STUDY PROTOCOL

The Good Health for Women Project (GHWP) - studies on the epidemiology and prevention of HIV and other diseases in a cohort of women involved in high risk sexual behavior and their male regular partners in Kampala and surrounding areas.

Good Health for Women Project

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Contents

I. Background

The Good Health for Women Project

One of the theme of the MRC/UVRI and LSHTM Uganda Research Unit in Uganda for the period 2017-2022 is research on the changing HIV epidemic targeting women at high risk for HIV and other sexually transmitted infections (STI) because of their engagement in high risk sexual behavior such as paid sex and multiple sexual partnerships. In 2008 the Good Health for Women Project (GHWP) located in Kampala, Uganda recruited the first Ugandan cohort of women involved in high-risk sexual behaviour with the aim of studying the epidemiology and dynamics of the HIV epidemic, conducting research on STIs and offering a platform for basic science, social science and future HIV intervention studies in this population. The first phase of the project recruited 1027 high risk women who were followed up every three months for three years. The project yielded information on epidemiological and behavioural data of this neglected population group to help plan targeted interventions and as such to contribute to the control of the HIV epidemic in Uganda. Results from previous epidemiological studies have shown a high prevalence of HIV and STIs (1), high prevalence of risk behaviors such as alcohol use and low condom use (1, 2), high HIV incidence (3), persistent problem drinking (4) and low partner notification for STIs (5). These results led to a collaboration with The President's Emergency Plan for AIDS Relief (PEPFAR) to enroll more women and offer enhanced prevention services to them, their male regular partners and children less than 5 years. Results from a survey conducted in Kampala by Crane survey in 2013 showed that an estimated 13,200 women in Kampala engaged in paid sex.

We propose to continue following up this high risk population having persistent high rates of HIV, other STI and alcohol use, and further research will answer some important research questions.

The GHWP has set up primary and reproductive health care services in Kampala for women engaged in high risk sexual behavior and their regular male partners. Attending women will continue to be invited to get enrolled in a cohort with the aim to conduct a wide scope of epidemiological, clinical, social science, basic science and intervention studies which will provide information on several key-aspects of the prevention and management of HIV/STI and other diseases in women at high risk, their clients and partners. The obtained information will first of all be of significance for policy makers and public health professionals but will also contribute to answering pending important research questions in the field of health research.

II. Study Objectives

The overall objectives of the GHWP can be summarized as follows:

1. To continuously assess risk of women involved in high-risk behavior in Kampala and surrounding areas for future HIV prevention intervention trials
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2. To study the overall social context of high risk sexual behavior in Kampala, to explore the nature of regular and casual partnerships of these women and to determine risk perception and risk behavior among male regular partners.

3. To study the virology and immunology of early HIV infection and of inter subtype dual infections, among women involved in high risk behavior in Kampala and their regular male partners, as part of the MRC/UVRI and LSHTM Unit's basic science research.

4. To evaluate the effectiveness of interventions that aim to a) reduce HIV acquisition or transmission and b) reduce HIV disease progression, among women involved in high risk behavior and their partners.

5. To investigate risk factors for non-communicable diseases among high risk women in Kampala and their male regular partners

This proposal covers objective 1, 2 3 and 4a.

Separate proposals will be developed for the other objectives.

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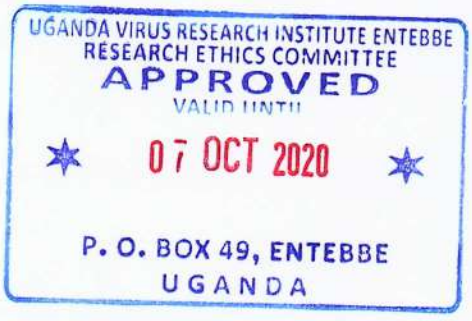

III. Selection of study population and study sites

Target population

The GHWP will continue to target a variety of groups of women at high risk of acquiring and/or transmitting HIV and other STIs because they ***may be*** engaged in high risk sexual behavior, together with their regular male partners. Some of these women will be earning their living by exchanging sex for money, goods or other favours in brothels, on the street, around entertainment places and in their homes. Others will be employed in entertainment facilities (for instance as waitress or karaoke singer) where they may have the opportunity to recruit men for transactional sex after working hours, in order to supplement their income.

