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Thematic area:

- ☐ Single site proposal
☒ "Core" proposal (for multicentre study)
☐ Centre-specific proposal under multicentre study

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Form II

HRP Research Proposal: Project details

Utility evaluation of Point-of-Care Tests in Non-Clinical Settings for the Screening of HIV and Syphilis in Men Who Have Sex with Men

1. Project summary

a. Background information and rationale

Serologic tests are the diagnostic tests of choice for HIV and syphilis. There are two types of serological tests (treponemal and non-treponemal tests) for laboratory diagnosis of syphilis. Traditionally, one non-treponemal assay is used for screening and a treponemal assay is used for confirmation for syphilis. For diagnosis of HIV EIAs are used for screening and Western blot for confirmation for HIV in high-resource settings. However, these tests are technically demanding, and require laboratory equipment that is not widely available in most resource-limited settings. Recently, dual tests that can be used at point-of-care for simultaneously detecting antibodies to HIV and syphilis (dual HIV-syphilis POCTs) have been developed for use with finger-pricked capillary whole blood specimens. Some of these dual POCTs are now commercially available. To date, they have shown encouraging performance compared with the reference tests in laboratory-based studies, but there is limited data on their utility in the field. As CBVCTs are effective providers of HIV and syphilis testing and counselling with high acceptability among MSM, evaluation of the utility of these dual tests in CBVCTs is a high priority.

b. Study hypothesis and objectives

The overall objective of the World Health Organization Point-Of-Care Diagnostics Evaluation Scheme for Sexually Transmitted Infections (STI) is to provide advice to WHO Member States and other relevant public health institutions on the performance and operational characteristics of commercially available STI diagnostic tests that can be used at the point-of-care. A number of tests that can simultaneously detect antibodies against HIV and *Treponemal pallidum* (Tp) from a single finger-pricked capillary whole blood specimen have been developed. This protocol will provide guidance on the assessment of the utility and operational characteristics of POCTs for the dual screening of HIV/syphilis in men who have sex with men (MSM), who seek or receive dual testing in non-clinical settings. Non-clinical settings are understood as community based voluntary counselling and testing services (CBVCTs). The specific objectives are to evaluate the feasibility of introducing the dual POCT for HIV and syphilis by assessing the acceptability and usability of performing the dual POCT among MSM CBVCT service users and providers and to assess the operational characteristics of the dual POCT for HIV and syphilis screening at the CBVCTs, and to compare them, if possible, with the operational characteristics of the tests that are performed routinely by the CBVCTs.

c. Study methods

Consecutive MSM presenting at the evaluation site or outreach settings will be informed about the study by a CBVCT provider. If the person is interested in participating (pre-consent), another CBVCT provider will evaluate whether he fits the inclusion criteria. If the potential participant fits the criteria and agrees to participate in the study, the latter CBVCT provider will take final consent and perform the routine care and the additional tests. Users will be informed by the CBVCT provider and the consent form. The sample size calculation depends on the estimated proportion of people who have accepted to be tested by the dual POCTs for the screening of HIV and syphilis in a CBVCT service. It is recommended that at least the 75% of the providers from the CBVCT service, who received the training and performed the dual POCTs for the screening of HIV and syphilis, answer the feasibility questionnaire.

The capillary whole blood sample will be collected and used immediately to perform the POCT according to manufacturer's instructions by a CBVCT provider. Staff performing the evaluation should be qualified and competent to undertake the task and demonstrate that they can perform the test properly through proficiency testing programme results. There should be a regular independent assessment of whether the evaluations are conducted in compliance with the Principles of Good Clinical Practice (GCP). Data from the evaluation will be entered into a standardised spreadsheet for analyses. A descriptive analysis will be performed on the results of those individuals who have had both syphilis and HIV POC testing and on those CBVCT providers who accept to participate in the study. The feasibility of introducing the dual POCT for HIV and syphilis in CBVCTs will be assessed quantitatively through descriptive statistics by the study coordinator.

A utility evaluation aims to determine the feasibility of performing the dual test among users and providers at the CBVCTs by assessing its acceptability and usability, and to describe its operational characteristics and compare them, if possible, with the tests that are performed routinely by the CBVCTs.

2. Detailed description of the project

2.1 Background information and rationale

The World Health Organization (WHO) Point-Of-Care (POC) Diagnostics Evaluation Scheme for Sexually Transmitted Infections (STI), comprises of three types of POCT evaluations. Firstly, laboratory-based evaluations aim at providing data on the analytical performance of POCTs. The results are used to guide the project on whether to conduct further evaluation in clinical settings. Thereafter, the clinic-based evaluation seeks to determine test performance when the test is performed by clinic personnel who are not trained laboratory technicians. This evaluation also includes the assessment of the operational characteristics of the POCTs, such as the ease of use and acceptability of the tests to patients and clinic personnel. Lastly, the third type of POCT evaluation pursues the assessment of the utility of POCTs in non-clinical settings, mainly CBVCTs.

A CBVCT is defined as any programme or service which offers voluntary HIV counselling and testing as one of its main activities, independently of clinical settings, targeted to specific groups of the population and clearly adapted and accessible to the communities to whom it is addressed. The heterogeneity of the services does not take into account physical location, staff characteristics, funding source or whether the service is provided for free or at a cost, but it excludes prisons, primary health care and STI clinics (1).

The CBVCTs strengthen a comprehensive prevention strategy by increasing the number of engaged at-risk individuals to both become aware of their HIV and syphilis serostatus and as an entry point for care and treatment. As the WHO consolidated guidelines on HIV testing services describe, community-based testing approaches may lead to earlier HIV and syphilis detection, as well as reach people who are not routinely accessing health services, but are willing to test in a community-based HIV testing environment (2).

Recently, dual tests that can be used at point-of-care for simultaneously detecting antibodies to HIV and syphilis (dual HIV-syphilis POCTs) have been developed for use with finger-pricked capillary whole blood specimens. Some of these dual POCTs are now commercially available. To date, they have shown encouraging performance compared with the reference tests in laboratory-based studies, but there is limited data on their utility in the field. As CBVCTs are effective providers of HIV and syphilis testing and counselling with high acceptability among MSM, evaluation of the utility of these dual tests in CBVCTs is a high priority.

