



World Health
Organization



**Standard protocol
to assess the prevalence
of gonorrhoea and
chlamydia among
pregnant women in
antenatal care clinics**



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Acronyms and abbreviations



ANC	antenatal care
CI	confidence interval
CT	<i>Chlamydia trachomatis</i>
NG	<i>Neisseria gonorrhoeae</i>
HPV	human papillomavirus
NAAT	nucleic acid amplification test
MSM	men who have sex with men
NGO	nongovernmental organization
PCR	polymerase chain reaction
PPV	positive predictive value
SDGs	Sustainable Development Goals
STI	sexually transmitted infection
TAG	technical advisory group
WHO	World Health Organization

Introduction

Around the world, more than 1 million sexually transmitted infections (STIs) occur each day. Some viral STIs, such as those due to human papillomavirus (HPV) and HIV, are still incurable and can be deadly, but some bacterial STIs – such as chlamydia, gonorrhoea, syphilis and trichomoniasis – are curable.

To address this global and critical issue, and to enable countries to reach the targets set by the Sustainable Development Goals (SDGs), the World Health Organization (WHO) developed the *Global health sector strategy on sexually transmitted infections, 2016–2021 (Global STI Strategy)*.¹

The *Global STI Strategy* positions the health sector response to STI epidemics as critical to the achievement of universal health coverage – one of the key health targets of the SDGs identified in the 2030 Agenda for Sustainable Development.

The *Global STI Strategy* describes priority actions for countries so that they can mount a stronger and more effective STI response that will help save millions of lives and improve the health of millions more. Global targets for 2030 include: (1) a 90% reduction in incidence of gonorrhoea and (2) syphilis; (3) the elimination of mother-to-child transmission of syphilis (defined as <50 infant cases/100 000 live births) and (4) 90% national coverage of HPV vaccination among girls to prevent cervical cancer. The range of actions includes strengthening data monitoring, STI prevention, early diagnosis, patient and partner management, improving syphilis screening and treatment in antenatal care (ANC), monitoring antimicrobial resistance in *Neisseria gonorrhoeae* isolates, expanded HPV vaccine coverage, as well as approaches to reach the most vulnerable populations to deliver STI services.

Five strategic directions underpin the *Global STI Strategy*:

1. Information for focused action
2. Interventions for impact
3. Delivering for equity
4. Financing for sustainability
5. Innovation for acceleration.

Strategic direction 1 – Information for focused action – has the goal of strengthening countries' information about STIs. This is needed in order to estimate the size of the burden and impact on health, plan adequate strategies, and evaluate the progress and outcomes of public health interventions.

One of the three focus areas of the *Global STI Strategy* is *Neisseria gonorrhoeae* infection because of the bacteria's increasing resistance to treatment and the risk of coinfection with other STIs. Gonorrhoea and chlamydia are causes of infertility; these infections can increase a person's risk of acquiring or transmitting HIV, and cause adverse pregnancy and infant health outcomes such as ectopic pregnancy, low birth weight, preterm birth, neonatal conjunctivitis and neonatal pneumonia. A 90% reduction in the incidence of gonorrhoea globally (from the 2018 global baseline) is among the global elimination targets and milestones for 2030.¹

Development of national, regional and global gonorrhoea and chlamydia estimates requires quality input from well-developed prevalence studies. At the national level, knowledge of the prevalence of infection with *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT) will complement the other key elements of STI surveillance, permitting a more complete measure of the national burden.

