES, how many times did the patient take PMTCT?

5. Has the patient been tested for HIV? ◯ Yes ◯ No *(If Yes go to 5a, If NO go to 6)*

5a. If yes, where was the test performed? (Tick one) *(If **PITC**, go to 5ai, else go to 5b)*

◯ PITC (ProviderInitiated HIV Testing and Counseling)
◯ VCT
◯ PMTCT
◯ Postnatal Clinic
◯ CWC(Child welfare Clinic)
◯ TB clinic
◯ Other (Specify) _____

5ai. Where was the PITC done ?

◯ Coptic Hospital-Outpatient ◯ Coptic Hospital-inpatient
◯ Hope TB clinic ◯ Private Hospital
◯ Hope Home-base care program ◯ Public Hospital
◯ Muangalizi Program ◯ Other(specify) _____

5b. When was the test done (DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

5c. What were the test results? ◯ Positive ◯ Negative ◯ Unknown

6. Has the patient been hospitalized in the last 1 year? ◯ Yes ◯ No

6a. If yes, how many times? ☐☐

7. Does patient have Penicillin allergy? ◯ Yes ◯ No ◯ Dont Know
8. Does patient have Sulfa allergy? ◯ Yes ◯ No ◯ Dont Know *(Medical and non-medical allegies)*
9. Does the patient have any other ◯ Yes ◯ No ◯ Dont Know

9a. If yes, please specify _____

(If Patient ticked any "YES" in Q7, 8 or 9 highlight allergy in chart)

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Section B: Female patients only [If Male go to 12]

10. How many times has the patient been pregnant? ☐☐ IF = 0 go to 13

11. How many children has patient given birth to? ☐☐ IF = 0 go to 13

12. How many of the children the patient has given birth to are alive? ☐☐ IF = 0 go to 13

12a) What is the age of the first child? Years ☐☐ Month ☐☐ Weeks ☐☐

12b) What is the age of the last child? Years ☐☐ Month ☐☐ Weeks ☐☐

13. Is the patient or partner using any form of family planning? ◯ Yes ◯ No

13a. If YES (tick all that apply)

- ◯ Condoms
- ◯ Oral contraceptive pills
- ◯ Injectable/implantable hormones
- ◯ Diaphram/Cervical cap
- ◯ Intrauterine device
- ◯ Vastectomy/tubal ligation/hysterectomy
- ◯ Natural method (specify) ☐
- ◯ Other (specify) ☐

Other Comments

☐

Scanned ☐ *Date ___ / ___ / __ Name of data person* ☐

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HOPE CLINIC
NUTRITION FOLLOW - UP

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**

1. Anthropometric Assessment

Weight ☐☐☐.☐ Kgs Height ☐☐☐cm Hip Circ. ☐☐☐ cm BMI ☐☐.☐

Waist circ. ☐☐☐ cm Waist:Hip ratio ☐.☐☐ cm MUAC ☐☐☐.☐ cm

2. Medical

Medication	Time	with food?	Time	with food?	Time	with food?

3. Is the client currently on multivitamins? ☐ Yes ☐ NO *(If YES go to 3a, If NO go to 4)*

3a. If yes, did you continue the multivitamins today? ☐ Yes ☐ NO

4. Is the client on food supplement? ☐ Yes ☐ NO *(If YES go to 4a, If NO go to 5)*

4a. If yes, which type of food supplement?

☐ First Food ☐ Advantaged ☐ Foundation ☐ Other (specify)

4b. If yes, what is the qualifying criteria

☐ BMI < 18.5 ☐ Pregnant ☐ Breastfeeding mother ☐ Other (specify)

5. Is the client initiating food supplements today? ☐ Yes ☐ No *(If YES go to 5a, If NO go to 6)*

5a. If yes, why?

☐ BMI < 18.5 ☐ Pregnant ☐ Breastfeeding mother ☐ Other (specify)

5b. If yes, which type of food supplement?

☐ First Food ☐ Advantaged ☐ Foundation ☐ Other (specify)

5c. If yes, has the patient been on food supplement before? ☐ Yes ☐ No

6. Is the client exiting food supplement today? ☐ Yes ☐ No *(If YES go to 6a, If NO go to 7)*

6a. If yes, Why?