The evaluation of these POCTs in a community setting is important as MSM at high risk of acquiring and transmitting STIs, including HIV, might face various barriers to access care, and the CBVCTs are often the first entry point to the healthcare system. The use of POCTs in CBVCTs could enhance the effectiveness of outreach screening in non-clinical settings, as POCT results are rapidly available and reduce loss to follow-up, allowing for timely counselling, referral, and treatment. Syphilis can be often asymptomatic. Undetected syphilis can result in serious long term complications and increased risk of HIV acquisition and transmission. Screening and appropriate treatment for asymptomatic individuals infected with syphilis can reduce the risk of developing serious long-term complications and interrupt onward transmission to their sexual partners. In the case of HIV, early diagnosis of the infection is essential to ensure that patients are referred promptly for evaluation, provided treatment and linked into counselling and related support services to help them reduce their risk for transmitting HIV to others.

A utility evaluation aims to determine the feasibility of performing the dual test among users and providers at the CBVCTs by assessing its acceptability and usability, and to describe its operational characteristics and compare them, if possible, with the tests that are performed routinely by the CBVCTs.

2.2 Study hypothesis and objectives

The overall objective of the World Health Organization (WHO) Point-Of-Care (POC) Diagnostics Evaluation Scheme for Sexually Transmitted Infections (STI) is to provide advice to WHO Member States and other relevant public health institutions on the performance and operational characteristics of commercially available STI diagnostic tests that can be used at the point-of-care (hereafter referred to as POCTs). A number of tests that can simultaneously detect antibodies against HIV and *Treponema pallidum* (Tp) from a single finger-pricked capillary whole blood specimen have been developed.

This protocol will provide guidance on the assessment of the utility and operational characteristics of POCTs for the dual screening of HIV/syphilis in men who have sex with men (MSM), who seek or receive dual testing in non-clinical settings. Non-clinical settings are understood as community based voluntary counselling and testing services (CBVCTs).

The specific objectives are:

- To evaluate the feasibility of introducing the dual POCT for HIV and syphilis by assessing the acceptability and usability of performing the dual POCT among MSM CBVCT service users and providers.
- To assess the operational characteristics of the dual POCT for HIV and syphilis screening at the CBVCTs, and to compare them, if possible, with the operational characteristics of the tests that are performed routinely by the CBVCTs.

2.3 Study conceptual framework

Question: Is the introduction of dual point-of-care tests for the screening of HIV and syphilis in MSM and sex feasible in CBVCTs?

P (participants): MSM > 18, presenting at the evaluation setting

I (intervention): perform the dual HIV-syphilis POCT in accordance with the manufacturers' directions

C (control): the routine HIV and syphilis diagnostic tests on the same person at the same time

O (outcome): feasibility* and operational characteristics

T (timeframe): until the required sample size is reached, with a maximum of 12 months

* The study will be designed following a model that explored the feasibility of new health technology introduction (3).

Regarding the CBVCT providers, the framework divides the concept of feasibility into two inter-related domains, acceptability and usability. Feasibility is defined as the process in which dual HIV/syphilis POCTs are deployed to CBVCT providers, leading to their acceptability and usability. These two domains have been further broken down into six sub-domains: learnability, willingness, suitability, satisfaction, efficacy and effectiveness (4).

The operational characteristics that will be assessed and compared are also part of the conceptual framework: the clarity of kit instructions, the ease of use and interpretation of results are part of the learnability domain, while the waiting time for test results, the hands-on time and the training time required are part of the efficacy domain.

Regarding the CBVCT users, the framework also divides the concept of feasibility into two inter-related domains, acceptability and usability, but these two domains are only broken down into three sub-domains: willingness, suitability and satisfaction.

1. Learnability: ability of the CBVCT providers to understand how to correctly perform the dual HIV/syphilis POTCs and accurately read the test results.
2. Willingness: CBVCT providers' intention to carry out a finger prick each time it is necessary, wait for the results, and refer the user when necessary. Regarding the CBVCT users, willingness was defined as the intention to have the test performed on themselves, wait for test results, and if it is necessary, follow the referral procedure.
3. Suitability: CBVCTs providers' beliefs that the test is relevant for their work and could be successfully integrated into existing services. Regarding CBVCT users, suitability was defined as belief that the test is relevant in determining whether or not they have HIV and/or syphilis.
4. Satisfaction: CBVCT providers' feeling that the test is convenient to perform and that it is a process they like doing. Regarding the CBVCT users, satisfaction was described as feeling that a test is convenient and that it is a process they would like to experience out again.
5. Efficacy: that the CBVCT providers are able to make the effort and time to perform a test, read, interpret, and record test results, as well as refer the user if required, as part of their daily routine work.
6. Effectiveness: that the enabling organisational and supporting systems, such as training, supervision, study aids, supplies, timers, storage, and disposal are present or carried out and are integrated into existing routine protocols.

These attributes work in an interrelated way to contribute to the feasibility of the introduction of a new technology. Acceptability comprises positive perceptions, beliefs, and attitudes towards dual HIV/syphilis POTCs among users and providers. Usability refers to the actions taken by the providers to apply the tool and its results to achieve specified outcomes, while among users refers to the actions taken to have the tests performed on themselves believing that the test is accurate and convenient. In turn, if acceptability and usability are high among both providers and users, then implementation is feasible.

2.4 Study design

The evaluation should be conducted according to the following guiding principles:

1. A diagnostic test should be evaluated for a clearly defined indication
2. A diagnostic test should be evaluated using methods and equipment fit for that purpose
3. Staff performing the evaluation should be qualified and competent to undertake the task and demonstrate that they can perform the test properly through proficiency testing programme results
4. There should be a regular independent assessment of whether the evaluations are conducted in compliance with the Principles of Good Clinical Practice (GCP).

2.5 Procedures

2.5.1 Study site(s)

Testing services will be eligible if they fulfil the following criteria:

- Correspond to the above mentioned definition of “CBVCTs”;
- Target mainly MSM;
- Have access to sufficiently large target population to be able to complete participant recruitment for the evaluation in 9-12 months;
- Ability to follow linkage to care with the local health services;
- Mechanism for ethical committee approval in 2-3 months;
- Human resources: CBVCT site staff capacity to be able to perform the study in accordance with the study protocol;
- Strong interest to work with new technologies;
- Offer testing for both HIV and syphilis as part of the CBVCTs activities.

The study can be implemented by a group of CBVCTs, which fulfil the selection criteria and are willing to coordinate the study with other CBVCTs as a network.

