WORLD HEALTH ORGANIZATION
Regional Office for the Western Pacific

STI

HIV

SEXUALLY TRANSMITTED INFECTIONS PREVALENCE STUDY METHODOLOGY

Guidelines for the implementation of STI prevalence surveys

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SEXUALLY TRANSMITTED INFECTIONS PREVALENCE STUDY METHODOLOGY

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STI/HIV

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ANNEXES

ABBREVIATIONS

ELISA	enzyme-linked immuno-sorbent assay
FSW	female sex worker
GUD	genital ulcer disease
GUM	genitourinary medicine
HIV	human immunodeficiency virus
HPV	human papillomavirus
IDU	injecting drug user
KOH	potassium hydroxide
LCR	ligase chain reaction
NGO	nongovernmental organization
PCR	polymerase chain reaction
PID	pelvic inflammatory disease
RPR	rapid plasma reagin
STI	sexually transmitted infections
TAG	technical advisory group
TPHA	treponemal pallidum haemagglutination
WHO	World Health Organization

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1 INTRODUCTION

The public health importance of sexually transmitted infections (STI) is well documented. They cause serious health, economic and social consequences. They have also consistently ranked among the five most important causes of adults seeking health care and of healthy productive life lost. The morbidity from STI (excluding HIV) in women aged 15-45 years, ranks second only to maternal causes. In recent years, epidemiological studies have shown that persons with ulcerative and non-ulcerative STI are more susceptible to HIV. People with HIV and non-ulcerative STI have increased shedding of HIV-infected cells and greater efficiency in transmitting the virus. In particular, genital ulcer disease (GUD) has been shown as a co-factor in the transmission of HIV. Sexually transmitted infections that cause genital inflammation have been shown to increase the efficiency of HIV transmission as much as fivefold. Treatment of STI and health education, including correct condom use, are efficient and cost-effective ways to prevent HIV epidemics.

For effective STI programmes, STI programme managers need to have an estimate of the prevalence of STI within their local community and country. This can in part be achieved by setting up improved STI surveillance mechanisms and conducting periodic baseline prevalence studies of selected STI.

Screening, diagnosis and treatment costs for many STI are expensive and likely to exceed the per capita health care budget in many countries. A cost effective public health strategy is the adoption of STI syndromic case management. In order to best apply syndromic case management it is important to know the epidemiology of STI in the community. This protocol has been designed to support local STI prevalence studies. The aim of this study is to obtain STI prevalence information and to strengthen the surveillance capacity. In some settings, this study may also contribute to strengthening of research and laboratory capacity.

This protocol provides a framework for conducting an STI prevalence study. Generally this type of study attempts to target several population subgroups from within the community who are characterized by different behavioural and

risk profiles. Examples of such subgroups are female sex workers, military recruits and pregnant women. Studies of this type are limited in that they do not represent all major population groups and so will not be a true prevalence study of STI pathogens. However, if used within these limitations these studies provide valuable data on the prevalence of selected STI in the studied populations. This data can be used for planning, refining STI case management programmes, and revising disease prevalence estimates for population subgroups.

This protocol describes a standardized survey methodology. This protocol uses a simple, reliable and reproducible study design that can be widely used and implemented at the local level. This prevalence study is designed to collect limited basic demographic information and clinical specimens for laboratory testing of STI. To simplify the study protocol, no risk factor or behavioural questions have been included. The principal investigator in each setting should modify the protocol to suit local needs and capacity.

2 METHODOLOGY

Prevalence

A prevalence rate is a measure of frequency of existing disease at a given time in a specific population, and is defined as:

$$P = \frac{\text{total number of cases of disease at a given time}}{\text{total population at the same time}}$$

An STI prevalence assessment is a determination of the number of persons infected with an STI among persons screened in defined populations.

Objectives of an STI prevalence survey

The objectives of an STI prevalence survey are:

- to describe epidemiologically the prevalence of STI, in specific population subgroups;
- to provide a basis to monitor trends and the impact of STI prevention and control programmes;

Additionally, in some situations, the study may strengthen:

- the capacity for epidemiological assessment and potential surveillance for STI; and
- the technical capacity of epidemiological, laboratory, and clinical based study investigators.

Principal investigator

Once a decision is made to conduct the prevalence study, a principal investigator will need to be identified. The primary role of the principal investigator will be to organize and conduct the prevalence study. The principal investigator needs to have past research experience in conducting epidemiological studies and a clinical, laboratory or management background in sexual or public health. Responsibilities of the principal investigator include identifying local resources and personnel, convening a technical advisory group (TAG) and adapting the study protocol to local conditions.

Technical advisory group

The TAG should be convened by the principal investigator and should include members with laboratory expertise, antenatal and sexual health experience, data management skills, and representatives from the study site(s). TAG member may cover several areas of expertise. It is expected that the study

period, including organization, design, data collection, analysis and reporting, would be approximately one year and it is important that the principal investigator be available for this period.

The principal investigator, in consultation with the technical advisory group, will need to determine the specific details of how the study will be conducted based on the protocol (e.g. study population, laboratory test selection and sample size).

Recommended STI for inclusion in the survey

Treponema pallidum (syphilis), *Neisseria gonorrhoea* (gonorrhoea), *Chlamydia trachomatis* (chlamydia), *Trichomonas vaginalis* (trichomonas) and HIV have all been classified as high priority for inclusion in the STI prevalence survey. The first four STI are curable, cause considerable adult and infant morbidity and mortality, are spread primarily by sexual transmission and are often asymptomatic in women (Table 1). HIV testing will also often be included in the survey.

***Table 1*: Classification of pathogens responsible for sexually transmitted infections (other than HIV) for inclusion an STI prevalence study**

Pathogen	Common Clinical Presentations	Priority/Gender
Treponema pallidum	Genital ulcer	High/Female and Male
N. gonorrhoea	Urethritis, epididymitis, mucopurulent cervicitis, pelvic inflammatory disease	High/Female and Male
C. trachomatis	Urethritis, epididymitis, mucopurulent cervicitis pelvic inflammatory disease	High/ Female and Male
T. vaginalis	Urethritis, vulvovaginitis	High/ Female

Testing options for STI

The aim of this prevalence survey is to obtain the most accurate and valid laboratory based diagnoses of the specified STI from the collected samples. The degree of precision required in the survey should be determined before decisions are made about the type of sample to be used and which tests the laboratory will use. There are three main categories of samples: 1) urine; 2) intravaginal, including vaginal and endocervical secretions; and 3) blood, including whole blood and dried blood. When deciding on the choice of sample and laboratory test, it is important to consider the following:

- local technical laboratory capacity;
- the sensitivity and specificity of the test in the proposed survey population;

- degree of difficulty in sample collection and what size of sample is required;
- robustness and logistics of sample transportation and storage; and
- the cost of tests.