☐ BMI >20 ☐ Non recoveries

☐ Defaulter ☐ Recovered

☐ Dead ☐ Transfer

☐ No longer breast feeeding ☐ Other (specify)

(Q7. applies to those initiated/or already on food supplement)

7.How would you Classify today's case? ☐ Severe Cases ☐ Moderate/Mild Cases

8. Assessment and Recommendations

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person***

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HOPE CLINIC
NUTRITION SCREENING

HOPE ID Number

Site Code	Today's date (DD.MM.YYYY)	Interviewer number
	/ /	

1. Anthropometric Assessment

Weight ___.___ Kgs Height ___ cm Hip Circ. ___ cm BMI ___.___

Waist circ. ___ cm Waist:Hip ratio ___.___ cm MUAC ___.___ cm

2. Medical

Nausea	◯ No	◯ Yes	Vomiting	◯ No	◯ Yes
Diarrhoea	◯ No	◯ Yes	Constipation	◯ No	◯ Yes
Weight loss greater than 10%	◯ No	◯ Yes	Chewing/teeth problem	◯ No	◯ Yes
Swallow difficulty	◯ No	◯ Yes	Taste changes	◯ No	◯ Yes
Poor appetite	◯ No	◯ Yes			
Other medical conditions	◯ No	◯ Yes			

If patient has other medical conditions, specify

1	
2	
3	
4	

Medications? ◯ Yes ◯ No (specify)

Medication	Time	with food?	Time	with food?	Time	with food?

3. Social History

Permanent housing	◯ No	◯ Yes	
Adequate food resoures	◯ No	◯ Yes	
Adequate cooking facilities	◯ No	◯ Yes	
Activity/excercise	◯ No	◯ Yes	
Smoking	◯ No	◯ Yes	specify
Alcohol	◯ No	◯ Yes	specify
Drugs	◯ No	◯ Yes	specify

4. Dietary History

4a. Number of meals or snacks per day ___

4b. Times per week eat out ___

4c. Who prepares food?

☐ Self ☐ Relative
☐ Spouse ☐ Caregiver
☐ Child/children ☐ Other (specify) ____
☐ Neighbour

4d. Special or alternative diets ◯ No ◯ Yes specify ____
4e. Food intolerances or allergies ◯ No ◯ Yes specify ____
4f. Food likes ◯ No ◯ Yes specify ____
4g. Food dislikes ◯ No ◯ Yes specify ____

5. Is the client currently on multivitamins? ☐ Yes ☐ NO *(If YES go to 5a, If NO go to 6)*

5a. If YES, did you continue the multivitamins today? ☐ Yes ☐ NO

6. Is the client on food supplement? ☐ Yes ☐ NO *(If YES go to 6a, If NO go to 7)*

6a. If YES, which type of food supplement?

☐ First Food ☐ Advantaged ☐ Foundation ☐ Other (specify) ____

6b. If YES, what is the qualifying criteria

☐ BMI < 18.5 ☐ Pregnant ☐ Breastfeeding mother ☐ Other (specify) ____

7. 24 hour recall /usual diet

B/Fast	M. Morning	Lunch	M. Afternoon	Dinner

8. Is the client initiating food supplements today? ☐ Yes ☐ No *(If YES go to 8a, If NO go to 10)*

8a. If yes, why?

☐ BMI < 18.5 ☐ Pregnant ☐ Breastfeeding mother ☐ Other (specify) ____

8b. If YES, which type of food supplement is client initiating today?

☐ First food ☐ Advantaged ☐ Foundation ☐ Other (specify) ____

8c. If yes, has the patient been on food supplement before? ☐ Yes ☐ No

(Q9. applies to those initiated/or already on food supplement)

9.How would you Classify today's case? ☐ Severe Cases ☐ Moderate/Mild Cases

10. Assessment and Recommendations

For the data use only (tick after scanning the form)

Scanned ☐ ***Date*** ___ / ___ / _____ ***Name of data person*** ____

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HOPE CLINIC
SOCIAL WORK SCREENING

HOPE ID Number

Site Code **Today's date (DD/MM/YYYY)** **Interviewer number**

Client's Residential and Telephone Contact Information

1. Public Transport to the House:

First trip

Ia. Type

☐ Bus ☐ Citi Hoppa ☐ Matatu ☐ Taxi ☐ Other(specify)

Ib. Number

Ic. Stage Name

Id. General name of the area

Second trip

IIa. Type

☐ Bus ☐ Citi Hoppa ☐ Matatu ☐ Taxi ☐ Other(specify)