2.5.2 Study participants

Inclusion Criteria:

The target populations for this HIV-syphilis POCT evaluation are MSM. According to the UNAIDS Action Framework, the term ‘men who have sex with men’ is used to describe those males who have sex with other males, regardless of whether or not they have sex with women or have a personal or social identity associated with that behaviour, such as being ‘gay’ or ‘bisexual’.

Exclusion criteria:

- 1) CBVCTs users who are not MSM
- 2) CBVCTs users who are younger than 18 years old
- 3) MSM, 18 years old or older who refuse to give written consent.

There is no mention of transgender persons in this protocol for the utility validation of dual POCTs for the screening of HIV and syphilis, because there is no consolidated clinical definition of what constitutes a transgender person.

2.5.3 Participant recruitment

Consecutive MSM presenting at the evaluation site or outreach settings will be informed about the study by a CBVCT provider. If the person is interested in participating (pre-consent), another CBVCT provider will evaluate whether he fits the inclusion criteria. If the potential participant fits the criteria and agrees to participate in the study, the latter CBVCT provider will take final consent and perform the routine care and the additional tests. Users will be informed by the CBVCT provider and the consent form (Appendix 1).

2.5.4 Sampling and allocation

Prospective sampling.

2.5.5 Sampling size calculation

Sample size for tested individuals

The sample size calculation depends on the estimated proportion of people who have accepted to be tested by the dual POCTs for the screening of HIV and syphilis in a CBVCT service. If the CBVCTs has a local estimate of this proportion, this percentage can be used to calculate the sample size, otherwise the CBVCTs can use the percentage that has been described elsewhere of 81% (5).

Given an 81% population acceptance rate, 300 study subjects will suffice to estimate the feasibility of introducing the dual POCT for HIV and syphilis, with a 95% confidence interval, with a maximum error of 0.5 and anticipating a replacement rate of 20% for those CBVCTs users who refuse to participate.

Sample size for providers

It is recommended that at least the 75% of the providers from the CBVTC service, who received the training and performed the dual POCTs for the screening of HIV and syphilis, answer the feasibility questionnaire.

2.5.6 Description of the intervention

2.5.6.1 Drugs and devices

POCTs and near patient diagnostic platforms for STIs are described in a landscape report commissioned by WHO RHR. Tests that have operational characteristics that are consistent with the TPPs and have acceptable analytical performance characteristics are invited to participate in the clinic-based and utility evaluations. A letter announcing the evaluation will be sent to the relevant companies with details of the evaluation including the core protocols. Companies interested in participating in the evaluation are asked to donate tests for the evaluations in accordance with the terms specified under a WHO confidentiality and material transfer agreement.

2.5.6.2 Innovation in service delivery

To increase access to screening and diagnostic testing, it is important that the tests to be included in this evaluation should have characteristics that are consistent with those set out in the Target Product Profiles (TPPs) developed by consensus at the first WHO RHR Technical Consultation on POCTs for STIs in 2014. These include the following operational characteristics:

1. Rapid -- test result is available within the duration of the clinic visit.
2. Simple -- test can be performed in 2-3 steps, requiring minimal training and no equipment
3. Easy to interpret -- card or strip format with visual readout or using a small reader

2.5.7 Admission procedure

- Standard testing and POCTs in any CBVCTs can only be carried out with the user's specific informed written consent (Annex I).
- If a user declines participate in the study, this decision should also be documented in the basic questionnaire (Annex II).
- Consent form will be translated to the language(s) of each participating CBVCTs.
A basic questionnaire (Annex II) will be completed by CBVCT service provider I after the signing of the consent form, who will perform the standard tests and interpret and record its results. The dual HIV/syphilis POCT(s) will be performed by another CBVCT service provider

II; he/she will interpret and record the result of the test. A second reading of the dual HIV/syphilis tests will be performed by the CBVCT service provider I and his/her interpretation of the results will be recorded in a separate spreadsheet.

- A user's feasibility questionnaire (Annex IV) will be self-completed after the performance of the dual HIV/syphilis POCT and the routine tests and after the consent is signed, but prior to receiving the tests results.
- A feasibility questionnaire (Annex III) will be completed by each CBVCT provider who took part in the study once the study period has finished, or when he/she leaves the study.

2.5.8 Follow-up procedures

Follow-up and referral of the patients will be based on the results of the standard tests. Participants with a positive standard routine test result will be referred to the STI clinic or the reference hospital. However, if the standard test result is negative, but one or both of the service providers' readings of the dual POCT(s) is positive for HIV and/or syphilis, the patient will also be referred for confirmation. Positive HIV POCT results are preliminary and therefore have to be confirmed with the conventional screening test before the diagnosis of HIV infection is conclusively established. In the case of syphilis, the result has to be considered as probable active syphilis, therefore referral has to be done to the reference hospital for active infection confirmation.

In order to retrieve information related to syphilis confirmation and treatment, the CBVCT provider will contact the user in two weeks later in order to ask for this information. In case the CBVCTs do not record the user's personal information, an appointment will be planned two weeks after the day of testing.

2.5.9 Criteria for discontinuation of a participant

If during the procedure it would turn out that the participant does not meet the inclusion criteria. If the participant wishes to discontinue participation.

2.5.10 Criteria for discontinuation of the study

The study should only proceed when the study team members are confident of their ability to conduct the study and all the materials required for the study are in place. If during the study it would become apparent that despite the principal approval of the (network of) evaluation site(s) does not fulfil the inclusion criteria. If the study monitor sent by WHO deems as impossible that the site can guarantee the required progress and quality of the study. If external events prevent the study from being executed with the required quality.

2.5.11 Laboratory and other investigations

The capillary whole blood sample should be collected and used immediately to perform the POCT according to manufacturer's instructions. Results of the standard routine test(s) and the POCT will be recorded in the basic questionnaire (annex 2).

General guidelines of the use of test kits

- Note lot number and expiry date: a kit should not be used beyond the expiry date.

- Ensure correct storage conditions: if a desiccant is included in the package, do not use the kit if the desiccant has changed colour.
- If test kits are stored in the refrigerator, they should be brought to room temperature (about 30 minutes) before use. The use of cold test kits may lead to false negative results.
- Damaged kits should be discarded.
- Use test kits immediately after opening.
- Reagents from one kit should not be used with those of another kit.
- Tests should be performed exactly as described in the product insert

2.6 Study instruments

Appendix 2. Basic questionnaire

Appendix 3. Feasibility questionnaire for the CBVCT providers

Appendix 4. Feasibility questionnaire for the CBVCT users

2.7 Project management

WHO will enter into an agreement with all the sites setting out the terms of reference for these evaluations; for coordination and operational purposes several sites can be joined in a network. The site will have a study management plan with the details of the roles and responsibilities of the study team well-defined. WHO will send study monitors to perform external quality assessments of each evaluation.