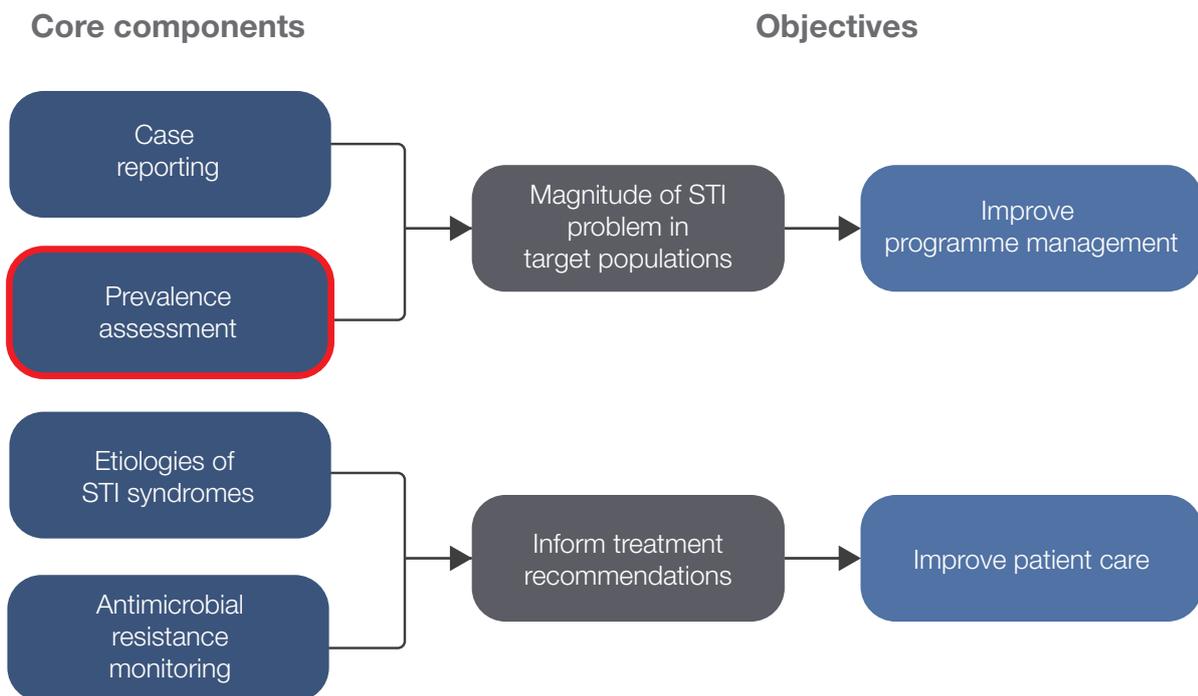
Suggested Annex 1: Add key points of the national STI strategy, including national prevalence or incidence targets if available.

¹ Global health sector strategy on sexually transmitted infections 2016–2021; towards ending STIs. Geneva: WHO; 2016 (<http://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16.09-eng.pdf?sequence=1>, accessed 24 August 2018).

Background

The objectives of STI surveillance are: (1) to measure the magnitude of the STI burden in the general and target populations to assist in programme planning; (2) to monitor trends over time and identify emerging infections and outbreaks; (3) to provide data to advocate for mobilization of resources; and (4) to assist in evaluating the effectiveness of the response. Prevalence assessment is one of the four core components of WHO-recommended STI surveillance programming (Fig. 1).²

Fig. 1. Core components and objectives of STI surveillance



Source: A tool for strengthening STI surveillance at the country level. Geneva: WHO; 2015 (<http://www.who.int/reproductivehealth/publications/rtis/sti-surveillance/en/>, accessed 21 August 2018).

Information about assessment of and trends in STI prevalence – whether, and by how much, the prevalence is increasing or decreasing and which populations are affected – can help a country monitor its epidemic and provide information on the effectiveness of prevention and control measures. Trends in STI prevalence are monitored through surveillance activities.

Prevalence is usually assessed from populations that are more or less representative of the general population (such as pregnant women), as well as populations considered to be at high risk of infection and transmission (sex workers, men who have sex with men [MSM], adolescents). An STI prevalence assessment is a determination of the number of persons infected with an STI among persons screened in defined populations. Conducting surveys among general populations is a core STI surveillance activity, which will provide input for national-level STI prevalence estimates and contribute, together with case reporting, to informing trends. National- and local-level data on STI trends are needed to inform programme planning and patient-level service improvement (Fig. 1).

Many countries have minimal information on the burden of STIs among the general population. Available data may be in the form of STI case reports, which are known to drastically underestimate the STI burden due to limited access to STI diagnostic services and underreporting of STI cases by providers. STI prevalence studies among the general population are the key data input for use in

² A tool for strengthening STI surveillance at the country level. Geneva: WHO; 2015 (<http://www.who.int/reproductivehealth/publications/rtis/sti-surveillance/en/>, accessed 21 August 2018).

analyses to estimate the STI burden. There are few groups that represent the general population and that have access to routine STI screening services.

Pregnant women are considered a good proxy for the general population. Most use ANC clinic services during their pregnancies and, in that context, clinical specimens may be collected for laboratory testing of *NG* and *CT*. Basic demographic information collected as part of a prevalence survey is then paired with laboratory results for analysis of prevalence. The prevalence rate is a measure of the frequency of existing disease at a given time in a specific population, and is defined as: $P = \text{total number of cases of disease at a given time} / \text{total population at the same time}$. This prevalence protocol can be modified to suit local needs and capacity.