Mapping of hotspots

Mapping of new hotspots is an ongoing activity done by the field workers of the project who work together with local community leaders and members such as bar managers, lodge owners and peer educators.

Hotspots are selected as study areas. Within each selected study area, brothels, streets where sex workers are operating, entertainment facilities, guesthouses or lodges and local beer shops were thoroughly mapped and the number of women working at the different places is estimated. This will enable the team to continue following up where new hotspots are opened and the potential for recruiting participants from there. The project field team will conduct their activities in Kampala and surrounding areas.

Study sites

Within the selected study areas, a study clinic is now established in Mengo, a location that is convenient and accessible for our study participants. The clinic offers reproductive health care, including syndromic management of STI, family planning services, HIV counseling and testing (HCT), health education, counselling for excessive alcohol use and gender based violence and condom distribution. The project provides basic antenatal care services at the study clinic in order to make reproductive health services as complete as possible. Primary health care is also offered for the women. Women, male regular partners and their children below 18 years who require anti-retroviral therapy (ART) under the "Test and Treat" program, TB screening and treatment and other HIV related care or support are provided with appropriate ART treatment at the clinic and are referred to nearby government facilities such as Kirruddu and Kawempe hospitals for further management as necessary.

IV. Methods

Mobilization and recruitment of study participants

i. The relevant health and local authorities have been informed about the project and their support is secured, mobilization sessions have been organized within hotspots in the selected study area to reach and recruit potential study participants as described below. The owners or managers of the mapped bars, guesthouses and lodges as well as some identified brothel and street based sex workers have been invited to separate meetings to explain the project and the study. They were asked to support their female employees, female customers and colleagues to join our project and allow us to meet these women and, are now involved in HIV prevention activities within these facilities.

ii. Peer educators have been identified at the hotspots and they play a role in identifying and referring high-risk women to the clinic for screening and possible enrollment.

iii. Enrolled women who have a male regular partner(s) are encouraged to refer these partners to the clinic for HIV prevention and treatment services, syndromic management for STIs, TB screening and treatment, counselling for excessive alcohol use and primary health care. Women and their regular male partners, who are willing and eligible to attend the clinic, get access to all provided health services. Women and their regular male partners are allowed to drop out of the study at any time. Refusing to enroll or dropping out does not affect the right to access health care offered by the clinic which they may be entitled to.

Pregnant women are not excluded from the project but offered antenatal care as described before. The criteria to attend the clinic and to get enrolled in the cohort are explained. The information leaflet and the informed consent sheet will be read to the potential participants. There is opportunity to ask questions and receive clarifications.

Study design

This continues to be a prospective cohort study

Size and duration of the cohort study

This project will enroll a cohort of up to 1500 high-risk women and their regular male partners who meet the eligibility criteria and follow them for 5 years. They will get access to the clinic and be followed for the duration of the project as long as they still meet the eligibility criteria.

Eligibility criteria:

Inclusion criteria

1) Women of 18 years or above and their regular male partners of 18 years and above, or being a mature or emancipated minor [1]

2) Involved in occupational activities generally known to expose women to high risk for HIV /STI (such as working in bars, guesthouses and other entertainment places or being a male partner of such a woman).

3) Living or working in Kampala and selected areas of Wakiso district

4) Willing and able to return for follow up visits and study procedures (3 monthly)

5) Willing and able to give written informed consent (literacy not required).

Exclusion criteria:
Women and men who opt out of HIV counseling and testing services provided by the clinic.

(1) Mature Minors are individuals 14-17 years of age who have drug or alcohol dependency or a sexually transmitted infection. Emancipated minors are individuals below the age of maturity, who are pregnant, married, have a child or cater for their own livelihood. (ref. *National guidelines for research involving humans as research participants, Uganda National Council for Science and Technology, March 2007).*

All women and men, who are eligible and willing to join the project will be registered to attend the screening and enrolment. Screening and enrolment may be done on the same day or enrolment within two weeks of screening. Thereafter an appointment card will be given to attend the clinic every three months.

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Study procedures

Screening and enrollment

Women registered by the field workers and attending the clinic with an appointment card will get access to the clinic for screening and possible enrolment into the cohort.