The laboratory protocol for the survey is detailed in Annex 1 which discusses test positivity, and options for sample collection, transportation and laboratory testing of syphilis, gonorrhoea, chlamydia, trichomonas and HIV. Further details on the laboratory diagnosis of STI are contained in the WHO/WPRO publication entitled Laboratory Tests for the Detection of Reproductive Tract Infections.

Information to be collected

The minimum information needed for the prevalence study is listed below. Additional data elements can be collected at some sites which will provide more detail of patient demographics, risk characteristics and diagnoses.

Minimum data elements for an STI prevalence study are:

- study identification number;
- study site;
- date of specimen collection;
- sex; and
- date of birth or age to be determined by study population.

Confidentiality

Confidentiality is the protection of personal information from disclosure to unwarranted people. Warranted persons learning confidential information must be made aware of their legal and ethical responsibilities to preserve confidentiality. The confidentiality of HIV and STI status must be ensured at all times, including during testing and treatment. Any disclosure should be justified on the basis of law and professional ethics.

Voluntary, confidential testing for STI

The STI prevalence study should use a voluntary confidential testing methodology for STI (excluding HIV) and an unlinked anonymous testing methodology for HIV.

Voluntary confidential testing of STI is where individuals may themselves ask for STI tests or may consent to a test on recruitment into a study. Their name is known only to the health professional involved in their direct patient management. In some jurisdictions, names of persons testing positive must be reported to the appropriate health authority and to a very limited number of individuals in the Ministry of Health, where access to this information is for programme purposes. However, confidentiality is nonetheless maintained.

Unlinked anonymous testing for HIV

Unlinked anonymous testing for HIV in seroprevalence surveys refers to the testing of specimens for markers of infection after the elimination of all personal identifying information from each specimen. Unlinked anonymous testing is

generally considered to be an accurate and effective method for public health surveillance of HIV infection. It is not a method to identify individual infections.

Study design

The most appropriate study design for the STI prevalence survey is a cross-sectional study. Cross-sectional studies are observational studies in which a sample of subjects in a population (e.g., pregnant women attending an antenatal clinic) are investigated for specific characteristics, in this instance laboratory confirmed STI. Prevalence studies do not establish causality.

Overview of sampling considerations

The elements to consider in deciding which sample procedure to follow are: a sampling frame that is representative of key epidemiological and socio-economic factors; study sites that have sufficient client numbers and medical and laboratory expertise and capacity; clients that are likely to consent to participation; and government support for the prevalence study.

Usually, a population is too large for the study investigator to examine every individual, so instead a sample is taken. If the sample is representative of the population, one can generalize the findings from the sample to the population they represent. The advantages of studying a sample are in saving time, study personnel and costs. The main disadvantage of a sample is that precision is lost by not observing the whole population. So, the sample estimate will have some margin of error. There are two main types of error: sampling errors, which occur because only part of the population is included in the study (generally the larger the sample size the smaller the sampling error); and selection bias (non-sampling errors) which occur if the sampling procedure is flawed and the sample is not representative of the whole population. Selection bias is independent of sample size. An example of selection bias is when freelance female sex workers are not included in a study of female sex workers (FSW) because sampling for the study is only from brothels.

Sample frame

A convenience sample with consecutive sampling should be used in the STI prevalence surveys. Enrolment should continue until the required number of study participants has been reached.

A convenience sample is where the study population is already accessible for a reason not related to the study such as pregnant women attending a hospital for antenatal care. Convenience sampling is used because it is a convenient, practical and cheaper way of recruiting study participants. It uses an existing infrastructure such as clinic facilities and staff. The disadvantage is that the sample population may not be representative of the study population in an economic, cultural or geographic sense.

Within a convenience sample framework, sampling can either be:

(1) random, where everyone has the same probability of being selected, making the sample more representative of the

population of interest (For random sampling, a full count of all clinic attenders for the study period is needed. The disadvantage is that it complicates recruitment, specimen collection and, potentially, clinical management of asymptomatic infections); or

(2) non-random (e.g. consecutive), where all eligible clinic attendees are recruited into the study until the sample size is reached.

Consecutive sampling is simpler, reduces the study period and is cheaper but it may increase selection bias.

Study population

Factors for consideration when determining a study population are listed in Table 2.

***Table 2*: Potential study populations for ad hoc prevalence studies of STI**

Sample frame - proposed types of population subgroup	Risk category of population subgroup	Characteristics of population subgroup
Female sex workers • Brothel • Massage parlours/bars • Casual freelance *Injecting drug users in specific populations* *Male sex workers* • Casual freelance • Sex with men/women	Core (high-risk) infection transmission subgroup – a small subgroup of people experiencing infections who are responsible, either directly or indirectly for a large number of STIs in the general population.	High rates of STIs compared to the general population; high rates of partner change; longer duration of infection; poorer access to health care facilities; very efficient transmission of STI per sexual exposure.
STI clinic (equivalent) clients (usually males) • Military • Police • Mobile populations (e.g. transport workers, fishermen)	Bridging (medium-risk) subgroup who are characterized by sexual contact with both the core transmission population and the low risk general population. Often males who frequent FSW and have at the same time a wife or girlfriend.	Assumed to include clients of sex workers and/or sex workers.
Women attending antenatal clinics	Maintenance (low-risk) population subgroup who are characterized by relatively lower rates of sexual partners and concurrent relationships, smaller numbers of sexual linkages, and relatively limited contact with other population subgroups. Represent this population.	Low-risk sexually active population. Equivalent to the general sexually active population rate, gives an indication of the level of disease burden.

In most settings the likely high-risk (STI core transmission) subgroups will include female and/or male sex workers and some mobile populations including fishermen, transport drivers, seasonal labourers and the military. Another low-risk group are pregnant women attending antenatal services, a convenient group similar to the general sexually active population.

The proposed sample frame should include persons aged 15-49 years. Ideally, there should be over-sampling of persons aged less than 25 years so that half the sample is aged 15-25 years. The aim of over-sampling young persons is to determine disease prevalence in those who are most recently sexually active. This also provides a baseline for monitoring the impact of the STI and HIV epidemic in that population.

Criteria for site selection

Table 3 details criteria to consider when selecting a study site.