Presently, knowledge of *NG* and *CT* prevalence is scarce in most countries, leading to a lack of interventions to address these largely asymptomatic infections. It must be pointed out that the aim of this protocol is to enhance surveillance and not to provide clinical care. However, better surveillance data can be used to guide clinical systems in enhancing STI testing services for pregnant women as well as other populations. Further studies will be needed to explore the most cost-effective *NG* and *CT* screening and treatment strategies at the national and local levels.

Suggested Annex 2: **Add main characteristics of national STI surveillance programme, including STI case report, prevalence and incidence data by year and infection.**

Purpose of the protocol



This document has been designed to provide a framework to support local and national STI prevalence studies. The aim of these studies is to understand the burden of disease of *NG* and *CT*, two priority STIs that can cause adverse birth outcomes. For this, the objective is to epidemiologically describe the prevalence of these two infections among pregnant women and, by proxy, the general population in the country.

Given the frequently asymptomatic nature of these infections, it is difficult to understand the true burden of disease without conducting prevalence assessments. There is a general lack of data on *NG* and *CT* at the local and national levels, and the burden in the general population is frequently unknown. Pregnant women in many cases are used as a proxy for the general population. Chlamydial and gonococcal infections, if left untreated among pregnant women, can lead to serious adverse birth outcomes such as prematurity and low birth weight. Also, because the incidence of these infections is highest among adolescents and young adults, screening efforts have focused on this age group.

This protocol describes a standardized survey methodology and uses a simple, reliable and reproducible study design that can be widely replicated and implemented at the local level.

Objectives

The objectives of an *NG* and *CT* prevalence survey are as follows:

- to epidemiologically describe the prevalence of *NG* and *CT* in pregnant women (or other specific population subgroups);
- to provide a basis for monitoring trends in and the impact of STI prevention and control efforts;
- to provide input to develop national prevalence estimates for *NG* and *CT*.

Additionally, in some situations, the study may strengthen:

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

The main users of the protocol are:

- the national STI programme; coordination will usually be done by those responsible for STI surveillance in the country;
- other institutions with research capacity and good understanding of the epidemiological surveillance of STI and in close collaboration with the national STI programme.

Intended use and adaptation of the protocol

This protocol aims to fill an existing gap in the collection of strategic information on STIs at the national level. Studies to determine the prevalence of *NG* and *CT* infections can support programme actions by providing information on the population burden and supporting prevalence and incidence estimates. *NG* prevalence assessments can be used to evaluate the population-based risk of antimicrobial resistance alongside laboratory surveillance for resistant *NG* isolates. Prevalence and incidence estimates are needed for advocacy, planning and monitoring the impact of the national public health response to STIs.

WHO recommends the routine performance (every 2–3 years) of STI prevalence assessments to allow estimation of the national burden of STIs within the general population. This protocol describes a standard method of performing a prevalence survey for *CT* and *NG* among pregnant women attending ANC clinics. STI prevalence among pregnant women can be used as a proxy for general populations.

WHO recommends syphilis screening for all pregnant women at least once during pregnancy to prevent adverse birth outcomes caused by congenital syphilis (stillbirth, neonatal death, prematurity, low birth weight, congenital anomalies).³ For countries that do not provide routine syphilis screening in ANC, this protocol can be used to periodically evaluate syphilis prevalence.

This protocol can be adapted for prevalence assessments of other sexually transmitted and reproductive tract infections in pregnant women including, but not limited to, trichomoniasis, herpes, bacterial vaginosis and HPV.

In addition, this protocol can also be considered for adaptation for use within other clinical settings and among other general adult populations. For example, this protocol could be adapted for STI prevalence assessments among women attending family planning clinics. STI prevalence data among general populations of men are limited. This protocol can be considered for adaptation to assess STI prevalence in populations of men such as military recruits.

WHO also recommends STI prevalence assessments among populations that are at high risk of acquiring STIs. Some of these populations include: adolescents, MSM and sex workers. Elements of this protocol could be considered by countries or subnational health programmes planning STI prevalence assessments among these populations.

3 WHO guideline on syphilis screening and treatment for pregnant women. Geneva: World Health Organization; 2017.

Ethical considerations in conducting prevalence studies



The basic principles of ethical medical research in human subjects should be applied to STI prevalence studies: persons should be respected, the endeavour should provide benefits – if not to the individual, to the population – and no harm should be done.⁴ However, not all medical concerns are public health concerns. The field of public health focuses on populations rather than individuals, and on preventive efforts rather than curative ones. National STI programmes should review and incorporate the basic principles of both medical and public health ethics in developing protocols for *NG/CT* prevalence studies. A national ethics committee should review the protocol to ensure that it respects and meets the country's national ethics code and evaluate the study as one conducted for surveillance purposes and not research.