During this first visit the different services offered at the clinic are explained. The women are informed again about the objectives, procedures and duration of the research. The inclusion and exclusion criteria for enrolment into the study cohort will be discussed again.

The women who meet all eligibility criteria for the research will be asked to sign or thumbprint the consent form and be enrolled into the project and attend the first visit. During this first visit, consenting women will be interviewed and data collected on various socio-demographic characteristics, alcohol consumption, drug use and sexual behavior with clients, casual and regular partners. Questions will be asked concerning contraception and condom use. Information on women's residence and workplace will be thoroughly collected as well as available phone numbers to enable the field workers trace participants for follow up. Permission will be requested to access their residence if needed for follow-up. Medical information will be collected regarding current and past gynecological and STI related problems (including treatment). The following procedures will be performed: women will be asked for the date of their last menstruation period: if more than 4 weeks ago or if unsure about the date, they will be asked to provide

- Urine pregnancy test.
- After the interview, pre-test counseling for HIV will be offered. Venous blood (10 ml) will be taken to test for HIV.
- A genital examination will be conducted (using a speculum for women) and a syndromic approach to management of STIs used.

- All women will be offered health education regarding HIV and other STI prevention; condoms will be promoted and provided.

Women with symptomatic STI will be given management for those conditions.. They will be contacted by phone or visited by a field worker and invited to the clinic to receive their results.

Women who are testing HIV positive will receive post-counseling and be referred to the GHWP ART clinic for further laboratory assessments and adherence counselling in preparation for ART initiation and follow up under the "test and treat" program. and referred for further care if necessary. Women who will already be enrolled on ART at another facility will be requested to continue getting treatment from those facilities. HIV positive ART naïve women who wish to receive ART at another facility will receive a referral letter to the facility of their choice.

Women who test HIV negative will be requested to attend follow up study visits every 3 months at which we shall conduct study procedures (sample collection and interviews) as well as receive on going health education, counselling and available HIV prevention interventions.

Source documents and study CRFs will be used to collect data.

3-monthly follow-up visits

Enrolled women will be asked to return for follow-up at the study clinic at 3-monthly intervals for the following procedures:

- HIV counselling and testing (3 monthly)
- STI management (3 monthly)
- Reproductive health assessment and family planning services for women (3 monthly)
- Sexual behaviour assessment (3 monthly)
- Alcohol use disorder assessment (once a year)
- Risk assessment and re-screen for eligibility (once a year)
- Screening for referral of Male regular partners

Referral of Male Regular Partners (MRPs)

Study procedures at the follow-up visits will be similar to those at enrolment; in addition, women will be screened for referral of male regular partners. The women are asked about regular male partners at follow up and are asked to encourage their regular male partner to attend.

If the men accept the invitation, they are brought to the clinic by the woman on a specified day to be screened. The screening procedure for men is to ascertain that the male partner brought to the clinic is the one the woman talked about when she was screened to refer the partner.

Eligible and willing men are asked to sign or thumbprint the consent form and then registered to attend the first visit that same day. The visit includes all procedures as for women except reproductive health. After the visit, the men are given an appointment card and scheduled to attend follow up visits every 3 months.

Men who test HIV positive and are ART naïve will receive post-counseling and be referred to the GHWP ART clinic for further laboratory assessments and adherence counselling in preparation for ART initiation and follow up under the "test and treat" program. Men who will already be enrolled on ART at another facility will be requested to continue getting treatment from those facilities. HIV positive ART naïve men who wish to receive ART at another facility will receive a referral letter to the facility of their choice.

All data will be documented on source notes and study CRFs.

Withdrawal from the cohort

A participant will be withdrawn from the cohort for the following reasons;

- Loss to follow-up
- Death
- Withdrawal of consent
- Non-compliance to study procedures
- No longer at risk for HIV and STIs
- HIV seroconversion

Loss to follow-up

Women and men failing to attend their clinic appointment will be traced in the community, either at their workplace or home, using the help of a peer leader or the local community member of the respective area. Traced women and men will be invited to access the clinic.

Women will be considered as lost to follow-up (LTFU) if they fail to attend and cannot be traced for 6 months (2 missed consecutive follow-up visits) or if they move out of the study area. They will be traced for another 3 months before their files are placed in the withdrawn pack (9 months after the last attended visit).