***Table 3*: Characteristics to consider when selecting a study site**

Characteristics to consider	Criteria for study site selection
Acceptability	study is acceptable to the government, local authorities and the proposed study population
Location	urban (big city), urban (town), rural/farming, coastal, or remote
Disease prevalence	areas likely to have high or low STI (and HIV) prevalence
Sample size	site that has a sufficient number of clients available for recruitment
Sector	government (health or military), or local or foreign nongovernmental or semi-governmental organizations (aid agencies, universities, trade unions, private clinics, outreach programmes)
Local capacity	technical and organizational skills to follow the study protocol
Suitability of site	physical layout, availability for the whole study period
Commitment	available and interested study site supervisor
Confidentiality and privacy	capacity to follow the study protocol requirements on confidentiality and privacy issues and record keeping
Laboratory	technical and organizational skills to follow with the study protocol requirements; adequate quality control and quality assurance programmes in place

Specific study site suggestions:

(1) For FSW, the study site will depend on local conditions. The FSW may visit private or public clinics, outreach services, nongovernmental services or alternate venues such as pharmacies. If the site identified is a public sector STI clinic (also known as social hygiene clinics, genitourinary medicine clinics, dermatology clinics, dermato-venereologist clinics, family planning clinics) it should be selected, provided the clinic sees a sufficient number of new STI patients each month.

(2) For pregnant women, the antenatal clinic may be identified as a site, provided the clinic sees the required number of new patients each month to support the sample needed for the study.

(3) For military recruits the identified site might be a military clinic; for transport workers or fishermen a network might have to be established or negotiations made with a union or other agency to set up a mobile health clinic.

Sample size considerations

The survey is designed to obtain a "one-time" estimate of the magnitude (prevalence) of STI in a population. The minimum acceptable sample size for assessing prevalence depends upon: the expected, often estimated, prevalence of the disease in the population; the degree of precision/certainty wanted in that prevalence estimate; and whether or not it is the intention to monitor disease trends over time. Generally, the more precise the required estimate, the larger the sample size needed. The sample size required is also much larger if the intention is to monitor trends over time as the sample has to be large enough to have sufficient statistical power to detect changes of a moderate size. The recommended parameters are that sample sizes are sufficient to measure changes in indicators of 15 percentage points at the 95% significance level and with 80% power.

Table 4 lists the different sample sizes you would need for ad hoc surveys using a series of estimated disease prevalence rates with varying degrees of precision. For example, if the estimated prevalence of the four STI for a survey in a population of female sex workers were: syphilis (5%), gonorrhoea (10%), chlamydia (10%) and trichomonas (20%) and precision of ±2.5% for disease prevalences 10% and 3% for disease prevalences >10%, then the largest sample size needed for trichomonas would be 683 (the other sample sizes would be 292 for syphilis, 554 for gonorrhoea and 554 for chlamydia). Therefore, 683 is the minimum number required in the survey to detect a prevalence of 20% for trichomonas with a 95% degree of confidence with a true population prevalence estimate between 17% and 23%. Often the sample size needed is rounded up (in this example it would be to 700) to account for specimen loss or contamination and indeterminate test results.

It is important to note that where the estimated disease prevalence is <2% the ability of a sample of <500 to detect disease is very limited. This table is only a guide. Principal investigators should consult a statistician prior to calculation of the sample size.

***Table 4*: Sample size needed based on estimated prevalence of STI and desired precision using a 95% confidence interval calculation**

Estimated prevalence of STI	Precision ±0.5% Sample size	Precision .± 1.0% Sample size	Precision .± 1.5% Sample size	Precision ± 2.0% Sample size	Precision ± 2.5% Sample size	Precision ± 3.0% Sample size
*1%**	1522					
2%	3012	753	335			
3%	4472	1118	497	280	179	
4%	5901	1476	656	369	237	164
5%		1825	811	457	292	203
10%			1537	865	554	385
15%				1225	784	545
20%					984	683
30%						897

*Precision 0.6%, 1.6%

Recruitment Criteria for study recruitment:

(1) the legal age of consent will need to be taken into account when recruiting participants for the study. As this is a non-experimental study, minors independently accessing health care facilities can be considered emancipated and eligible for study inclusion;

(2) for antenatal clinic sites use only first (book-in) visits by pregnant women;

(3) for all other categories of study participants (e.g. sex workers, military, family planning clients, fishermen and transport workers) all new and existing clinic patient should be recruited for the study when they attend the study site with a new presentation. However, patients attending study sites for results or post-treatment review (follow-up) should not be included in the study;

(4) consent is the process of explaining to a potential study participant the conditions of study participation (including tests and specimen collection procedures) so that the individual is sufficiently informed to understand the personal risks and benefits involved. Consent may be written, or verbal if the study participants is of low literacy;

(5) all study participants will undergo a series of tests for the STI being studied irrespective of symptoms;

(6) satisfaction of any other specific study site criteria such as sex (e.g. female sex workers), pregnancy (antenatal clinic attendees) and other individual study population criteria; and

(7) study participants will only be included in the study once.

Interview and examination

Women participating in the study should be interviewed and examined as outlined in Annex 2, with the information recorded on the form in Annex 3. Men participating in the study should also be interviewed and examined as outlined in Annex 2 with the information recorded on the form in Annex 3.

Collection of laboratory specimens

At the clinic, which specimens are collected depends upon the tests being used. Annex 1 describes the possible types of specimen (urine, blood, cervical and vaginal) that can be collected from study participants.

Tests at the laboratory

The tests to be carried out at the laboratory are described in Annex 1 and are related to local capacity and specimen type.

Laboratory accession

Specimens collected at the study sites should be logged (accessioned) in a study register when they reach the laboratory. If a specific test is not performed at the laboratory the specimens should be stored under appropriate laboratory conditions before being sent to the referral laboratory.

Test results

The results of tests should be entered as shown in Annexes 4 and 5 and should be handled as follows:

(1) STI test results excluding HIV (Annex 4). One copy of the results should be kept in the laboratory, one copy should be sent to the clinic concerned and one copy should be sent to the principal investigator. Results should be sent to the clinic concerned within one week of receipt of specimens.

(2) HIV test results (Annex 5). One copy of the HIV test results should be kept at the laboratory in a file and one copy should be sent to the principal investigator on a weekly or monthly basis.

Syndromic diagnosis

Study clinicians (doctors or nurses as appropriate) should interview and examine all patients. In the presence of symptoms and signs, a syndromic diagnosis should be made.

Treatment All study participants (patients) with STI-related syndromes are to be treated syndromically according to the WHO or national guidelines at the time of examination and diagnosis, without waiting for laboratory results.

Training The principal investigator should identify and coordinate the training needed to conduct the study. The principal investigator should coordinate staff recruitment for the study. Standardized training of nurse practitioners, clinicians and laboratory personnel will be needed for each study site. This should include training in patient recruitment, examination, specimen collection and management using the syndromic approach to STI care.

Laboratory staff should be supervised by the Director (or equivalent) of the laboratory. Two laboratory staff for participation in the study should be identified at the laboratory, with at least one supervisor at any level. At least one of the laboratory technicians doing the tests should be trained in the study protocol. Training should include specific instructions on how to: handle clinical specimens; log specimens in a study register; label specimens; separate and aliquot serum specimens; perform tests; fill out laboratory results sheets; and send results to the study sites and the principal investigator.

Time frame A time frame for a 12-month study period is outlined in Annex 6.