Potential harms and risks to participants should be well described in consent forms, particularly when patients might not otherwise learn of a diagnosis of *CT* and *NG* through routine ANC. Although surveillance studies may be deemed non-research, the study staff have the responsibility to clearly describe how the data will be shared and for what purpose. It can be explained that the data will help to understand the burden of these infections within the country and local area. Countries should submit prevalence survey proposals to local and/or national ethics committees and, where these do not exist, should contact the WHO regional office for consideration of a regional-level ethics review. National ethics committees should be aware of any special considerations related to consenting and conducting disease surveillance studies among emancipated minors, ethnic minorities and indigenous populations.

⁴ Declaration of Helsinki, revised October 2000. Edinburgh, Scotland: World Medical Association; 2000 (<https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-oct2000>, accessed 24 August 2018).

Protocol

Studies based on women attending public ANC clinics provide ready access to sexually active women from the general population who are not using contraceptive methods. In most resource-constrained countries, pregnant women are likely to visit an ANC clinic at least once during their pregnancy, especially in more urban settings. Conducting STI prevalence surveys among pregnant women requires that operational procedures be documented in a protocol where they are described in detail.

The following are important operational procedures to include in the protocol:

- Selection criteria for sites (including the number of sites and location)
- Patient eligibility criteria
- Use of data collection forms
- Data and specimen collection (local and national levels)
- Laboratory-based testing (*Neisseria gonorrhoeae* and *Chlamydia trachomatis*) (in addition to HIV and syphilis testing)
- Supervision of operations (local and national levels)
- Data analysis and dissemination
- Budgeting.

Surveillance staff at the national level should tailor the protocol in accordance with the country context, and a national institutional ethics committee should review the protocol before it is implemented. The local-level personnel who will conduct the survey should be trained in conducting the procedures before the survey begins. This training should include ethical principles and considerations relevant to the protocol.

Sampling

Sampling is the process of selecting and surveying a small part of a larger population to determine the characteristics (e.g. *NG* and *CT* prevalence) of the larger population. Different sampling methods can be used in surveys. The success of the survey will depend on the sampling method used, good organization and records, and good judgement. It is important to find the appropriate sampling method while considering the limitations, such as human and financial resources and time.

Before *NG* and *CT* surveys are conducted, the sentinel sites and populations (e.g. pregnant women attending ANC clinics) for inclusion in the survey must be selected. The sampling method will depend on the purpose of the study, and will affect the design of the survey and the analysis of data from the survey; specifically, what analyses can be performed, whether data must be weighted, the utility of the data, and how the data should be interpreted.

Either probability or non-probability sampling can be used to select a sample. In probability sampling, random sampling methods are used to determine which population members are chosen. Each population member has a known and non-zero probability of being selected in the sample.

Examples of probability sampling include simple random sampling, stratified sampling, systematic random sampling and cluster sampling with probability proportional to size. In non-probability sampling, subjective judgement, convenience or quota are used to determine which population members are included in the sample.

In the first case (probability sampling), the procedure ensures equal (random) opportunity for subjects to be selected. It is more complex but ensures better representation of the studied populations. In

the second case (non-probability sampling), the subjects are chosen based on convenience and may, depending on the study, introduce bias in the results.

Sampling is usually performed in two phases (multistage sampling):

Phase 1: selection of the sample of ANC clinics

Phase 2: selection of the sample of pregnant women attending the selected ANC clinics.

Phase 1: Sampling antenatal care clinics

The selected ANC clinics should be able to obtain the sample size needed for the survey, and also provide a national picture of the epidemic. This entails obtaining information from:

- different geographical locations, including those that have areas with a high risk of HIV/STI infections (e.g. borders, transport corridors);
- areas with different population densities and sizes;
- both urban and rural clinics;
- women from different socioeconomic strata;
- women from younger age groups (18–24 years).

There can be two approaches to clinic sampling.

- A. *Sentinel surveillance*. Where several sites (non-representative of the full country or area) are selected, the prevalence at each site should be monitored periodically. Data are representative only of each site.
- B. *Cross-sectional national/subnational survey*. Select a representative sample of sites (possibly weighted by the number of ANC clinic attendees) to obtain a representative national/subnational prevalence figure.⁵

Approach A

In this approach, it may be preferable to start with a small number of urban sites accessed by a large number of pregnant women. As both financial and human resources permit, additional sites can be added, leading to enhanced coverage of different geographical areas, and both urban and rural areas. No matter how clinics are selected, if at all possible, they should be included in the sample each year the survey is conducted so that reliable trend data may be obtained over time.