Reasons for defaulting will be recorded.

Women who are LTFU or those who no longer meet eligibility criteria at the annual assessment will be exited from the cohort and replaced.

3. Laboratory procedures

Serology

From each consenting participant, 5 mls of venous blood (serum) will be collected during their first visit. The blood will be centrifuged within 24 hours of collection at the MRC/UVRI & LSHTM Serology Laboratory at the Kampala site. The serum will be used to test for HIV; the plasma and remaining serum will be stored for future work on HIV, other infectious diseases and non-communicable diseases (NCDs).

HIV serology

A highly sensitive rapid HIV test (currently Determine) will be performed on the spot. Patients testing negative will be considered as HIV negative. Patients testing positive or indeterminate will have their status confirmed according to the MoH algorithm (see Annex 1).

HIV testing will be done at screening and at quarterly intervals (if testing HIV negative previously).

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Plasma collection

At every visit, 5mls of blood will be collected and plasma processed for sample storage for future virology work on NCDs and acute HIV infections and among those who seroconvert.

Pregnancy test

The participants will be asked for the date of their last menstruation periods: they will be asked to provide a urine sample for pregnancy test using HCG strips every 3 months.

Transport and storage of samples

All specimens will be stored in the clinic at 4°C and transported in a cool box within 12 hours of collection to MRC/UVRI Serology Laboratory.

For participants who consent to sample storage, plasma and serum samples will be frozen at the Kampala clinic at -80°C for future studies relevant to the study objectives, and for quality control procedures (but not for genetic studies). Temperatures are monitored daily using both manual and automated systems.

Data collection and data management

Data collection

Case Report forms (CRFs) have been designed to collect data at first visit and at follow-up visits. In order to ensure comparability an identical core set of data will be collected at each follow-up visit, but additional questions may be added over time to collect information in specific topics, e.g. regarding exposure to yet unknown risk factors. The questionnaires will be written in English and Luganda

The routine questionnaire will collect information on socio demographic characteristics, alcohol and substance abuse, sexual behaviour with clients, casual and regular partners, intravaginal practices, family planning, history of general and reproductive health problems, current and past signs and symptoms of STI.

Genital symptoms or signs, the diagnosis made and any treatment given, will be recorded. Laboratory results obtained by the MRC/UVRI and LSHTM Serology laboratory will be filled in on separate laboratory forms.

Qualitative data shall be collected by trained social science interviewers using interview guides which will be formulated to answer specific project objectives

For Objective 1 we shall collect data on sexual risk behaviour, alcohol and substance use, gender based violence, uptake of HIV prevention interventions such as condoms, oral pre-exposure prophylaxis (PrEP) and HIV counselling and testing(HCT). These data will contribute to trends of risk behaviour patterns and HIV incidence in the cohort to enable the study team maintain a cohort suitable for HIV prevention intervention trials.

For Objective 2 (Social science) data shall be collected on the overall social context of high-risk sexual behaviour for women and the identified regular partners. In general, we will target the social aspects of health for the women and regular partners. The research questions around acceptability, feasibility, adherence, behavioural patterns, risk perceptions, gender based violence, and economic implications of the intervention in this cohort shall be answered by the social science research. In addition, research questions shall be formulated targeting specific research proposals under the GHWP.

For Objective 3 we shall continuously collect data on willingness and uptake of HIV prevention strategies including condom use, PrEP, HIV vaccines among others. Oral PrEP is currently the only available HIV prevention intervention and will be offered to HIV negative participants. This data will help assess adherence and HIV incidence while on oral PrEP or any other intervention to inform future studies.

Data management

All CRFs except laboratory forms will be electronic and will be checked by a dedicated data manager allocated to the project in collaboration with the project leader. He/she will check the number of forms and ensure that there are no missing data. Samples of data returned from the laboratory will be checked periodically against original laboratory registers for accuracy before entry.

Data entry will be done by designated study staff. Consistency checks will be conducted within 48 hours of data entry. Access to databases will be restricted using appropriate security methods (user name, password and any other encryption method). Automated data entry using desk top and ultra-mobile personal computers will be used. Offsite Data backups will be done weekly following the SOPs. Data analysis will be done at the Kampala site in Stata version 14.0.