3 DATA MANAGEMENT

Data entry

Data obtained from the interviews and the results of the laboratory tests should be entered into and analysed using Epi-Info or another appropriate computer software. The principal investigator should be responsible for the development of a data entry protocol and data entry template. To minimize data entry errors, a data entry template should be developed that restricts the range of values that can be entered for any data item and requires mandatory entry for all data fields. At a minimum, 10% of the data should be double entered to review the level of data entry error. If the error is higher than 10% then data entry procedures will need to be reviewed and the accuracy of the data entry checked. This is critical because for some of the infections the absence or presence of additional positive laboratory results may have wider STI programme planning implications.

To ensure the confidentiality of the study data, access to the data should be restricted to the principal investigator and other persons nominated by him/her. Security of data can usually be controlled by having password protected access to study computer files. When not in use, the paper copies of the results and data collection forms should be kept in a locked filing cabinet in a secure room. The computer record files should be saved regularly, especially, during data entry to prevent loss of data due to technical difficulties. All computer files should be backed-up, and paper copies printed, at least once a day during data entry.

It is critical to train the data entry persons in the data entry protocol and use of the study records. The principal investigator should review the data regularly during data entry for any apparent inconsistencies, so that laboratory or data entry errors can be identified early in the study.

The results of the study should be analysed as follows for each study site:

Data analysis

(1) number and proportion of persons with positive test results for each STI and HIV;

(2) prevalence of the surveyed STI and HIV pathogens; and

(3) stratified by the population subgroup and where applicable by:

a) age - which should be stratified into equal age groups such as 5-year or 10-year age groups depending on the sample size.

b) sex

(4) where indicated odds ratios should be calculated with 95% confidence intervals and/or the chi-square tests to assess the association of variables with a particular STI.

4 LOGISTICAL SUPPORT

Transport of specimens

Specimens should be collected from the participating clinics and transported to the local laboratory on a daily basis for either testing or storage.

Laboratory opening hours

Arrangements will need to be made to coordinate the delivery of specimens with the laboratory. The timing of the collection of specimens from recruited subjects at the study site will need to be worked out to fit in with the working hours of the laboratory e.g., sampling among sex workers might be done in the evening.

Staff

The sex and professional qualifications required for staff at the study sites should be in accordance with local cultural, religious and social customs. Two clinical staff will need to be able to enrol, interview, examine and investigate study participants. In the laboratory, a senior laboratory scientist or an experienced senior laboratory officer will supervise the technician.

Reporting of results

Results should be sent out on the laboratory form given in Annex 4. One copy of the results should be kept in the laboratory and filed there, one copy should be sent to the clinic concerned and one copy should be for the Principal Investigator. The results should be sent out as they become available, or where testing is done in batches, within the week of test result availability. The results of the HIV tests (Annex 5) should not be sent to the clinics; one copy should be kept in the laboratory and one should be collected by the principal investigator.

Supplies

A list of supplies and equipment necessary for conducting the study needs to be made once study sites and sample size are confirmed. The supply requirements will vary according to the STI studied, local conditions and the testing protocol. The following gives an indication of what supplies may be needed (Table 5).

***Table 5*: List of supplies needed for STI prevalence study for a sample of 500**

Study forms	Specimen collection	Laboratory
study protocol (30)	10 ml blood tubes (1100)	microscope slides
telephone contact list of study coordinator/group	syringes (1100)	cover slips (550)
study site log book (1 per study site)	needles (550)	microscope (1)
recruitment instruction sheet (10)	latex rubber gloves (550)	oil
consent forms (550)	specula (50)	pipettes (550)
study survey form (550)	cotton wool (100)	buffer
clinical specimen collection instruction sheet (30)	sterile urine collection jars (550)	centrifuge (2)
laboratory accession protocol (10)	light source (2)	refrigerator (1)
laboratory log book (1 per laboratory)	bucket & detergent (5)	T. vaginalis PCR test as specified (550)
specimen storage and transport protocol (4)	kidney dishes (10)	HIV ELISA tests (550)
laboratory results protocol (10)	tourniquet (2)	HIV test 2nd method (40)
laboratory results forms (550)	sharps disposal (2)	RPR test (550)
HIV results forms (30)	saline & KOH	TPHA /TPA (20)
data entry forms / protocol (5)	chlamydia transport media	chlamydia PCR/LCR test as specified (550)
supplies list (2)		gonorrhoea PCR test as specified (550)
folder for blank forms (10)	retractable lancet (550)	rubber gloves
	swabs /tampons (550)	1ml serum tubes (550)

Supply of forms The principal investigator will need to supply and distribute all the forms required for the study including interview/examination forms and area specific protocols. The principal investigator will organize study forms in the appropriate language for the study site. Study sites should be supplied with good quality photocopied forms. Study sites should be supplied with approximately 10%-15% more forms than required, to allow for technical difficulties.

Checklist An organizational checklist is detailed in Annex 7 for use in conducting the study.

5 REPORT WRITING AND DISSEMINATION

The reporting of the data should be sensitive to the local community and government concerns. The type of information likely to come from the study should be discussed before conducting the study. This will help develop wider government support for the study and for the reporting of results on its completion.

Study staff as well as the population sampled should be informed of: (1) the outcome of the study once it is completed; and (2) prevention or other activities that arise from the study. This will help keep the interest of the study population and study staff and assist in the implementation of any programmes arising from the study.

There should be a report of the study design, study process, results and recommendations with a summary at the beginning of the report. The report should be accompanied by an overhead or slide set for presentation of the study.

6 BUDGET

A budget for the study will need to be prepared. The cost of the study will vary according to local conditions, sample size requirements, the number and location of study sites, STI selected for investigation, existing laboratory capacity and the costs of laboratory supplies and tests. The cost of conducting the study is made up of direct costs and indirect costs. Direct costs are any that are incurred above the normal running costs of the specific clinic (e.g. antenatal clinic). They include such costs as the study survey forms, additional tests required by the study protocol that would not be normally ordered in the clinic setting, additional treatment costs, and data related costs. Indirect costs include such things as the fixed clinic overheads or the cost of using existing laboratory equipment. Many of these costs may be supported by the local study site and may not need additional funding. An example of a study budget is given in Table 6.