Taking into account specific organizational features of networks, the study team at each evaluation site shall consist of a CBVCT coordinator, who coordinates the protocol implementation at the site, and the CBVCT service providers. The composition and number of study team members can be adapted at each site according to local needs and network characteristics. Networks will have an overall coordinator of the study. The responsibilities of the team members are :

CBVCT/network coordinator

- Supervise the pilot run and the day-to-day CBVCT activities that are related to the POCT evaluation, such as user recruitment, interview, testing and data collection.
- Develop the consensus protocol
- Obtain ethical committee approval
- Ensure the evaluation is conducted according to the consensus protocol as approved
- Make sure that CBVCTs providers and tested individuals are answering the feasibility questionnaire
- Perform the lot release panel in order to evaluate the quality of the new kits, prior to the release of kits to storage
- Weekly monitoring of the temperature where the kits will be stored and recording of information in the dual POCTs kit storage temperature log
- Perform the review and analyses of evaluation results
- Send the analysed data to WHO
- Prepare a technical and financial report of the evaluation of the performance of CBVCTs
- Perform results dissemination.

CBVCT service provider I

- Inform incoming persons about the study
- Gauge for interest in participating in the study
- Record pre-consent
- Inform CBVCT service provider 2 if the user has pre-consented
- Perform, interpret and record the results of the standard tests.
- Complete the basic questionnaire (Annex II).
- Read the results of the dual HIV/syphilis test after it has been performed by CBVCT service provider II, and record its results in a separate spreadsheet
- Complete the basic questionnaire (Annex II).
- Compare his/her interpretation of results of the dual POCT, with the interpretation of CBVCT service provider II (after unblinding) and with the results of the standard tests

CBVCT service provider II

- Check whether the users who pre-consented fit the inclusion criteria
- Take final consent if the user fits the criteria and agrees to participate
- Perform the dual POCTs in accordance with manufacturers' directions and record tests results
- Give the dual POCT(s) and his/her blinded, but unblindable, interpretation to CBVCT provider I to enable independent second reading and comparison
- Provide the feasibility questionnaire to the CBVCT users to be self-completed
- Answer the feasibility questionnaire for CBVCT providers once the study has finished.

The network coordinator should review the core protocol with the study team to adapt the protocol to meet local needs, study team, and sample size estimation. The adapted protocol should be sent to WHO for review to minimize procedural differences amongst sites that may account for the difference in study outcomes from site to site. The local protocol should be translated into the appropriate language(s) for the site.

The performance of this study should disturb as little as possible the daily activities and the organizational model of each CBVCT. Staff members already performing HIV tests will be trained to be able to perform the dual HIV/syphilis POTCs.

All staff, employees and volunteers, who are involved in the performance of the CBVCTs dual POCT HIV/syphilis testing programme, shall undertake and should successfully complete the training programme.

The application and training will include as a minimum:

- Knowledge of the research protocol;
- Use of POCTs in accordance with manufacturers' directions;
- Procedure to use the standard testing kits used regularly by the CBVCT service;
- Procedure to collect and record data; and
- Feasibility evaluation.

At each site, the CBVCT staff member(s) who perform(s) the POCTs should try out the testing procedure with positive and negative control specimens (can be requested from WHO if necessary) under the supervision of the technical supervisor. The POCTs should be read independently by both CBVCT providers. If the results are invalid, the testing procedure should be repeated with a new test. The test will be recorded as "invalid" if the result of the repeated test

is still invalid. The study should only proceed when the study team members are confident of their ability to conduct the study and all the materials required for the study are in place.

The questionnaires for CBVCTs providers and users have to be piloted before using them to collect data. It is recommended to test them on a minimum of five individuals that are similar to people who are going to answer the questionnaires. Pretesting and piloting will identify questions that don't make sense to participants, or problems with the questionnaires that might lead to biased answers. It is important to ask participants of the pilot study to provide feedback on the clarity of questions and response options, as well as the length of time it took them to complete the questionnaires.

Sites encountering problems with the evaluation should contact Dr. Igor Toskin for technical support.

2.8 Data quality assurance

Internal quality controls

In order to ensure the integrity of the testing materials, a control and proficiency testing control will be established by the CBVCT coordinator. Upon receipt of a new lot number of POCT kits, a lot release panel will be performed and evaluated prior to the release of kits to storage.

The monitoring of the temperature of the kits, including the acceptable range, will be established according to manufacturer's' directions (Annex V). Additionally, the CBVCT coordinator should run positive and negative controls on each new box of kits prior to distribution to the CBVCT/Outreach Team.

External quality controls

WHO will perform two external quality controls to assess that the site is following the protocol indications. A competency checklist and a site preparation checklist will be completed during each visit (Annex VI and VII).

2.9 Data management

Depending on the site. Will be specified in the site consensus protocols. Evaluation of diagnostic tests only requires specimens from the subject. The subject is not affected in any way; he/she does not ingest anything or is he/she injected with any experimental material and the result of the evaluation is not used to treat the participant. Therefore it is exempted from having a DSMB. Data from the study will be kept for a minimum of one year after publication of its results and will then be destroyed.

2.10 Data analysis plan

Data from the evaluation will be entered into a standardised spreadsheet for analyses. A descriptive analysis will be performed on the results of those individuals who have had both syphilis and HIV POC testing and on those CBVCT providers who accept to participate in the study.

The feasibility of introducing the dual POCT for HIV and syphilis in CBVCTs will be assessed quantitatively through descriptive statistics by the study coordinator.

Following the structure in the conceptual framework, the analysis should be performed in 3 stages (for individual questions, sub-domains and domains): first calculate the median score for each question (excluding “Don’t know/Don’t want to answer”), secondly the median score should be calculated for all questions within a sub-domain, and lastly the total median score for all questions within a domain should be reported.

The operational characteristics should be compared by means of the chi-squared test.