IIb. Number

IIc. Stage Name

IId. General name of the area

2. Walking directions to house from the stage?

3. Landmarks that aid in locating the household: (Names of schools, Churches, businesses etc.)

4. How is the client called or referred to in the home area:

4a. How is the caregiver called or referred to in the home area: ☐ N/A

5. Does the patient have a treatment supporter? ☐ Yes ☐ No *(If yes, go to 5a, if no go to 6)*

5a. Treatment supporter name(Last, First, Middle)

5b. Treatment supporter home address

5c. Treatment supporter postal address (P.O Box)

5d. Treatment supporter number (Cell) ☐☐☐☐.☐☐☐☐☐☐

5e. Treatment supporter number (Landline) ☐☐☐☐.☐☐☐☐☐☐

6. Upcountry name for the client? ☐ N/A

6a. Upcountry contact home address? ☐ N/A

6b. Upcountry contact postal address? ☐ N/A

6c. Upcountry contact phone number (Cell) ☐☐☐☐.☐☐☐☐☐☐ ☐ N/A

6d. Upcountry contact phone number (Landline) ☐☐☐☐.☐☐☐☐☐☐ ☐ N/A

7. During the last year from today,have you been hit, slapped, Kicked, or hurt by someone?

☐ Yes ☐ No ☐ Refused to answer

7a. If yes Who?

☐ Spouse ☐ Steady Partner

☐ Casual Partner ☐ Sibling

☐ Parent ☐ Other(specify)

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8. During the last year from today,have you ever hit, slapped, Kicked, or hurt someone?

☐ Yes ☐ No ☐ Refused to answer

8a. If yes Who?

☐ Spouse ☐ Steady Partner

☐ Casual Partner ☐ Sibling

☐ Parent ☐ Other(specify) ☐

9. In the past 12 months have you:

9a1. Smoked? ☐ Yes ☐ No ☐ Refused to answer

9a2. If yes, number of cigarretes per day ☐☐☐

9b1. Chewed Miraa ☐ Yes ☐ No ☐ Refused to answer

9b2. If yes, number of times per month ☐☐

9c1. Smoked marijuana ? ☐ Yes ☐ No ☐ Refused to answer

9c2. If yes, number of times per month ☐☐☐

9d1. Used cocaine? ☐ Yes ☐ No ☐ Refused to answer

9d2. If yes, number of times per month ☐☐☐

9d3. If yes, how? ☐ Sniff ☐ Inject

☐ smoke ☐ Other (specify) ☐

9e1. Used intravenous drugs? ☐ Yes ☐ No ☐ Refused to answer

9e2. If yes, number of times per month ☐☐☐

9e3. If yes, do you share needles? ☐ yes ☐ No ☐ Refused to answer

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10. Do you drink alcohol? ☐ Yes ☐ No

10a. If yes, number of drinks per week ☐☐☐

10b. In the last month, how often did you get drunk?

☐ Never ☐ Daily ☐ Weekly ☐ 1-3 times a month

10c.In the last month, have you experienced any of the following after drinking alcohol?

Gotten in to a fight	☐ No	☐ Yes	☐ Refused to answer
Had accident/ Injured	☐ No	☐ Yes	☐ Refused to answer
Been arrested	☐ No	☐ Yes	☐ Refused to answer
Been raped(sex was forced on you)	☐ No	☐ Yes	☐ Refused to answer
Sexually assaulted someone	☐ No	☐ Yes	☐ Refused to answer

11. Can you use a condom during sex after you have been drinking or taking drugs?

☐ Yes ☐ No ☐ Do not drink or use drugs ☐ Refused to answer

12. What is your Current Marital Status (tick one)

◯ Married (monogamous) ◯ Separated
◯ Married (Polygamous) ◯ Widowed
◯ Cohabiting(come we stay) ◯ Single
◯ Divorced

13. What is your occupation?

◯ Unemployed ◯ Housewife
◯ Employed ◯ Causal labourer
◯ Self-employed ◯ Student

14. Housing roof type?

◯ Corrugated iron sheet ◯ Makuti
◯ Tiles ◯ Asbestos
◯ Concrete ◯ Tin
◯ Grass ◯ Other (specify) ☐

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15.How many adults live in the home? ☐☐ 16. How many children live in the home? ☐☐