***Table 6*: Example of a study budget**

Category	Item	Estimated Cost (US$)
Study team	Principal investigator and Technical Advisory Group: costs associated with meetings, planning, implementing survey-telephone/fax/stationery	1 500
Data management	Data base development, questionnaire preparation (5 hours); entry (30 hours); analysis (5 hours)	300
	Equipment computer, printer, software	NA
	Survey Report: writing, printing, dissemination	700
Staff	Training – study protocol, clinical and laboratory, data management skills	200
	Office (data entry, analysis, questionnaire preparation, collation of results)	N/A
	Clinic staff (nurse practitioners, doctors, receptionist)	100
	Laboratory (technicians, senior scientists)	100
Transportation	Laboratory specimens (500 specimens)	NA
Laboratory	Test kits, test reagents, culture medium, pipettes (550 tests)	4000
	Equipment (e.g. microscope, incubator, refrigerator, centrifuge)	N/A
	Specimen collection (transport media, swabs, serum tubes, urine jars)	500
	Testing for particular STIs (550 tests)	20 000 - 47 500
Clinic	Study site (rent)	N/A
	Study support material (data forms, consent forms, study registers, study protocol)	100
	Equipment for examination	N/A
	Blood and specimen collection instruments (speculum, syringes, needles, labels, swabs, antiseptic)	100
	Medications for treatment	300
Total		**28 000-55 500**

* Cost to be supported by existing clinic service
N/A – not applicable

ANNEXES

Annex 1

LABORATORY PROTOCOL

Selecting sampling methods and tests

In undertaking a prevalence survey, it is important to have accurate and valid laboratory based diagnoses of the STI from the collected samples. The choice of sampling methods and tests is dependent upon;

- the acceptability of the sampling method to the survey population (for example: tampon testing may not be culturally appropriate in some settings where women do not use tampons);
- the feasibility of the sampling procedures (for example: are there qualified staff at the study site to perform speculum examination and endocervical swabs?);
- the sensitivity and specificity of the proposed sample type and test in the survey population (for example endocervical or tampon specimens are the sample of choice for detecting chlamydia in females, PCR and LCR are the tests with the highest sensitivity and specificity for Chlamydia detection);
- laboratory technical capacity including the amount of handling that must be done before testing or sending it to another referral laboratory (for example: urine centrifuging, decanting and refrigeration of samples);
- the robustness of samples in transit (for example: tampons travel very well for up to a week in appropriate transport media);
- the transport involved if the specimen has to be exported. Is it considered a biosafety hazard and requiring special packaging (only the dried blood spot testing is able to be sent through the regular international post)?; and
- the funds available.

There are three main categories of samples, that are proposed for use in these STI prevalence surveys (Table 7). These are: urine, vaginal/endocervical secretions; and blood.

Table 7: Laboratory level, cost and logistics issues associated with sample type and tests used to detect pathogens responsible for STI

Pathogen	Sample	Category of test	Laboratory level - Local=L - Referral: • in country=R • outside of country=O	Issues for consideration when selecting test	Average Reagent/kit cost per test ($US)
HIV	Blood	EIA (repeat if positive)	Local	• transportation, quality control and assurance	2.00-3.00
	Dried blood spot	EIA or PCR	R or O	• training needed for collection of sample, and correct innoculation on filter paper	22.00 12.00
Treponema pallidum	Blood	RPR	Local	• transportation, quality control and assurance	0.50
		FTA-ABS MHA-TP	L, R or O	• transportation, quality control and assurance	1.50
	Blood (50µl)	Rapid immunochrom-atographic	Local	• cost, confirmatory test only	
Neisseria gonorrhoea	Urine	PCR/LCR	R or O	• local laboratory handling (urine centrifuge/decant); local laboratory storage of sample (refrigeration)	12.00
	Tampon	PCR	R or O	• sample culturally acceptable; patient self samples; local laboratory storage of sample (refrigeration)	25.00
	Endocervical swab	PCR	R or O	• local laboratory storage of sample (refrigeration); international transportation requirements	12.00
Chlamydia trachomatis	Urine	PCR/LCR	R or O	• local laboratory handling (urine centrifuge/decant); local laboratory storage of sample (refrigeration);	16.00
	Tampon	PCR	R or O	• sample culturally acceptable; patient self samples; local laboratory storage of sample (refrigeration); international transportation requirements;	25.00
	Endocervical swab	PCR	R or O	• local laboratory storage of sample (refrigeration)	16.00
Trichomonas vaginalis	Tampon	PCR	R or O	• sample culturally acceptable; local laboratory storage of sample (refrigeration); transportation requirements; sample collection, quality control	25.00
	High vaginal swab	Wet preparation	Local	• sample collection, quality control	1.00
		PCR	R or O	• local laboratory storage of sample (refrigeration)	11.00
	Vaginal swab sample	DNA detection	Local or R	• need for qualified laboratory technicians to perform the test on site	12.00

1. EIA is an enzyme Immunoassay which is a test that recognizes a complimentary antibody or antigen by immunological reaction that can then be detected.
2. Tampon is a small (absorbent material) plug used to absorb secretions or stop haemorrhage.
3. PCR - polymerase chain reaction - is a method used to amplify sequences of DNA which are then hybridized to detect the pathogen.
4. LCR - ligase chain reaction - is a method used to amplify sequences of DNA for detection of the pathogen.
5. TPHA/TPA is a specific hemagglutination assay - it should only be used as a retesting test of the positive RPRs.
6. RPR - rapid plasma reagin - is a non-treponemal test. It is a flocculation test where the reaction is visible to the laboratory technician.
7. The estimated costs are based upon reagent and specimen collection kits for laboratories.
   (more detailed information may be found in the "Laboratory Tests for the Detection of Reproductive Tract Infections" - WHO WPRO 1999

Sensitivity, Specificity, Negative Predictive Value, Positive Predictive Value

Sensitivity and specificity are measures of the ability of a test kit to accurately distinguish between infected individuals and uninfected individuals.

Sensitivity

The ***sensitivity*** of a test is the frequency with which it recognises a positive sample as reactive (that is the percent of true positives) and predicts the false negative rate. Therefore, a test kit with a high sensitivity produces few false negative results (i.e. there will be only a small number of people who, although infected, will not be detected by the test).

Specificity

The ***specificity*** of a test is the frequency with which it shows a non-reactive result in a negative sample (that is the percent of true negatives) and predicts the false positive rate. Therefore, a test with high specificity produces few false positive results (i.e. there will be only a small number of people, who although not infected, will test positive).

Negative predictive value

The ***Negative Predictive Value*** is the likelihood that a sample identified as a non-reactive (negative) by a test is truly negative .

$$\text{Negative Predictive Value} = \frac{\text{True Negatives}}{\text{True negatives + False Negatives}} \times 100$$

Positive predictive value

The ***Positive Predictive Value*** is the likelihood that a sample identified as a reactive (positive) by a test is truly positive.

$$\text{Positive Predictive Value} = \frac{\text{True Positives}}{\text{True positives + False Reactives}} \times 100$$

Generally in a: low prevalence population **True Positives <False Reactives**

high prevalence population **True Positives >False Reactives**

It is important to remember that for a given sensitivity and specificity, the probability that a test identifies the true infection status of an individual changes in accordance with the prevalence of the infection in the population studied. With increasing infection prevalence, the proportion of positive results from a test that are falsely positives decreases. At the same time, the proportion of negative results that are falsely negative increases.