Suggested Annex 3: Describe the national structure of ANC clinics and main functioning elements.

Once the sites have been selected, information concerning the specific characteristics of each site should be gathered before commencing the survey. Information on the number of pregnant women who access the clinic per month, a description of the site's geographical catchment area, general characteristics of the clinic population, such as age distribution and residence (rural, semiurban, urban) will be helpful during interpretation of the survey findings.

The following information on site-specific characteristics should be gathered for each of the selected sites:

- number of patients per month as well as proportion who are repeat visitors
- age distribution of clients
- geographical locality of the clinic (urban, semiurban, rural)

⁵ Sexually transmitted infections prevalence study methodology. Guidelines for the implementation of STI prevalence surveys. Manila: WHO Regional Office for the Western Pacific; 1999 (http://www.wpro.who.int/hiv/documents/docs/Guidelines_for_the_Implementation_of_STI_Prevalence_Surveys.pdf, accessed 31 August 2018).

- residence of the clinic population (urban, semiurban, rural)
- description of services provided at the clinic (family planning, voluntary counselling and testing, prevention of mother-to-child transmission).

Suggested Annex 4: **Describe the characteristics of participating clinics.**

Approach B

Develop the sampling frame from a list of ANC clinic sites. ANC clinic sites can be selected randomly or stratified according to various criteria (e.g. urban, rural). The number of pregnant women sampled from each site can be determined based on the number of women who usually attend the site in a given time period (probability proportional to size).⁶

Phase 2: Sampling pregnant women attending the selected ANC clinics

After the sample of ANC clinics has been selected, a sample of pregnant women at each of the sampled ANC clinics should be selected based on inclusion and exclusion criteria. Consecutive sampling (a type of convenience sampling) is recommended to select the women whose specimens will be tested for *NG* and *CT*.

Consecutive sampling has several advantages:

- It facilitates the process of obtaining a sufficient sample size in a given time frame.
- It is convenient, feasible and easy to employ.
- It reduces the likelihood of selection bias introduced by on-site personnel.

With consecutive sampling, the first eligible pregnant woman and each subsequent eligible pregnant woman attending the clinic during the survey period thereafter are included in the survey until the desired sample size is achieved or until the survey period ends. Site personnel should consult the intake registry to ensure that pregnant women who meet the inclusion criteria and who have provided consent are consecutively selected, and test specimens are collected from these women for *NG* and *CT*.

Sample size determinations

The sample size of pregnant women required for the survey must be determined, as well as the number of women per selected ANC clinic site. If the sample size is too small, the results are imprecise and of little use, and if the sample size is too large, resources are wasted. It is important to document the sample size per ANC clinic site in the protocol and in any reports that are generated from the surveillance data, especially if the data are aggregated for the analysis.

Considerations that affect the sample size are as follows:

- estimated *NG* and *CT* prevalence in a geographical area;
- accuracy needed for the prevalence estimate (width of the confidence interval [CI]);
- degree of certainty that the change in *NG* and *CT* prevalence is statistically significant (level of significance or alpha), usually 0.05;
- percentage of pregnant women eligible for inclusion in the survey. This will involve being able to estimate or determine the patient volume in the ANC clinic during the survey period;
- whether prevalence levels are to be obtained among subgroups such as younger (18–24 years) and older women;

6 Steps in applying probability proportional to size and calculating basic probability weights (http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/prevalence_survey/psws_probability_prop_size_bierrenbach.pdf, accessed 24 August 2018).

- magnitude of change in *NG* and *CT* prevalence that one wants to be able to detect (if future studies will be conducted to determine trends);
- degree of certainty that a statistically significant change, if it occurred, can be detected (power or beta), usually 0.80;
- resources available for conducting the survey (e.g. costs, logistics).

Sample sizes must be sufficiently large to provide a reasonably accurate estimate of prevalence at each sentinel site selected. The *NG* and *CT* prevalence calculated during a survey for a specific clinic is usually only an *estimate* of the true prevalence for that clinic. If a 95% CI is calculated for this estimate, a range is created within which one can be 95% confident that the true prevalence falls. The narrower the CI, the more precise and reliable the estimated prevalence will be in describing the true prevalence at the selected sentinel sites. Prevalence estimates based on small sample sizes will have wide CIs.