17. How much do you or your spouse earn in one month? (Ksh)

- ◯ 0 - 2,000 Ksh
- ◯ 2,001 - 5000 Ksh
- ◯ 5,001 - 10,000 Ksh
- ◯ 10,001 - 20,000 Ksh
- ◯ 20,001 - 30,000 Ksh
- ◯ 30,001 - 50,000 Ksh
- ◯ > 50,001 Ksh
- ◯ Refused to answer

18. What is your highest level of education?(Tick one)

- ☐ No education
- ☐ Lower primary education (< 5years education)
- ☐ Five to eight years of primary education
- ☐ Some secondary education
- ☐ Beyond secondary education

19. How long does it take for you to travel to the clinic from home one way (Hrs/ Minutes) Hours ☐☐ Minutes ☐☐

20.Do you have piped water in your home? ◯ Yes ◯ No

21. Do you have electricity at home? ◯ Yes ◯ No

22. What is your main source of cooking at home?

◯ Electricity ◯ Paraffin ◯ Firewood ◯ Solar Energy ◯ Other (Specify) ☐

23. Social worker, does the client require home assessment ☐ Yes ☐ No

23a. If YES, why?

- ☐ Physically or mentally disabled adult
- ☐ Adult dependent on care-giver
- ☐ Client requests a home visit
- ☐ Disclosure (patient would like help disclosing status to family members)
- ☐ Family testing (patient would like other family members to be tested)
- ☐ Other (specify) ☐

☐

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HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

HOPE ID Number

Site Code ☐☐

Today's Date (DD.MM.YYYY) ☐☐ / ☐☐ / ☐☐☐☐

Interviewer number ☐☐☐

REASONS FOR FOLLOW-UP VISIT

1. What is the reason for today's follow-up visit, as specified by previous visit (Check all that apply)

☐ Clinic attendance and/or ART adherence monitoring
☐ PMTCT Client
☐ Follow-up on physical health, HBC or first aid
☐ Hospital Admission
☐ Monitoring consistency of caregiver
☐ Lost to folow up client
☐ Follow-up on psyco-social issue or refferal made(specify refferal)
☐ Counseling ☐ Social work ☐ Clinic ☐ Pharmacy

☐ Homebased counseling for patient or caregiver/household members *(Specify all that apply):*

☐ Patient	☐ Counseling for the Caregiver/Household
☐ ART and Adherence	☐ Care and support for PLWHA
☐ Management of side effects	☐ General HIV: Prevention, Transmission and management
☐ Disclosure	☐ knowing HIV status: Testing and care options
☐ General counseling	☐ Management of side effects for client needs
☐ Hygiene	☐ ART and Adherence
☐ Client basic care	☐ Disclosure
☐ Nutrition	☐ General counseling
☐ HIV prevention	☐ Hygiene
☐ PMTCT and Family Planning	☐ Nutrition
☐ Other (specify)	☐ Other (specify)

1a. This visit is taking place at the client's

☐ Place of residence
☐ Place of work or school
☐ Central market, shop or other public meeting place
☐ Hospital due to client's admission

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HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

PHYSICAL HEALTH MONITORING

2. During this visit how would you describe the client's physical condition/health?

- ☐ Stable and self dependent
- ☐ Immobile
- ☐ Sought medical attention for health complaints from previous visit *(Specify outcome)*
  - ☐ Condition improving ☐ No change ☐ Condition worsening
- ☐ Did not seek medical attention for health complaints from previous visit *(Specify outcome)*
  - ☐ Condition improving ☐ No change ☐ Condition worsening
- ☐ Presenting new health complaints at this visit *(Specify in question 3)*

3. Current symptoms or complaints assessed during this visit:

☐ None	☐ Minor Health Complaints	☐ Severe Health Complaints
	☐ Low grade fever (below 38)	☐ Bedridden/immobile
	☐ Headaches	☐ Severe coughing (2 weeks or more) with difficulty breathing
	☐ Fatigue	☐ Severe Burning/tingling in extremities
	☐ Nausea and or occasinal vomiting	☐ Poor feeding
	☐ Mild diarrhea (occasinal and loose stool)	☐ Severe Diarrhea (frequent and watery)
	☐ Abdominal pain	☐ Severe vomiting
	☐ Cough	☐ Persistent or high grade fever (above 39)
	☐ Fat changes	☐ Jaundice
	☐ Burning tingling in extremities	☐ Sores or skin lesions
	☐ Skin rush ☐ Other (specify) _____	☐ Mental confusion/Dementia ☐ Other (specify) _____