2.11 Study timeline

	Timeline							
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Finalise study protocol by adapting the core protocol								
Submit to WHO ethics committee								
Submit to local ethics committee, when necessary								
Obtain ethical approvals								
Train staff on the study protocol								
Prepare supplies								
Receive testing kits under evaluation								
Pilot SOPs								
Conduct evaluation								
Analyse the study data								
Send results to WHO								
Prepare the evaluation report								
Disseminate the study results								

2.12 Main problems anticipated and proposed solutions

Will be included in the consensus protocols as they are site-specific.

2.13 Applicability of results

Dual POCTs with acceptable levels of feasibility can improve access to testing and the timely detection and referral for treatment of HIV and syphilis infected persons in non-clinic-based settings.

2.14 Links with other projects

Laboratory-based evaluations of POCTs will be the source of the POCTs used for the (non-)clinical evaluations. Those evaluations of POCTs for HIV-syphilis will be done in screening of MSM and sex workers and in pregnant women. Performance and utility of eligible POCTs for diagnose of chlamydial, trichomonas and gonococcal infections will also be evaluated in clinic-based settings and in non-clinical settings (only utility).

2.15 References

1. Reyes-Urueña J, Breveglieri M, Furegato M, Fernández-López L, Agusti C, Casabona J. Heterogeneity of community-based voluntary, counselling and testing services for HIV in Europe: the HIV-COBATEST survey. *Int J STD AIDS*. 2015 Dec 14;
2. World Health Organization (WHO). Consolidated guidelines on HIV testing services. Geneva, Switzerland; 2015.
3. Asiimwe C, Kyabayinze DJ, Kyalisiima Z, Nabakooza J, Bajabaite M, Counihan H, et al. Early experiences on the feasibility, acceptability, and use of malaria rapid diagnostic tests at peripheral health centres in Uganda-insights into some barriers and facilitators. *Implement Sci. BioMed Central Ltd*; 2012 Jan 23;7(1):5.
4. Ansbro ÉM, Gill MM, Reynolds J, Shelley KD, Strasser S, Sripipatana T, et al. Introduction of Syphilis Point-of-Care Tests, from Pilot Study to National Programme Implementation in Zambia: A Qualitative Study of Healthcare Workers' Perspectives on Testing, Training and Quality Assurance. *PLoS One. Public Library of Science*; 2015 Jan 1;10(6):e0127728.
5. Bergman J, Gratrix J, Plitt S, Fenton J, Archibald C, Wong T, et al. Feasibility and Field Performance of a Simultaneous Syphilis and HIV Point-of-Care Test Based Screening Strategy in at Risk Populations in Edmonton, Canada. *AIDS Res Treat*. 2013 Jan;2013:1–8.

3. Gender considerations

3.1 Describe how women and men are affected by the public health need that the study addresses, and whether this is a need expressed or felt by women and/or men

MSM are at high risk of acquiring and transmitting STIs, including HIV. They may not present to clinics for screening because they are often marginalised from the healthcare system. Moreover, these STIs are often asymptomatic. Undetected syphilis can result in serious long term complications and increased risk of HIV acquisition and transmission. Screening and appropriate treatment for infections in asymptomatic individuals can reduce the risk of developing serious long-term complications and interrupt onward transmission to their sexual partners. Screening MSM and sex workers for these curable STIs at non-clinical or outreach settings is a high priority as recommended in the WHO Guideline for MSM/Transgender People in 2011 and for Sex Workers in 2012.

3.2 Explain how the research contributes to identifying and/or reducing inequities between women and men in sexual and reproductive health and health care

MSM might find it difficult to access sexual health services. POCTs will enable them to be screened in outreach settings. This will support reducing HIV and syphilis inequities between MSM and the general population.

3.3 Describe measures taken to facilitate the individual participation of women or men in the research process in light of their different life situations.

NA, prospective sampling in non-clinical settings.

3.4 Describe measures taken to ensure that community involvement is inclusive

NA, prospective sampling in non-clinical settings.

3.5 Describe the sex composition of the research team, and their duties and responsibilities in the proposed research

NA, will be added in site specific consensual protocols

4. Ethical issues

4.1 Ethical considerations:

The core protocol should be approved by the WHO Ethics Review Committee. Each evaluation site must obtain institutional review board or ethical committee approval for performing the evaluations in accordance with the final site protocol. The letter of approval with the names and affiliation of all the members of the ethical committee should be signed by the chair of the committee on behalf of the committee members and sent to WHO for documentation. An agreement with WHO can only be provided to the sites on receipt of documentation of local ethical approval.

4.1.1 Study population, recruitment strategy and informed consent process

MSM presenting for testing care will be informed about the study and their (non-)participation will not affect the standards of care that they receive in the non-clinical setting. Pre-consent and CBVCT routine integrated research activities will be handled by two separate CBVCT providers.

4.1.2 Perceived risks and benefits of the study, both at the individual and community levels

Participation involves extracting two additional drops of blood from the fingertip to perform the new HIV and syphilis dual test in addition to the standard routine tests. There will be no immediate benefits in the participation in the study. When the study results are known and if the new combination rapid tests are found to be acceptable in terms of accuracy and utility, users may benefit from having a combination rapid test available to diagnose probable HIV and/or syphilis and be referred to receive the treatment.

4.1.3 Safeguards to protect any recognized vulnerability of the study participants

The records concerning the participation are to be used only for the purpose of the research project. Names will not be used on any study form or label on specimens or in any report resulting from the study. At the beginning of the study, a study identification number will be given and this number will be used on the forms and on the specimens. Any information obtained in connection with this study will be kept strictly confidential.

Autonomy of the users to decide to participate in the study will be safeguarded by the division of the roles of taking pre-consent on the one hand and performing the study, integrated in the CBVCT's routine, on the other. The final consent has to be taken by the CBVCT provider who performs the test, as he/she will also check the if the user fits the inclusion criteria, for confidentiality reasons.

4.1.4 Reimbursement or compensation to study participants

There will be no monetary compensation for this study, but routine consultation and appropriate referral services will be provided.

4.1.5 Access to treatment or counselling for conditions either identified during screening of potential participants or resulting from the study intervention

If agreement to participate in the study is given, the CBVCT provider will ask some questions according to standard procedure. Referral will be done based on the standard routine test results rather than result of the POCT under evaluation.

4.1.6 Responsiveness of the project to community needs and priorities

The introduction and withdrawal of the intervention will have no influence on the community. The product evaluated might be bought by countries for use in non-clinical settings, benefitting the community.