For surveillance purposes the testing strategy (selection of test - incorporating only a one test or also a second confirmatory test), will depend upon the accuracy required in the survey population being tested. It is essential that rates of false reactivity (false positive tests) and positive predictive values are estimated in each testing strategy and in each survey population.

However, it should be noted that, in general, the cost of surveillance testing increases if some false results cannot be accepted.

For the HIV component of the survey, in a population with an estimated HIV prevalence of 10%, an appropriate strategy is to first test all samples with one EIA and then to re-test all reactives (positives) in a more specific test with a different principle and/or antigen. There is no need for testing reactives a third time with a different test such as the Western Blot.

Laboratory selection

Laboratory selection

Highly technical laboratory tests (for example PCR or LCR) should only be done in laboratories where they are already performed for some time and with an established quality control and assurance programmes (and not just introduced for the purpose of the survey).

Quality control means that the laboratory which is performing the tests has a programme to check its own results. The level of quality control in a proposed laboratory should be assessed individually for: specimen collection; specimen handling; specimen accession into the laboratory; testing procedures; reproducibility of results; and documentation of results.

Quality assurance mean that the laboratory performance is checked by an external agency (reference laboratory or international agency). External quality assessment involves: periodic monitoring of test quality; spot checking of identification tests; and sometimes of laboratory techniques. The WHO regional reference laboratory may support some countries with quality assurance and proficiency testing.

Preparation of a protocol for sample collection and testing

Protocol preparation

The principal investigator will be responsible for writing a locally specific laboratory protocol once a choice of sample population and tests are made. A local protocol should use the following guidelines, and should include sections on sample collection; transportation; storage; and test procedures.

On the study site: collection and transportation of laboratory specimens

Collection of samples

The type of specimens collected depends upon the specific tests being used and includes the specimens from female and male study subjects noted below.

Urine - (Males) First void (catch) urine specimen 10-50 mls (no urination previous 2 hours) should be placed in a sterile plastic urine collection jar with the lid closed (urine PCR or LCR for *Neisseria gonorrhoea*, and *Chlamydia trachomatis*).

Vaginal - (Females) For detection of *Trichomonas vagina*lis a high vaginal swab should be obtained from the posterior fornix using a cotton-wool-tipped swab. Use this swab to collect material from the vault of the vagina behind the cervix. Also twist or roll the swab against the vaginal wall 2 or 3 times ensuring that the entire circumference of the swab has touched the vaginal wall. A thin smear of the material obtained with the high vaginal swab should be made on a microscope slide or placed into the liquid transport medium/collection tube.

Endocervical swab - (Females) For PCR/LCR of *Neisseria gonorrhoea* and *Chlamydia trachomatis* an endocervical swab should be obtained. The type of swab used here will depend upon the Chlamydia test. The swab is used to collect material from inside the cervix. Insert the tip of the swab into the endocervical canal, roll it a few times to collect endocervical material, remove the swab and then place the end with the endocervical material into the special transport medium, break off the swab and leave the tip in the material and close the tube.

Self administered T swab (Tampon) (Females) for detection of *Neisseria gonorrhoea, Chlamydia trachomatis* and *Trichomonas vaginalis*. The tampon should be inserted and immediately withdrawn by the patient or the examiner and placed in provided PCR transport medium.

Blood - (Males and Females) for testing for HIV and syphilis 10 ml of venous blood should be obtained from each patient and 5 ml of the blood should be placed into one tube labelled only with the patient's age and sex and the initials of the clinic. The remaining 5 ml of blood should be placed in another tube which should be labelled with the subject's study number, the date and the initials of the clinic.

Dried Blood Spots - (Males and Females) for testing for HIV, label the filter paper to be used for collecting the sample with the patient's age and sex and the initials of the clinic. Make sure that the finger to be pierced is warm, the finger should be grasped firmly to impede blood clearance. A sterile retractable lancet should be used to pierce the skin. Droplets of blood should be directly applied to the labelled filter paper filling the designated areas completely or the blood should be collected into unsealed microhemocrit tubes and applied to the filter paper in a circular (spiral) motion from the centre of the spot.

Sample handling

Every afternoon all samples that have been collected during the day should be transported to the participating laboratory. New collection kits and any other materials that are required should be brought in. Supplies should be replenished as necessary.

Laboratory accession

Each sample will need to be logged in (accession) a laboratory register and processed on reaching the laboratory. Specimens should be stored correctly as soon as possible and not be left lying on tables for long periods of time.

Laboratory tests

The type of tests to be carried out at the laboratory are dependent upon which specimens and what tests are being used in the prevalence survey. The instructions of the manufacturers of the specific test kits should be followed.

Urine: urine should either be refrigerated immediately awaiting transportation to a referral laboratory or should be centrifuged, extracted, and pellets decanted into a buffer for refrigerated storage and transportation. A PCR or LCR test for *Chlamydia trachomatis* and *N.gonorrhoea* should be carried out.

High Vaginal/Vaginal: if detection of *Trichomonas vaginalis* is made using a wet preparation, a fresh wet mount of fluid (preparation) should be made from the liquid medium in which the high vaginal swab was placed. A search should be made for motile *Trichomonas vaginalis* using a microscope under low power (x 400). Otherwise (DNA detection), the Vaginal swab will be broken in the collection tube and sent to the laboratory within one hour is stored at room temperature or 4 hours at 2-8 C. In case of PCR test for the detection of *Trichomonas vaginalis*, the swab should be refrigerated immediately awaiting transportation to the referral laboratory.

Tampon: the tampon should be refrigerated immediately awaiting transportation to a referral laboratory. A PCR test for *Chlamydia trachomatis*, *Trichomonas vaginalis* and *N.gonorrhoea* should be carried out at the referral laboratory. The test should be carried out according to the manufacturer's guidelines.

Endocervical swab: the swab should be refrigerated immediately awaiting transportation to a referral laboratory. A PCR test for detection of *Chlamydia trachomatis* and *N. gonorrhoea* will be performed on cervical material obtained according to the manufacturer's guidelines.

Blood: the blood should be centrifuged and have the serum separated off for storage and transportation. A rapid plasma reagin test will be performed on all sera. If reactive, the sera should be tested with *Treponema pallidum* haemagglutination assay.

The second blood specimen (marked with the patient's age and clinic identifier) should be tested for HIV antibodies using an ELISA (rapid) method. On receipt of the specimens at the laboratory the tubes of blood should be spun down and the serum should be collected and aliquots should be stored frozen. On the serum obtained from this tube an HIV ELISA test should be carried out. If this is positive, a second HIV ELISA test based on a different principle should be done. The national recommended algorithm for the laboratory testing for HIV antibody should be used.