4. How many meals does the client eat per day?

☐ One ☐ Two ☐ Three ☐ More than three ☐ None

HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

CAREGIVER/HOUSEHOLD MONITORING

5. Has the caregiver changed since the last visit? ☐ Yes ☐ No *(If NO, go to Q6)*

5a. If YES, specify reason

- ☐ No longer able or willing to care for the patient
- ☐ Found more suitable long term caregiver
- ☐ Patient refused care from this person
- ☐ Patient's condition no longer requires the need of a caregiver
- ☐ Patient's condition now requires the help of a caregiver
- ☐ Other (Specify) _____

5b. If YES, who is the new caregiver?

- ☐ Self (No caregiver needed)
- ☐ Parent
- ☐ Spouse
- ☐ Relative
- ☐ Neighbour
- ☐ Friend
- ☐ Social worker/Institution
- ☐ Other (Specify) _____

5c. If YES, is the new caregiver aware of the clients HIV status? ☐ Yes ☐ No

6. At this visit are there areas of counseling or education which are needed in the household? (Tick all that apply)

☐ Patient	☐ Counselling for the Caregiver/Household
☐ ART and Adherence	☐ Care and support for PLWHA
☐ Management of side effects	☐ General HIV: Prevention, Transmission and management
☐ Disclosure	☐ Knowing HIV status: Testing and care options
☐ General counselling	☐ Management of side effects for client needs
☐ Hygiene	☐ ART and Adherence
☐ Client basic care	☐ Disclosure
☐ Nutrition	☐ General counseling
☐ HIV prevention	☐ Hygiene
☐ PMTCT and Family Planning	☐ Nutrition
☐ Opportunistic Infections and STIs	☐ Opportunistic Infections and STIs
☐ Other (specify) _____	☐ Other (specify) _____

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HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

PSYCO-SOCIAL MONITORING

7. Was referral made at the previous visit? ☐ Yes ☐ No *(If NO go to Q8)*

7a. If YES, specify

☐ Domestic violence ☐ Food Insecurity
☐ Drug or Alcohol abuse ☐ Legal aid
☐ Sexual violence ☐ Other (Specify) _____

7b. If YES did the client seek referral services? ☐ Yes ☐ No

☐ Transportation costs ☐ Client went but was turned away
☐ Client refused to go ☐ Forgot or lost referral slip
☐ Other (specify) _____

8. Have there been any noticeable changes from the last visit in the psycho-social issues that were identified?

☐ No noticeable change ☐ Improvement ☐ Issues are worsening ☐ Cannot assess

9. During this visit were there any concerns in the household regarding any of the following? (Tick all that apply)

Physical abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Sexual abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Emotional abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Alcohol abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Drug abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Potential to self-inflict harm	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Depression	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Stigma and isolation	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Food insecurity	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Neglect by caregiver	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
NO CONCERNS	☐ Client Reported	☐ Staff Assessed	☐ Household Reported

HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

CLINIC ATTENDENCE AND ADHERENCE MONITORING

10. Is the client on ARVs? ☐ Yes ☐ No

11. Since the last visit has the client refilled their prescription? ☐ Yes ☐ No *(If YES go to Q 12)*

11a. If NO specify reason:

- ☐ Client was not due for a refill since the last home visit
- ☐ Unable to get to clinic due to transport costs
- ☐ Unable to get to the clinic due to illness or weakness
- ☐ Travelled
- ☐ Lacked someone to assist to clinic
- ☐ Forgot
- ☐ Refused to go
- ☐ Other (specify) _____

12. Since the last visit, has the client missed any doses?

☐ One ☐ Two ☐ Three ☐ More than three ☐ None

12a. If doses were missed specify reason:

- ☐ Refused to take medications
- ☐ Forgot
- ☐ Doses were administered by caregiver who did not give
- ☐ Ran out of medication and could not refill prescription
- ☐ Felt better and decided to stop
- ☐ Drug or alcohol use affecting adherence
- ☐ Stigma,disclosure or privacy issues
- ☐ Was stopped by physician
- ☐ Side effects
- ☐ Felt too ill or too weak to take
- ☐ Medications lost or stolen
- ☐ Sharing medications with others
- ☐ Other (specify) _____