4.1.7 Deception

NA

4.2 Forms required (include or attach as a scanned copy, as appropriate)

4.2.1 Information sheet for participants and/or responsible persons

Appendix 1

4.2.2 Informed consent forms for participants and if appropriate, responsible persons

Appendix 1

4.2.3 Local (institutional, community and/or national) ethics approval

NA

5. Environmental impact of the project

Biosafety guidelines for CBVCT providers

- Treat all specimens as potentially infectious
- Wear protective gloves and laboratory gown while handling specimens
- Do not eat, drink or smoke while testing
- Clean up spills with appropriate disinfectants e.g. 1% bleach
- Decontaminate all materials with an appropriate disinfectant
- Dispose of all waste, including test kits, in a biohazard container

6. Plans for dissemination and use of project results

Results from this evaluation will be published in a WHO report for member states and posted on the WHO STI website and they will be part of a scientific publication in peer review journals.

7. Other support for the proposed research project

7.1 Project support by other institution(s)

Site specific.

7.2 Consideration of the proposal by other institution(s)

NA

8. Other current research projects of the principal investigator.

NA

Please list all other research projects currently in progress.

Title of project	Source of support	Duration of project (dates)	Per cent of time spent on project by principal investigator
-------------------------	--------------------------	------------------------------------	--

9. Curricula vitae of the principal investigator and co-investigator(s)

NA

10. Additional Information

Appendix 1. User information and consent form

A. Purpose of the study

HIV or syphilis are infections that can lead to serious negative influences for your health. To avoid that those infections go from one person to another during sexual contact, early detection and treatment of these infections are important.

We can already detect probable infection with standard routine tests during this counselling session, but they are separate tests. There are new combination tests available that can give us results for both HIV and syphilis from the same test within a half hour, but we do not know if it is as practical to use as the ones we now use. We would like to ask for your help in evaluating the new test. If the new test works well, perhaps in the future we will be able to give a rapid result of both HIV and syphilis using a single test.

B. Procedures to be followed

Participation involves extracting two additional drops of blood from your fingertip to perform the new HIV and syphilis dual test in addition to the standard routine tests. If the routine test or the new test(s), or both, indicate that you might be infected with HIV or syphilis, we will refer you to a health centre to be sure about this result.

In addition to the collection of the usual personal data, a short acceptability questionnaire will be performed.

C. Voluntary participation

During the study, you can choose not to answer any particular question or not to provide the blood specimens. A decision not to participate or to withdraw from participation will not affect the care you will receive at the centre in any way. If you do agree to become a study participant, you can withdraw from study at any time (verbally).

D. Benefits

There will be no immediate benefits in your participation in the study. When the study results are known and if the new combination rapid tests are found to be acceptable in terms of accuracy and utility, users may benefit from having a combination rapid test available to diagnose probable HIV and/or syphilis and be referred to receive the treatment.

E. Confidentiality statement

The records concerning your participation are to be used only for the purpose of this research project. Your name will not be used on any study forms or labels on specimens or in any report resulting from this study. At the beginning of the study, we will give you a study identification code and this code will be used on the forms and on the specimens. Any information obtained in connection with this study will be kept strictly confidential.

F. Questions and freedom to withdraw from the study

You may withdraw from the study at any time without affecting your present or future medical care at the centre. You may contact any of the study staff if you have questions about the research. You may speak with the staff at the centre (name _____). You can also call the centre during working hours at tel.: _____.

G. Results publication

Data from the study will be kept for a minimum of one year after publication of its results.

H. Participant statement

I have been informed verbally and in writing about this study and understand what is involved. I also know whom to contact if I need more information. I understand that confidentiality will be preserved. I understand that I am free to withdraw from the trial at any time without affecting the care I normally receive at the clinic. I agree to participate in this study as a volunteer subject and will be given a copy of this informed consent to keep.

Date

Signature

I. Investigator's statement

I, the undersigned, have defined and explained to the user in a language he understands, the procedures of this study, its aims and the risks and benefits associated with his participation. I have informed the user that confidentiality will be preserved and that he is free to withdraw from the trial at any time without affecting the care he will receive at the centre. Following my definitions and explanations the user agrees to participate in this study.

Date

Signature

Name of investigator who gave the information about the study

Appendix 2. Basic Questionnaire

1. **Questionnaire number:** _____
2. **CBVCT provider initials** _____
3. **Date:** __ / __ / __
4. **User unique identifier**
|_| |_|_| |_|_| |_|_|_|_|_|
5. **Date of birth**
|_|_| |_|_| |_|_|_|_|_|
6. **Foreign national**
[1] Yes
[2] No
[8] Don't know / Don't want to answer

Dual POCTs for the screening of HIV and syphilis results

7. **Does the CBVCT user agree to perform the dual HIV/syphilis POCT?**
[1] Yes (*Jump to Question (9)*)
[2] No (*Just answer question (8)*)
8. **Why the CBVCT user did not want to perform the dual HIV/syphilis POCT**
[1] Don't want be tested for HIV
[2] Don't want to be tested for syphilis
[3] Don't trust the dual test results
[4] Don't want to wait the extra time
[5] Other (please describe): _____
[9] Don't know / Don't want to answer

HIV test result (test performed regularly at the CBVCT service)

9. **HIV test result**
[1] Positive
[2] Negative (*Jump to Question (13)*)
[3] Inconclusive
10. **Has a HIV confirmatory test been performed?**
[1] Yes
[2] No
[9] Don't know / Don't want to answer
11. **Confirmatory HIV test result**
[1] Positive
[2] Negative
[3] Inconclusive

In the case of a confirmed HIV diagnosis

12. **Has been the CBVCTs user been linked to the healthcare system?**
[1] Yes
[2] No
[9] Don't know / Don't want to answer

Syphilis test result

13. **Syphilis test result (test performed regularly at the CBVCT service)**
[1] Positive
[2] Negative (*Jump to Question (16)*)
[3] Inconclusive
14. **Has the patient been referred for syphilis confirmation?**

- [1] Yes
- [2] No (***Jump to Question 16***)
- [3] Don't know (***Jump to Question 16***)

15. In the case that the user has been derived for confirmation, what is the syphilis diagnosis?

- [1] Active
- [2] Serological scar (old or cured infection)
- [9] Don't know / Don't want to answer

Dual HIV/Syphilis POCT results (own interpretation)

16. HIV result

- [1] Positive
- [2] Negative
- [3] Inconclusive

17. Syphilis result

- [1] Positive
- [2] Negative
- [3] Inconclusive

Dual HIV/Syphilis POCT results (interpretation CBVCT service provider 1, only unblind the results after you have filled out your reading of the test results)