Sample sizes can be calculated by using published tables based on setting the CI for a given level of prevalence (from a previous survey) (Table 1), or by using statistical programs.

Table 1. Ninety-five per cent confidence intervals for observed prevalence by sample size*

Observed prevalence (%)	Sample size				
	50	100	250	500	1000
0	0–7	0–4	0–2	0–1	0–0
2	0–11	0–7	1–5	1–4	1–3
10	3–22	5–18	7–14	8–13	8–12
20	10–34	13–29	15–26	16–24	18–23
30	18–44	21–40	24–36	26–34	27–33
40	27–55	30–50	34–46	36–44	37–43
50	36–64	40–60	44–56	46–54	47–53

*Based on a binomial distribution.

Sources: Fleiss JL. Statistical methods for rates and proportions, first edition. London: John Wiley & Sons; 1981.
Snedecor GW, Cochran WG. Statistical methods, sixth edition. Ames, Iowa: The Iowa State University; 1967.

The table, which is based on 95% CIs, shows that, for a given level of observed *NG* or *CT* prevalence, 95% CIs become smaller as the sample sizes become larger. For a given sample size, the 95% CIs grow wider as the observed prevalence increases. However, the precision in the observed *NG* or *CT* prevalence increases because the variation is proportionally lower. For example, for a sample of 250 women, if the observed prevalence is 2%, the 95% CI is 1–5%; and, if the observed prevalence is 30%, the 95% CI is 24–36%. Proportionally, the 95% CI for the 2% prevalence is more than twice the prevalence, while the 95% CI is only 20% larger (or smaller) for the 30% observed prevalence, and thus provides more precise information. Therefore, in low-prevalence areas, a large sample size is needed, even if the 95% CI is small.

To use Table 1 to calculate sample size, and the observed prevalence closest to the one in the geographical area of interest, set the width of the 95% CI, and then select the sample size. If an estimate of the *NG* and *CT* prevalence for the geographical area of interest is unknown, one can use an estimate from a similar geographical area or from studies or surveys believed to be similar for that area. This table may be used to determine the minimum sample sizes needed for surveys at each sentinel site. For example, if the observed prevalence is 20% and the 95% CI is set at 15–26%, the sample size needed would be 250.

Sample size determination to monitor trends in NG and CT prevalence

Monitoring trends in NG and CT prevalence over time requires a larger sample size than does determining one estimate at one point in time. To monitor prevalence trends, national STI programme staff should select a sample size large enough for changes to be detected over several years. The smaller the increase or decrease in the estimates of prevalence over time, the larger the sample size required to detect a statistically significant change. Therefore, STI epidemiology staff must decide on the magnitude of change they wish to be able to detect and at what level of granularity (individual clinics, district or provincial level), and determine if resources allow for the increased sample size that may be needed. In concentrated and low-level epidemics, it may be very difficult and expensive to obtain a large enough sample size to detect changes over time in NG and CT prevalence at the level of a single ANC site.

Sample sizes required to detect a change (decrease or increase) in prevalence rates at a specific clinic between two survey periods are shown in Table 2. For example, if the baseline prevalence is 20%, a sample size of 197 is required to detect a 50% decline in prevalence between two time periods (from 20% to 10%).

Table 2. Sample size required for determining a significant change between two proportions*

Baseline prevalence (%)	Sample size, given % proportional change								
	10%	20%	30%	40%	50%	60%	70%	80%	90%
1	145 800	34 000	14 000	7 290	4 280	3 000	2 070	1 459	1 060
5	28 000	6 550	2 800	1 500	903	585	400	282	204
10	13 300	3 200	1 350	718	432	280	190	135	97
15	8 500	2 030	850	457	275	178	122	86	62
20	6 000	1 425	612	326	197	128	87	61	44
25	4 500	1 090	463	247	149	97	66	46	33

*With a power of 80% (beta = 0.80) and a significance level of $P < 0.05$.

Eligibility criteria

ANC clinic sites

Regardless of the sampling design used to select ANC clinics or pregnant women, programmes should specify eligibility criteria for inclusion in the survey.

Eligibility criteria for ANC clinics are as follows:

- The clinic agrees to participate and implement survey protocol.
- A pelvic examination is conducted and laboratory samples are routinely collected from clients.
- There is a reliable laboratory for processing specimens for NG and CT testing.
- The site is accessible to surveillance staff.
- On-site staff members are willing to cooperate and are trained to conduct the survey.
- The site provides services to a sufficiently large number of clients.