13. Is the client/caregiver able to recall critical information related to thier ARV regime?

Drug names	☐ All	☐ Some	☐ None
Doses	☐ All	☐ Some	☐ None
Times taken	☐ All	☐ Some	☐ None
Side effects	☐ All	☐ Some	☐ None
Food related indications	☐ All	☐ Some	☐ None

14. Client adherence since the last visit has

☐ No change ☐ Improved ☐ Worsened ☐ Refer to clinician for review

HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

15. Since the last visit, has the client attended all their scheduled clinic visits? ☐ Yes ☐ No ☐ Not due for visit

15a. If NO, Specify

- ☐ Too ill to come
- ☐ Forgot
- ☐ Lost appointment card
- ☐ Stigma within the household related to disclosure or privacy
- ☐ Need assistance from care-giver and none was available
- ☐ Traveled
- ☐ Depression
- ☐ Alcohol or drug use affected ability to come
- ☐ Refused to come or continue with program
- ☐ Could not afford transport
- ☐ Was seen at another clinic
- ☐ Work
- ☐ Other (specify) ☐

FOLLOW - UP PLAN

16. Is the client eligible for discharge from the tracer and home care services ☐ Yes ☐ No

16a. If NO, Next visit scheduled for:

☐ One week ☐ Two weeks ☐ One month ☐ Two months

Specify date of next visit((DD/MM/YYYY) ☐☐ / ☐☐ / ☐☐☐☐

16b. What actions will be taken as follow-up to this visit?

- ☐ Follow-up counseling in the home for client or caregiver/household
- ☐ Follow-up on physical health
- ☐ Adherence monitoring
- ☐ Refferal for household member for site based VCT services
- ☐ Refferal for suspected TB of client or household member
- ☐ Follow-up and monitoring of social conditions and actions previously taken
- ☐ Alert authorities for further investigation of neglect, sexual or domestic violence
- ☐ PMTCT
- ☐ Organise Hospital ambulatory services for immediate and urgent medical needs
- ☐ HIV positive Family /Household member for HIV/AIDS management
- ☐ Home based VCT for household member
- ☐ Organization referral or accompaniment
- ☐ Accompany client to clinic
- ☐ Counselor assisted disclosure
- ☐ No Action

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HOPE CLINIC
ADULT TRACING AND HOME CARE FOLLOW-UP FORM

17. During this visit, was an appointment booked for the client at the clinic? ☐ Yes ☐ No

If YES, Specify date of next appointment((DD/MM/YYYY)) ☐☐ / ☐☐ / ☐☐☐☐

If YES, specify the appointment type:

☐ Doctor ☐ Social worker

☐ Counselor ☐ Nutritionist

☐ Pharmacy

Comments

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HOPE CLINIC
ADULT TRACING AND HOME CARE SCREENING FORM

HOPE ID Number

Site Code ☐☐ **Today's Date (DD.MM.YYYY)** ☐☐ / ☐☐ / ☐☐☐☐ **Interviewer number** ☐☐☐

1. The reason for this client to be monitored trhough the tracer and Home Care program is

☐ Adult on ARVs not adhering to medications or clinc appointments ☐ Lost to folow up client
☐ Adult dependent on care-giver
☐ Post-partum mother
☐ Staff reffered for other reason: (Specify) _____

1a. This visit is taking place at the client's

☐ Place of residence
☐ Place of work or school
☐ Hospital due to client's admission
☐ Central market, shop or other public meeting place
☐ Other(specify _____

PHYSICAL HEALTH ASSESSMENT

2. At this initial screening in what physical condition did you find the client?

☐ Stable , mobile and able to take care of self
☐ Weak but mobile and able to take care of self
☐ Immobile or needs assistance to walk or move, reliant on caregiver

2a. Current symptoms or complaints assessed during this visit:

☐ None	☐ Minor Health Complaints	☐ Severe Health Complaints
	☐ Low grade fever (below 38)	☐ Bedridden/immobile
	☐ Headaches	☐ Severe coughing (2 weeks or more) with difficulty breathing
	☐ Fatigue	☐ Servere Burning/tingling in extremities
	☐ Nausea and or occasional vomiting	☐ Poor feeding
	☐ Mild diarrhea (occasional and loose stool)	☐ Severe Diarrhea (frequent and watery)
	☐ Abdominal pain	☐ Severe vomiting
	☐ Cough	☐ Persistent or high grade fever (above 39)
	☐ Fat changes	☐ Jaundice
	☐ Burning tingling in extremities	☐ Sores or skin lesions
	☐ Skin rash	☐ Mental confusion/Dementia