18. HIV result

- [1] Positive
- [2] Negative
- [3] Inconclusive

19. Syphilis result

- [1] Positive
- [2] Negative
- [3] Inconclusive

Appendix 3. Feasibility questionnaire for the CBVCT providers

1. Demographic Data and Experience with dual HIV/Syphilis POCTs

1.1. **Date** __ / __ / __

1.2. **Questionnaire number:** _____

1.3. **Date of birth**

 |_|_| |_|_| |_|_|_|_|_|

1.4. **What is your employment status in this CBVCT?** Circle only ONE

[1] Employee

[2] Volunteer

[3] Other, Specify: _____

[9] Don't know / Don't want to answer

1.5. **What is your background training?** Circle only ONE

[1] Doctor

[2] Nurse

[3] Social worker

[4] Psychologist

[5] Peer educator

[6] Other, Specify: _____

[7] I do not have any training

[9] Don't know / Don't want to answer

1.6. **How long have you been performing HIV and syphilis rapid tests?**

Years: | || |

Months: | || |

1.7. **Approximately how many users have you tested with the dual HIV/syphilis tests during the study period?** Circle only ONE

[1] 1-10 users

[2] 11-20 users

[3] 21-30 users

[4] More than 30 users

[5] None

[9] Don't know / Don't want to answer

2. Learnability of dual HIV/ Syphilis Testing

2.1. **Overall, performing dual HIV/ Syphilis test is :** Read all choices; Circle only ONE

[1] Very Easy

[2] Quite Easy

[3] Neither easy nor difficult

[4] Quite Difficult

[5] Very Difficult

[9] Don't know / Don't want to answer

2.2. **Correctly reading and interpreting the dual HIV/ Syphilis test results is:** Read all choices; Circle only ONE

[1] Very Easy

[2] Quite Easy

[3] Neither easy nor difficult

[4] Quite Difficult

[5] Very Difficult

[9] Don't know / Don't want to answer

2.3. **Interpreting weak positive test results is:** Read all choices; Circle only ONE

[1] Very Easy

[2] Quite Easy

[3] Neither easy nor difficult

- [4] Quite Difficult
- [5] Very Difficult
- [9] Don't know / Don't want to answer

2.4. Do you think that the training offered was enough to perform the dual test? Circle only ONE

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

3. Willingness of the CBVCTs provider to perform the dual HIV/syphilis test

3.1. Are you willing to perform the dual HIV/syphilis test instead of the two HIV and syphilis separated tests at your CBVCTs? Read all choices: Circle only ONE

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

3.2. Do you think that the current supporting components of the study, including training, supervision and quality maintenance are sufficient to integrate the dual HIV/syphilis test into the routine activities in your CBVCTs? Read all choices; Circle only ONE

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

4. Suitability of performing the dual HIV/ Syphilis test in your CBVCTs

4.1. Are you confident in the results of the dual test? Read all choices: Circle only ONE

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

4.2. Do you think routine dual HIV/syphilis testing should continue in your CBVCT? Read all choices: Circle only ONE

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

5. Satisfaction with the dual HIV/syphilis Testing

5.1. In your opinion, how do new users feel about the dual HIV/syphilis tests? Read all choices; Circle only ONE

- [1] Very positive

- [2] Quite positive
 - [3] Neither negative nor positive
 - [4] Quite negative
 - [5] Very negative
 - [9] Don't know / Don't want to answer
- 5.2. **Do you think that the use of dual testing at this CBVCT does not change or reduce workload?** Read all choices; Circle only ONE
- [1] Strongly agree
 - [2] Agree
 - [3] Neither agree nor disagree
 - [4] Disagree
 - [5] Strongly disagree
 - [9] Don't know / Don't want to answer
- 5.3. **One of the reasons to support the use of dual testing at this CBVCT is that it is more acceptable by users than the separate HIV and syphilis tests?** Read all choices; Circle only ONE
- [1] Strongly agree
 - [2] Agree
 - [3] Neither agree nor disagree
 - [4] Disagree
 - [5] Strongly disagree
 - [9] Don't know / Don't want to answer
6. **Efficacy to integrate dual HIV/syphilis Testing with CBVCT Workflow**
- 6.1. **Do you think rapid dual HIV/syphilis tests could be successfully integrated in this CBVCTs?** Circle only ONE
- [1] Strongly agree
 - [2] Agree
 - [3] Neither agree nor disagree
 - [4] Disagree
 - [5] Strongly disagree
 - [9] Don't know / Don't want to answer
- 6.2. **Do you think adding dual HIV/syphilis tests will change users waiting time at the CBVCT service?** Circle only ONE
- [1] Strongly agree
 - [2] Agree
 - [3] Neither agree nor disagree
 - [4] Disagree
 - [5] Strongly disagree
 - [9] Don't know / Don't want to answer
7. **Effectiveness to integrate dual HIV/syphilis Testing**
- 7.1. **Do you think that the current provider of the HIV and Syphilis tests can provide you with the dual HIV/syphilis test?** Circle only ONE
- [1] Strongly agree
 - [2] Agree
 - [3] Neither agree nor disagree
 - [4] Disagree
 - [5] Strongly disagree
 - [9] Don't know / Don't want to answer
- 7.2. **Do you think that the dual HIV/syphilis test can be easy integrated into the national and/or regional HIV testing guidelines?**
- [1] Strongly agree

- [2] Agree
 [3] Neither agree nor disagree
 [4] Disagree
 [5] Strongly disagree
 [9] Don't know / Don't want to answer

8. Operational characteristics of POCTs (Circle only ONE in each question of this section)

8.1. **Name of kit:**

8.2. **Manufacturer:**

8.3. **Mark for each test the following characteristics.** Tick one box for each test and for each question.