Dried Blood Spot: the blood spot filter should be air dried for 3 hours until the blood is dry. The sample is then placed into a labelled plastic bag with a silica desiccant pack or folded into an individual stiff paper folder depending upon the requirements of the testing laboratory for transport to the laboratory.

Reporting of results

Results of tests should be reported according to the results sheets as shown in Annex 4. Except for the results of the HIV test, one copy should be delivered to the clinic concerned, the original kept by the testing laboratory and another copy sent to the Principal Investigator. The transportation of results by mail or by some type of courier will be determined by the TAG. The local study site coordinator will be responsible for this and a log book should be kept of results being sent out.

The results of the HIV tests (Annex 5) should not be sent to the clinics but should be collected by the principal investigator. The HIV results should be completely unlinked and anonymous.

Transportation of specimen

Local transportation of samples to the laboratory on a minimum of daily basis is required. Transport of samples must be in a biosafe manner and appropriate environment (e.g. refrigerated) as specified by the test instructions.

If samples are being tested within a country, samples should be transported to the laboratory on a weekly basis is required. Ability to transport the samples in a biosafe manner and appropriate environment (e.g. refrigerated) as specified by the test instructions.

If samples are being tested in another country, and are being sent by air, packaging and transport should comply with International Air Transport Association (IATA) guidelines for transportation of diagnostics specimens. Blood, urine, cervical and tampon samples are all classified as biological products and diagnostic specimens for the purposes of international transportation by aircraft. As such have stringent packaging, documentation, and custom requirements. The final authority of whether specimens are transported on the day is made by the captain of the aircraft.

Annex 2

INTERVIEWS, EXAMINATIONS, AND TAKING LABORATORY SPECIMENS

The principal investigator in consultation with the TAG will refine the study protocol to suit the local conditions. This is one format the study may take.

Introduction

Introduction

This study should be conducted with attention to all details. At the study site there are three tasks to perform:

- recruiting study participants;
- interviewing and examining the patient; and
- taking the correct specimens.

Recruiting study participants

Recruiting study participants

All women attending for antenatal care for the first time during this pregnancy and all women and men (who satisfy the study inclusion criteria) attending the public or private study sites for the first time are potential study subjects. Explain to each potential participant that this is a study of the health of women and men and obtain their consent to participate. It is important that consent is obtained in a private and confidential manner. Enrol patients consecutively as they come to the clinics. Remember patients should be enrolled on the first visit. If a patient has visited the clinic earlier for this pregnancy or this episode of illness (e.g. follow-up or result visit), do not enrol her or him in this study.

Interviewing and examining study participants

Interviewing and examining study participants

All women and men who agree to take part in the study will need to be interviewed and their responses entered in the interview form shown in Annex 3. After the patient has been interviewed he/she will need to be examined and the findings recorded in the patients clinical record. We shall discuss these two areas further.

Interviewing participants

Look at the form in Annex 3. The section on interview has six questions and each has to be answered. Questions 1 to 4 relate to the study number, the date the patient was admitted into the study and examined, the clinic number and the patient's clinic number as issued by the clinic registration clerk. Do not enter the patient's name anywhere on the form. Look at each individual question now.

All sample materials should be ready and labelled before patients are examined. Two staff members should be attending to each study subject. Study questions should be asked, all the forms should be filled out correctly and all the specimens should be taken. The staff team should double check all steps in completing the study form and tasks.

(1) Study number

Study number

This question is for the study number. Indicate the clinic number. The first patient to be recruited in clinic 1 will be number 01 001. Write this number in the spaces provided as follows:

0	1		0	0	1
(clinic number)					

You should write clearly. Remember this number will be entered on every sheet of paper related to this study subject and also on all the sample tubes (urine collection jar, swab containers, microscope slide and blood tubes)

NOTE: If unlinked anonymous HIV testing is being used then this number will not be written on the second blood tube which will be tested for HIV. The only information that will appear on the HIV blood tube will be the patient's age, sex and the clinic identifier.

(2) Date

Date

The second question relates to the date the patient was examined and samples taken. Write the date in the spaces provided. Enter the day, the month and the year in TWO digits. The date SECOND MAY 1998 is entered as follows:

Day	0	2	Month	0	5	Year	9	8

(3) Clinic Name

Clinic name

In question 3, write out clearly the name of the clinic.

(4) Clinic Number

Registration number/ record number

In question 4 look at the patient's clinic records number and write the number in the spaces provided. A clinic registration or records number of EF 111 will be entered as follows:

E	F	1	1	1

(5) Age

Age

In question 5 enter the patient's age on their last birthday. No patients under the age of 15 nor over the age of 49 will participate in the study. A number with two digits will be entered in this space. The age 25 years will be entered as follows:

2	5

(6) Sex

Sex

In question 6 enter the patient's sex. Put a cross in the appropriate box for the sex of the patient. If the sex was male it will be entered as follows:

Male [X] Female [ ]

Examining participants

The principal investigator and TAG should modify the examination protocol depending upon local customs, culture and other relevant conditions. All study sites must ensure the privacy of study participants during the examination. The suitability of health care workers examining patients of the opposite sex will be decided, taking into account cultural issues, by the principal investigator and TAG. A male health worker should be accompanied by a female member of staff when interviewing and examining a female patient.

Before the examination is started, the staff should check the interview form to see if anything has been left out. The staff should check that the study number is written on all forms. Except for the blood tube in which blood will be sent for HIV testing, all specimen bottles, tubes, slide, and swab bottles must have the study number, clinic initials and date written on each item.

	Female	
Preparing for examination	(i)	A female patient should be asked to remove her clothes so that she is undressed from the chest down. She does not need to take off all her clothes. The health worker should explain that he or she will carry out an examination on the patient and this will include an internal examination as well.
	(ii)	The patient should be comfortable and the room should be well illuminated.
	(iii)	Make sure that the speculum and the light source are ready for the examination.
Examination	(i)	The examination should be carried out (including a genital examination) according to presenting history, symptoms and signs.
	(ii)	The health worker should inform the patient what is being done during the examination.
Taking the correct specimens	(i)	The health worker should use a cotton-wool-tipped swab (swab No.1) to make a thin smear of material on a microscope slide, and should then break the swab head into the Diamond agarless medium. Discard this swab.
	(ii)	The health worker should then take a swab (swab No. 2) from the cervix (endocervical) canal. This swab should be placed in the appropriate transport medium for the selected LCR or PCR test. The speculum should now be removed and dropped into the antiseptic filled bucket. Alternatively if a tampon is being used then the tampon should be inserted and removed immediately by the patient (whilst they are alone in the examination room before any speculum examination and then they should be examined according to the local study protocol).
	(iii)	The patient may now be asked to get dressed and sit on a chair.
	(iv)	Blood will now need to be drawn by the health worker from the patient. About 10 ml blood will need to be collected from the patient. Place half this amount into a tube labelled with the patient's study number. For unlinked anonymous testing place the rest of the blood into another tube which is marked only with the patient's age, sex and the clinic identifier.