Skip to Question 4 if the residence is an institution/organisation

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HOUSEHOLD ASSESSMENT

3. Describe the type of residence this is: *(Skip to Question 4 if the residence is an institution/organisation)*

☐ Private residential home

☐ Institution/organization (specify name): _____

3a. Who is the head of the household

☐ Patient (Self)
☐ Patient's mother
☐ Patient's sibling (Specify age) ☐☐☐ years
☐ Patient's relative (Aunt, Uncle, grandparent, cousin)
☐ Other (Specify) _____
☐ Patient's Father
☐ Both parents
☐ Neighbour
☐ Friend

3b. How many individuals living in the household?

3b1. Adults (Age 15 and over) : ☐☐

3b2. Children (Age 14 and below) : ☐☐

3c. Number or rooms in the house:

☐ One ☐ Two ☐ Three ☐ More than three

3d. Does the house have electricity? ☐ Yes ☐ No

3e. What is the household's water source?

☐ Piped to the house
☐ Water tank and piping to the house
☐ Communal water tap within the vicinity
☐ Communal water tank within the vicinity
☐ Water from river, pool or open water source
☐ No water source in the vicinity

3f. What is the household's sanitation system?

☐ Own flash toilet in the house
☐ Private pit latrine
☐ Shared toilet in vicinity of house
☐ Shared pit latrine in vicinity of house
☐ None

3g. What is the source of Energy for cooking?

☐ Gas ☐ Paraffin
☐ Wood ☐ Electricity
☐ Charcoal ☐ None

4. Does the patient have any special needs? ☐ Yes ☐ No ☐ Unknown

4a. If YES specify:

4a. If YES specify:

- ☐ Advanced illness
- ☐ Physically handicapped or disabled
- ☐ Mentally handicapped or disabled
- ☐ Emotionally/psychologically unstable or unwell
- ☐ Other(specify) _____

4b. If YES does the client currently have a caregiver? ☐ Yes ☐ No ☐ Unknown

4b1. If YES specify

- ☐ Spouse
- ☐ Friend
- ☐ Partner
- ☐ Neighbour
- ☐ Parent
- ☐ Social worker/local community health worker
- ☐ Relative
- ☐ Other(specify) _____

5. Is the client living in an environment where hygiene is neglected? ☐ Yes ☐ No

5a. If YES specify:

- ☐ Foul smell in the room where the client is staying
- ☐ Client is sleeping in soiled beddings
- ☐ Client has not had a bath for more than 2 days
- ☐ Other(Specify) _____

6. How many meals is the client eating per day?

☐ One ☐ Two ☐ Three ☐ More than three ☐ None

7. Does the client have access to food? ☐ Always ☐ Sometimes ☐ Never

NO CONCERNS

8. Are there there any concerns in the household regarding any of the following? (Tick all that apply)

Physical abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Sexual abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Emotional abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Alcohol abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Drug abuse	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Potential of self-inflict harm	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Depression	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Stigma and isolation	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Food insecurity	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
Neglect by caregiver	☐ Client Reported	☐ Staff Assessed	☐ Household Reported
NO CONCERNS	☐ Client Reported	☐ Staff Assessed	☐ Household Reported

COUNSELLING AND DISCLOSURE ASSESSMENT

9. Is the client aware of his or her status? ☐ Yes ☐ No ☐ Unknown

9a. If NO, is the caregiver willing to begin the disclosure process with the patient? ☐ Yes ☐ No ☐ Unknown

10. If the client has a caregiver, is the current caregiver aware of the patient's status?

☐ Yes ☐ No ☐ Unknown ☐ There is no caregiver

10a. If NO, is the patient willing to begin the disclosure process with the caregiver?

☐ Yes ☐ No ☐ Unknown

11. Are other household members aware of the client's status? ☐ All ☐ Some ☐ None

11a. If NO, is the patient/caregiver willing to begin the disclosure process with other household members?

☐ Yes ☐ No

12. Is there a need for HIV counseling and testing of other household members? (Tick all that apply)

☐ Spouse/Partner ☐ Siblings

☐ Mother ☐ Other household members of unknown status in need of testing

☐ Father ☐ None

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13. What areas of counsellling and education are necessary for the Patient and household?