Pregnant women

Eligibility criteria (inclusion and exclusion) should be specified so that only women meeting the inclusion criteria will be part of the survey. Ideally, all women attending an ANC clinic should be eligible to allow for a relatively unbiased assessment of the women at the clinic. However, in reality,

eligibility should be restricted to the following recommended criteria, with national STI programme surveillance coordinators determining the eligibility criteria.

Proposed inclusion criteria for pregnant women

- Able and willing to provide consent
- Pregnant women attending the clinic for the first time during their current pregnancy during the survey period
- Pregnant women aged 18*–49 years (*or legal age of consent)
- Able and willing to provide laboratory specimens for testing.

Exclusion criteria

- Pregnant women who previously visited the clinic during the survey period (to avoid duplicate sampling)
- Pregnant women who do not give their informed consent to participate in the study.

Survey implementation

Duration

The survey duration in each ANC clinic will be determined by the time required to reach the desired sample size. Therefore, the length of the survey will depend on the following: (1) number of first-time visits by eligible pregnant women to the sentinel sites per week or month; and (2) proportion of eligible patients who agree to participate.

Although it is not possible to calculate *NG* and *CT* prevalence among ANC clinic attendees at a single point in time, the closer the sample collection period represents a single point in time, the more comparable the data are over time. Therefore, it is recommended that the survey be conducted over a period of 4–12 weeks to reach the desired sample size. In some instances, it may be necessary to extend the survey period up to an agreed-upon time for a maximum period of 4–6 months. For example, if a national STI programme has decided to use a larger sample size or if rural clinics cannot reach the desired sample size in the given period, the survey period should be extended.

Frequency

Data from sentinel surveys among pregnant women provide information for advocacy and planning/evaluating prevention programmes. Therefore, surveys should be conducted biennially in order to monitor trends, using the same methods and same sentinel sites, if feasible. It is critical to maintain a list of the clinics in which surveys were conducted and in which years they were conducted.

Options to achieve the required sample size

As a rule, surveys should not be conducted in settings where the minimum sample size cannot be achieved. National STI programmes that have not been able to achieve the desired sample size at the selected sites – most commonly in rural sites – within the suggested sampling period can use one of the three methods below to address this situation.

- *Lengthen the sampling period*

Surveillance coordinators may extend the sampling period beyond 12 weeks. If this is done, *NG* and *CT* prevalence estimates obtained will not be strictly comparable with the estimated prevalence found in sentinel sites completing the survey in the designated time frame.

- *Accept the reduced sample size*

Surveillance coordinators may accept the reduced sample sizes achieved at individual sites. If so, the CI should be calculated and reported for the observed prevalence. With smaller sample sizes, the CIs will be wider. Therefore, statistically significant changes over time will be difficult to determine. A weighted analysis would reduce the influence of this site on any provincial, regional or national estimate.

- *Aggregate data from multiple sites*

Another way to reach the desired sample size is to combine data from various sites. This can be useful in more rural areas with low population density, where none of the clinics in a district or region may have a sufficient number of women to reach the desired sample size. However, if prevalence data from three or four clinics can be combined, then a reliable measure can be obtained of the aggregate prevalence for these sites. The advantage in this approach is that smaller and more rural areas are included in the surveillance system. The limitation is that prevalence data for the individual sites (that have been combined) will not be reliable, due to the smaller sample size.

Regardless of the approach taken, it is important to document the methods used at a sentinel site and to report it to the national level so that it can be taken into consideration during analysis.

Survey personnel and training

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), adapting the study protocol to local conditions and presenting it to the research ethics committee for clearance as a surveillance and non-research study (if deemed appropriate).

The period from the inception to the organization, design, data collection, analysis and reporting is estimated to last approximately 1 year and it is important that the principal investigator be available for this period.

The principal investigator, in consultation with the national STI programme, 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).

A successful prevalence study relies on effective leadership, training of health-care workers, and quality assurance for laboratory testing, study operations and data management. In addition to an experienced principal investigator, a well-conducted study can benefit from the commitment of the Ministry of Health and donors to support collection of reliable and valid information.

Survey personnel

Personnel required for surveys include clinic staff, laboratory technicians, supervisory staff, data managers/statisticians and survey coordinators. The responsibilities of all surveillance staff members (regardless of their position in the programme) should be clearly defined in the survey protocol. Table 3 outlines the appropriate responsibilities of survey personnel.