	Male
Preparing for examination	(i) The male patient should be asked to pull down his trousers/shorts so that he is undressed from the chest down. He does not need to take off all his clothes. Make sure that the patient is comfortable and that the room is well illuminated.
Examination	(i) The health worker should explain to the patient that he will now be examined.
	(ii) The health worker should inform the patient what is being done during the examination.
Taking the correct specimens	(i) The health worker will need to collect about 10 ml blood from the patient. Place half this amount into a tube labelled with the patient's study number. For unlinked anonymous testing place the rest of the blood into another tube which is marked only with the patient's age, sex and the clinic identifier.
	(ii) The patient should be given a sterile plastic jar and asked for a first void urine, that is to urinate their first pass urine directly into the jar (about 20ml) and to bring it back to the health worker.

Diagnosis

Any abnormal findings and syndromic diagnosis of an STI should be written in the patient's clinic notes.

Treatment

Once the examination of the patient is completed, and a diagnosis made, treatment should be carried out immediately according to the national syndromic case management guidelines.

Follow-up

The patient should be asked to return in one week's time for his/her results. The laboratory results should then be available. The patient should be informed of these results, and provided with any additional needed treatment.

Annex 3

SURVEY STUDY FORM

STI Prevalence Survey Study Form

(Clinic Number)

1. Study Number ☐☐ ☐☐☐

2. Date Specimens Collected Day ☐☐ Month ☐☐ Year ☐☐

3. Clinic Name _____

4. Registration Card Number/Record Number ☐☐☐☐☐

5. Age Years ☐☐

6. Sex Place an X in the box for the sex of the patient. Male ☐ Female ☐

Thank you for completing the form. Please check that there is an answer for every question.

Annex 4

PATIENT TEST RESULTS

Patient Test Results STI Prevalence Survey

1. Study Number ☐☐ ☐ ☐☐ (Clinic Number)
2. Clinic Name _____
3. Registration Card Number/Record Number ☐☐ ☐☐
4. Date Specimens Collected Day ☐☐ Month ☐☐ Year ☐☐
5. Date Report Sent Out Day ☐☐ Month ☐☐ Year ☐☐
6. T. vaginalis (wet mount) Positive ☐ Negative ☐
7. T. vaginalis PCR (tampon) Positive ☐ Negative ☐
8. N. gonorrhoea PCR (urine) Positive ☐ Negative ☐
9. N. gonorrhoea PCR (cervical/tampon) Positive ☐ Negative ☐
10. Chlamydia PCR (cervical/tampon) Positive ☐ Negative ☐
11. Chlamydia PCR (urine) Positive ☐ Negative ☐
12. Syphilis RPR Positive ☐ Negative ☐
13. Syphilis TPHA/TPA Positive ☐ Negative ☐

Annex 5

HIV TEST RESULTS

HIV Test Results

Clinic Month Year

Age	Sex	First Test Result	Second Test Result

Timeline – STI Prevalence Study

	Months												
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Appoint Principal Investigator	/----------/												
Convene Technical Advisory Group	/----------/												
Refine study protocol			/----------/										
Appoint Study Site Coordinator			/----------/										
Identify laboratories			/----------/										
Study supplies equipment medicine tests					/----------/								
Training						/----------/							
Questionnaires, study protocols (translated)					/----------/								
Survey period							/----------/						
Laboratory tests							/----------/						
Data entry								/----------/					
Data analysis										/----------/			
Report writing										/----------/			
Report dissemination													/---/

Annex 7

STUDY CHECKLIST

Checklist for Conducting STI Prevalence Survey

Specific Task	Task Completed Yes/No
Convene Technical Advisory Group	
Refine study protocol	
Identify study population	
Identify study site, do site visit	
Identify type of samples and tests	
Calculate sample size	
Appoint Study Site Coordinator	
Identify laboratory, do site visits	
Organize referral laboratory, technical assistance	
Identify other study personnel	
Order supplies, equipment, medicine tests	
Organize training	
Study protocols, study data form (translated)	
Training workshop, delivery of supplies to study site	
Recruitment	
Survey period visit study site/laboratory	
Review supplies, recruitment, laboratory logistics	
Survey (halfway date) review progress	
Data entry	
Data analysis	
Report writing	
Report dissemination	

Annex 8

Consent form for antenatal mothers

This study is designed to find out how many antenatal mothers have a sexually transmitted infection (gonorrhoea, chlamydia, syphilis or trichomonas). If you have an infection it may give rise to serious pelvic infection, infertility, pregnancy complications and infections in new born babies. However, these infections can be treated and complications prevented by early treatment. This study is also designed to find out how many antenatal mothers have HIV. This test will not have your name or IC number on it.

It is your choice whether you participate in the study or not. If you do your results will be kept private and confidential. You will be asked to wash your hands and then pass urine into a paper cup. You will also be asked to take a swab and wipe it around the wall in the lower part of your vagina. The nurse can explain how to do this. The nurse will also take a blood sample. These will be sent to the laboratory. If any of these tests are positive you will receive treatment.

We would greatly appreciate your participation but you will not be compensated in any way for your participation. Your refusal to participate will not affect future treatment in any way.

I have read the foregoing information / The foregoing information has been read to me.

I have had the opportunity to ask questions about it and the questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Date _____

Signature _____

Name _____

IC No _____

Consent form for people attending private clinics

This study is designed to find out how many sex workers have a sexually transmitted infection. The study is testing for four infections (gonorrhoea, chlamydia, syphilis and trichomonas). If you are a woman and have an infection it may give rise to serious pelvic infection, infertility, pregnancy complications and infections in new born babies. If you are a man or transexual you may pass these infections on to sexual partners and they may also increase your risk of getting HIV. However, some of these infections can be treated and complications prevented by early treatment.

If you participate in the study these results will be confidential and the treatment will be free.

This study is also designed to find out how many sex workers in Kuala Lumpur have HIV. This test will not have your name or IC number on it. Nobody will know if you have HIV or not. The doctor will not know, the laboratory will not know, the Ministry of Health will not know, you will not know. The Ministry of Health only wants to know numbers not names.

It is your choice whether you participate in the study or not. If you do your results will be kept private and confidential. You will be asked to wash your hands and then pass urine into a paper cup. If you are a woman you will also be asked to take a swab and wipe it around the wall in the lower part of your vagina. The doctor or nurse can explain how to do this. The doctor or nurse will also take a blood sample. These will be sent to the laboratory. If any of these tests are positive you will receive treatment.

We would greatly appreciate your participation but you will not be compensated in any way for your participation. Your refusal to participate will not affect future treatment in any way.

I have read the foregoing information / The foregoing information has been read to me.

I have had the opportunity to ask questions about it and the questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Date _____

Signature _____

Name _____

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