☐ Patient	☐ Counselling for the Caregiver/Household
☐ ART and Adherence	☐ Care and support for PLWHA
☐ Management of side effects	☐ General HIV: Prevention, Transmission and management
☐ Disclosure	☐ Knowing HIV status: Testing and care options
☐ General counselling	☐ Management of side effects for client needs
☐ Hygiene	☐ ART and Adherence
☐ Client basic care	☐ Disclosure
☐ Nutrition	☐ General counseling
☐ HIV prevention	☐ Hygiene
☐ PMTCT and family planning	☐ Nutrition
☐ Other (specify) ____	☐ Other (specify) ____

CLINIC ATTENDANCE AND ARV ADHERENCE ASSESSMENT

14. Is the client on ARVs? ☐ Yes ☐ No *(If NO, skip to question 16)*

14a. If yes,isthe client able to tell you the following information?

Drug names	☐ All	☐ Some	☐ None
Doses	☐ All	☐ Some	☐ None
Times taken	☐ All	☐ Some	☐ None
Side effects	☐ All	☐ Some	☐ None
Food related indications	☐ All	☐ Some	☐ None

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14b. During the last 7 days, how many doses did the client miss?

☐ One ☐ Two ☐ Three ☐ More than three ☐ None

14c. During the last 30 days, how many doses did the client miss?

☐ One ☐ Two ☐ Three ☐ More than three ☐ None

14c1. If the patient missed any doses, please specify reasons (Check all that apply)

☐ Refused to take medication	☐ Medications lost or stolen
☐ Forgot	☐ Sharing medications with others
☐ Doses are administered by caregiver who did not give	☐ Felt better and decided to stop
☐ Ran out of medication and could not refill prescription	☐ Stigma, disclosure or privacy issues
☐ Was stopped by physician	☐ Drug or alcohol use affecting adherence
☐ Side effects	☐ Other (specify)
☐ Felt too ill or too weak to take	

14d. When is the client due for a refill (check prescription)

☐ Date passed in a previous month
☐ Within the current month
☐ Next month
☐ Last month
☐ 2 months or more
☐ No prescription available to confirm

15. Has the client/caregiver missed the client's last clinic visit? ☐ Yes ☐ No

15a. If YES, what reason did the client/caregiver fail to return to the clinic for your appointments?

☐ Too ill to come
☐ Forgot
☐ Lost appointment card
☐ Stigma within the houosehold related to disclosure or privacy
☐ Could not afford transport
☐ Need assistance from care-giver and none was available
☐ Other (specify)

☐ Alcohol or drug use affected ability to come
☐ Refused to come or continue with program
☐ Was seen at onother clinic
☐ Depression
☐ work
☐ Travel

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FINAL ASSESSMENT AND FOLLOW-UP PLAN

16. Based on this initial asssment, what actions will be taken as follow-up to this visit? (check all that apply)

- ☐ Follow-up counseling for client or caregiver/household *(refer to Question 13)*
- ☐ Refferal for household member for site based VCT services
- ☐ HIV+ family/household member for HIV/AIDS management
- ☐ Refferal for suspected TB of client/household member
- ☐ Follow-up on physical health
- ☐ PMTCT
- ☐ Organize hospital ambulatory services for immediade and urgent medical needs
- ☐ Alert authorities for further investigation of neglect, sexual or domestic violence
- ☐ Follow-up and monitoring of social conditions and actions previously taken
- ☐ Home based VCT for household member
- ☐ Counselor assisted disclosure
- ☐ Organization referral or accompaniment
- ☐ Accompany client to clinic
- ☐ Adherence monitoring
- ☐ No Action

17. Next home visit scheduled for:

☐ One week ☐ Two weeks ☐ One month ☐ Two months

Specify date of next home visit((DD/MM/YYYY)) ☐☐ / ☐☐ / ☐☐☐☐

18. During this visit, was an appointment booked for the client at the clinic? ☐ Yes ☐ No

If YES, Specify date of next appointment((DD/MM/YYYY)) ☐☐ / ☐☐ / ☐☐☐☐

If YES, specify the appointment type:

☐ Doctor ☐ Counselor ☐ Pharmacy ☐ Social worker ☐ Nutritionist

Comments

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