All data will be analysed at the MRC/UVRI and LSHTM Statistics section using Stata.

Qualitative data will be managed at the study site by the interviewers who collect it. The interviews will be written out as soon as possible and stored securely on password-protected computers. Then later uploaded in the social science folder on the main server. The notebooks will be locked away in cabinets and only study staff will have permission to access these cabinets.

Data will be analysed by coding and developing appropriate thematic frameworks.

Statistical methods

We will analyse trends in high-risk behaviour, current HIV incidence and HIV incidence while on oral prep. The HIV incidence will be estimated as number of HIV infections divided by the person time at risk. Person time at risk will be calculated as the sum of the time from baseline to the date of the last HIV-uninfected result, or to the estimated date of HIV infection for each participant. Date of HIV infection will be estimated as the mid-point of the interval between the last HIV-uninfected and the first HIV-infected result date.

The overall proportion of uptake will be estimated as the sum all participants who took up oral prep divided by the total number of participants interviewed expressed as a percentage. Chi-square tests will be used to compare the proportions uptake of oral prep by the different participant's characteristics (factors). Associations between uptake of oral prep and participants' factors will be determined using odds ratios with 95% confidence intervals (CIs), by fitting logistic regression models or risk ratios with 95% CI using log binomial models if the proportion uptake of oral prep is greater than 25%.

To assess adherence, we shall administer a card, which will be corroborated with the self-reported adherence, pill counting and appointment dates. Adherence will be measured as the proportion of number of pills taken divided by the total number of pills expected to be taken expressed as a percentage. Adherence will be good if this proportion is $\geq 95\%$. Details will be added in the Statistical Analysis Plan(SAP)

V. Community participation

In order to improve compliance and to improve the quality of our services, a community liaison system has been established. Women working in neighbouring facilities or other work places each elect their community representative. This representative could be the peer leader, but not necessarily so. These representatives form a Community Advisory Board who meet regularly with the study team in order to discuss problems that may arise in the context of the study or with respect to their health care, and search for appropriate solutions. The CAB comprises of local community leaders, representatives from KCCA, Uganda police, peers and other partner organisations. They also assist at meetings that are be held with stakeholders and government representatives (Stakeholders Advisory Group). During the meetings of the Community Advisory Board, the women's representatives are encouraged to stimulate their colleagues to adhere to the project.

The owners or managers of the mapped bars, guesthouses and lodges as well as some identified brothel and street-based sex workers have been involved in quarterly meetings organized by the project since 2013. The meetings also target health education and topics including awareness about HIV, Test and Treat intervention, role of gender-based violence in increasing vulnerability to HIV, alcohol reduction, nutrition and also respond to research and health related questions raised during the meetings. The project has also been involved in distributing condoms to the hotspots were women can access them free of charge.

VI. Ethical considerations

Ethics Approvals

Ethical approval will be requested from the UVRI Research Ethics Committee and from the Uganda National Council for Science and Technology and the London School of Hygiene and Tropical Medicine. If amendments are made to the study protocol and approved by the Research Ethics Committees, all existing participants will be informed about the amendments and re-consented before they continue study participation.

Legal aspects

Prostitution is illegal in Uganda. This project may gather knowledge about prostitution. The project does not support or facilitate prostitution. Women who wish to stop sex work will be assisted to do so and may be referred to NGOs that provide social support and vocational training. The aim of the project is to provide health care and to reduce HIV/STI transmission in the community.

Participant confidentiality

Procedures will be in place to ensure confidentiality. Consultations at the clinic will be held in private rooms. All data collection forms, laboratory specimen and administrative forms will be identified by a coded number only (personal ID). All records that contain names (ex. clinic records, appointment registers) or other personal identifiers (consent forms) will be stored separately from the study records in locked filing cabinets. Similarly, strict measures to protect the confidentiality of electronic data are in place at all the sites of MRC/UVRI and LSHTM and are overseen by the Statistics section.

All staff will be trained on the importance of and how to maintain confidentiality.