	Dual HIV and Syphilis POCT	HIV single rapid test	Syphilis single rapid test
A. Clarity of kit instructions			
Very unclear	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
Quite unclear	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Quite clear	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Very clear	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3
B. Ease of use			
Very complicated to use	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
Quite complicated to use	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Quite easy to use	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Very easy to use	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3
C. Ease of interpretation of results			
Very difficult to interpret	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
Quite difficult to interpret	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Quite easy to interpret	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Very easy to interpret	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3
D. Waiting time for test results			
<20 minutes	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
20-30 minutes	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
>30 minutes	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
E. Hands-on time			
<5 minutes	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
5-10 minutes	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
>10 minutes	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
F. Training time required			
<30 minutes	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0
30-59 minutes	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1
1-2 hours	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2
>2 hour	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3

Appendix 4. Feasibility questionnaire for the CBVCT users

1. **Questionnaire number:** _____

2. **Date:** __ / __ / __

3. **User unique identifier**

4. **What is your educational level?**

- [1] Primary education or less
- [2] Secondary education
- [3] Undergraduate education
- [9] Don't know / Don't want to answer

5. **What is your current occupation?**

- [1] Current regular job
- [2] Unemployment
- [3] Disabled or retired
- [4] Student
- [7] Others
- [9] Don't know / Don't want to answer

6. **Have you been tested before for HIV?**

- [1] Yes
- [2] No
- [3] I don't remember
- [9] Don't know / Don't want to answer

7. **Have you been tested before for Syphilis?**

- [1] Yes
- [2] No (*Jump to Question 8*)
- [3] I don't remember (*Jump to Question 8*)
- [9] Don't know / Don't want to answer (*Jump to Question 8*)

7.1. **What was the result of the latest Syphilis test that you have performed?**

- [1] Active
- [2] Serological scar (old or cured infection) (*Jump to Question 8*)
- [9] Don't know / Don't want to answer (*Jump to Question 8*)

7.2. **Did you receive any treatment for the active syphilis infection?**

- [1] Yes
- [2] No
- [3] I don't remember
- [9] Don't know / Don't want to answer

8. **Willingness to perform the dual HIV and syphilis test on yourselves**

8.1. **Before today, have you ever heard about the dual HIV and syphilis test?** Read all choices; Circle only

- [1] Yes
- [2] No
- [9] I don't remember

8.2. **Do you prefer the dual HIV and syphilis test instead of the two separate tests for HIV and syphilis?** Read all choices; Circle only

- [1] Strongly agree
- [2] Agree

- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

8.3. Are you willing to wait more time for the results of dual HIV and syphilis test, compared with the time that you have to wait for the results of the separate tests?

Read all choices; Circle only

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

9. Suitability of performing the dual HIV/ Syphilis test in your CBVCTs

9.1. Do you trust the results of the dual test for HIV and syphilis? Read all choices; Circle only

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

9.2. Do you think that the dual HIV/ Syphilis test is more reliable than the two separate rapid tests for HIV and syphilis? Read all choices; Circle only

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

10. Satisfaction with the dual HIV/syphilis Testing

10.1. Are you satisfied with the performance of the dual HIV/syphilis test compared to the separate tests for HIV and syphilis? Read all choices; Circle only

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

10.2. In the future, would you prefer a rapid test kit to simultaneously detect HIV and syphilis (dual test) or two single tests to separately detect HIV and syphilis? Read all choices; Circle only

- [1] Strongly agree
- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

11. Would you recommend the dual test for HIV and syphilis to a friend? Read all choices; Circle only

- [1] Strongly agree

- [2] Agree
- [3] Neither agree nor disagree
- [4] Disagree
- [5] Strongly disagree
- [9] Don't know / Don't want to answer

Appendix 5. Dual POCT Kit Storage Temperature Log

(Check _____, as scheduled, or after trigger event such as power outage)

Thermometer location: _____

Month/year: ____/____

Acceptable temperature range: _____ To be completed by WHO _____

[illegible]

Initial Review ___/___/___

Final Review __/__/__















Signature _____

Date _____

Appendix 6. External quality controls - Competency Checklist

Date: _____ **CBVCT service:** _____

Name of the CBVCT provider: _____

-  Gathers/arranges all materials
-  Fills in the initial questionnaire
-  Provides to the CBVCT user the acceptability questionnaire
-  Makes sure that all questionnaires and the tests vials have the same user identification number
-  Examines test kit pouch (unopened, absorbent packet)
-  Affixes user identification number to back of vial
-  Successfully opens and positions vial in stand (no spillage, vial to bottom of stand)
-  Wears gloves for all subsequent steps
-  Visually examines loop to ensure it is full of sample
-  Stirs in sample, loop to biohazard
-  Successfully inserts test kit (no spillage, window forward, pad touching bottom of vial)
-  Did NOT remove test kit until ready to insert
-  Did NOT touch flat pad when inserting test kit
-  Successfully completes all steps (if not, note what was missing/incorrect below):

Notes:






Evaluator Name: _____ **Evaluator Signature:**

Appendix 7. Site Preparation Checklist




CBVCT service: _____

Date: _____






Test Kit Storage

-  Area secured against unauthorized access _____
-  Temperature controlled/acceptable _____
-  Thermometer located in storage area _____
-  Temperature control log sheet posted _____
-  Inventory procedures established _____


Control Unit Storage

-  Non-food refrigerator _____
-  Thermometer located on refrigerator shelf _____
-  Temperature control log posted _____


Testing Area


-  Secured against unauthorized access _____
-  Confidentiality measures in place _____
-  Clock near testing area _____
-  Testing area clean & well-lit _____
-  Flat surface for undisturbed test kit processing _____

Notes


 Biohazard disposal (sharps and non-sharps)


Materials

 Testing materials (Test kits, loops, stands, etc.)


 Phlebotomy materials (finger stick devices, bandages, etc.)


 Questionnaires


 Protective gear (gloves, lab coats, etc.)

 Test kit and control unit package inserts

Testing Process Verified

 Complete testing process “dry run” successful

 Personnel proficient with process, paperwork

 Personnel familiar with confirmatory guidelines and linkage to care procedures

Quality Assurance Plan

Appendix 8. Budget template

Budget template for the utility evaluation of POC STI diagnostics: Costing based on patient recruitment for 9 months and study completion at 12 months.

Item	Cost (USD)	Subtotal/Total (USD)
Personnel:		
	40,000	40,000
1. Study coordinator (0.5 FTE)		
2. Technician		
3. CBVCT health workers (2)		
4. data manager (0.5 FTE)		
Supplies		
(consumables: gloves, pipettes, etc)	3,000	3,000
Travel		
Local travel (field work)	3,000	3,000
Training and mentoring	1,500	
Communication	500	
Publishing	2,000	4,000
Other (please specify and justify below)		
TOTAL BUDGET		55,000

The study budget does not include the costs of POCTs as these will be provided from the companies. International travel for research staff will be budgeted separately.