Consent procedures

Interactive individual and group discussions will be organized at the selected high risk work places, to explain the project and the study. Women who are interested to join the study will be invited for a first visit at the clinic where they will be informed about the running of the clinic. An information sheet, written both in English and Luganda, will explain the purpose of the study, what participation entails, the potential risks and benefits and the ability to withdraw from the study at any time without negative repercussions for the quality of management they receive for STI and HIV infection. There will be opportunity to ask questions and receive clarifications, and comprehension will be tested by the counselor before written consent is obtained. The participant will sign or thumbprint 2 copies of the informed consent document. One copy will be given to the participant and the other kept on site. If the participant does not wish to take their copy, it will be kept for them on site. Separate consent forms will be provided for sample storage and future use of samples.

Regular male partners referred by the women will go through similar consent procedures.

Withdrawal of consent

A participant will be free to withdraw their consent to participate in the study and withdraw their samples stored from future use.

Benefits for the study participants

- Participating women will benefit from the reproductive health care services offered by the clinic. The clinic will furthermore provide primary health outpatient care for other health problems for participating women.

- HIV infected participants will have access to available HIV care and support services and ART. Referral will be provided whenever necessary.

- Participants will be offered accompanied referral to maternity and inpatient care if needed.

VII. Project management

Collaborating Institutions

- MRC/UVRI and LSHTM Uganda Research Unit, Entebbe, Uganda
- London School of Hygiene and Tropical Medicine (LSHTM), London, UK
- Health care services operating in Kampala such as Nsambya Hospital, Kisenyi Health centre III, Mulago National referral hospital, Kirrudu Hospital, Kawempe hospital.

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Community representatives

In order to ensure that the purpose of proposed project is well understood and achieves support by the local authorities, close collaboration will be established with local governments (local council members LC1 and LC3), Kampala City Council Authority (KCCA) and law enforcement authorities (local police).

Funding Sources

- MRC Medical Research Council, London UK
- Other funders may be sourced to support clinic services over the duration of the project

VIII. References

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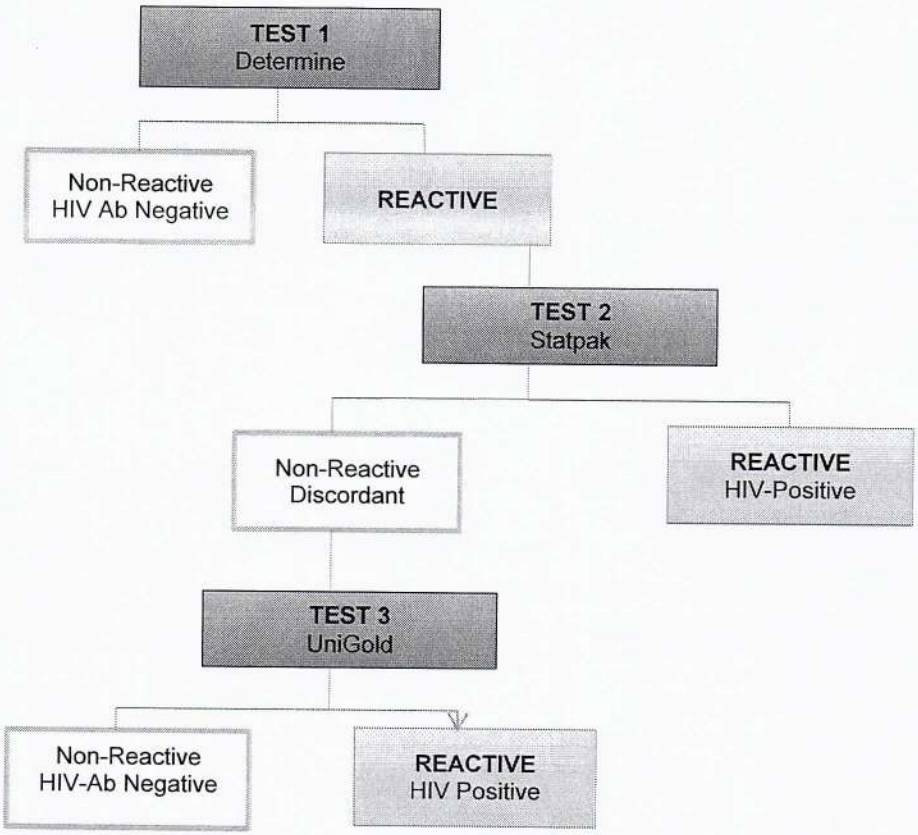
IX. Annexes

MoH algorithm for HIV testing



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