Table 3. Appropriate responsibilities of survey personnel

Level and title	Appropriate responsibilities
Local level (clinic)	
Clinic staff	<ul style="list-style-type: none"> • Ensure that eligible women are included in the survey at the time of their first antenatal visit. • Complete data collection forms. • Provide test results and treatment to participants.
Laboratory technician	<ul style="list-style-type: none"> • Obtain and process specimens.
Supervisory staff	<ul style="list-style-type: none"> • Provide adequate oversight at the clinic and ensure confidentiality.

Level and title	Appropriate responsibilities
Regional level	
Laboratory technician	<ul style="list-style-type: none"> • Ensure provision of equipment, supplies and test kits. • Conduct <i>NG</i> and <i>CT</i> tests.
Survey coordinator	<ul style="list-style-type: none"> • Ensure provision of equipment, supplies and test kits. • Ensure adequate oversight and confidentiality at the regional level. • Ensure that training takes place for local-level staff. • Enter data in the programme's database. • Manage data. • Analyse data. • Disseminate survey findings.
National level	
Laboratory technician	<ul style="list-style-type: none"> • Ensure provision of equipment, supplies and test kits. • Conduct <i>NG</i> and <i>CT</i> tests. • Oversee quality assurance of testing procedures at regional and local levels.
Data manager/statistician	<ul style="list-style-type: none"> • Enter data in the programme's database. • Manage data. • Analyse data.
Surveillance coordinator	<ul style="list-style-type: none"> • Develop survey protocol with programme staff. • Ensure adequate funding. • Provide adequate oversight and training at the regional and national levels. • Ensure confidentiality. • Interpret findings in conjunction with regional-level survey coordinator and prepare survey report for dissemination.
National STI programme manager	<ul style="list-style-type: none"> • Have the protocol approved by the national ethics committee.

Staff required at clinic level for data collection

Staffing at the clinic level is critical to the success of prevalence surveys and should include:

- one clinic staff member (nursing supervisor or senior laboratory technician) responsible for ensuring the efficient operation of the survey and for supervising other survey staff on site;
- one clinic staff member (nurse or laboratory technician) responsible for ensuring that the data forms are complete and that samples are obtained (as well as labelled, stored properly) in preparation for transport to the testing laboratory;
- one clinic staff member trained in survey operations to assume duties in the absence of the person responsible for conducting the survey;
- a laboratory technician, if available, to assist with processing and preparing survey specimens for transport to the testing laboratory; and

- a courier. In some cases, someone from the Ministry of Health will be available to transport specimens to the testing laboratory. If not, the clinic laboratory technician may be required to do so, especially if specimens are tested in the same town or city. Commercial courier services may be used.

Suggested Annex 5: **Add the list of study locations, study staff and staff roles.**

Training of survey personnel

To conduct a survey with adequate quality and oversight, all personnel involved must be trained. This training should include all ethical aspects of the study. After appropriate individuals to conduct the survey are identified and selected at the local, regional and national levels, the national surveillance staff should conduct training before every survey. Participants at the training should include supervisors, laboratory staff and clinic staff. Training should include a review of operational procedures, field protocol and findings from previous surveys. During the training session(s), surveillance staff should have the opportunity to discuss concerns and obtain further clarification on survey operations. Training sessions may be conducted either at the site or in a central location at the regional or national level. Sessions that involve multiple staff members from each site would give staff the opportunity to share experiences from their respective sites. Training should be offered on a regular basis, and take place at least once before every round of surveillance. Maintaining motivation among survey personnel will facilitate satisfactory completion of survey activities.

Recruitment, counselling and consent of eligible participants

During the period of recruitment for the prevalence survey, patients should be approached by staff of the participating clinics and notified of the occurrence of the study and the opportunity to undergo *CT* and *NG* testing and treatment at no cost. Following explanation of the availability of *CT* and *NG* testing as part of the prevalence study, clinic staff will take patients' consent for testing. Additional locally specific details on the consent process should be provided as part of subsequent site-specific protocols.

Although the risks associated with participation in a routine prevalence study are minimal, it is important that potential risks be described to eligible participants during the recruitment and as part of the informed consent process.

1. *Risks to privacy.* Participants' attendance at study visits may be accidentally noticed by others. Efforts to maintain confidentiality should be prioritized and fully described in site-specific protocol adaptations. Participants should receive counselling and assurance that the results of testing are confidential and will not be shared outside of the prevalence survey or clinic setting.
2. *Psychological risks.* Receiving a positive chlamydia or gonorrhoea diagnosis could be upsetting to a participant. However, chlamydia and gonorrhoea diagnoses can occur as part of standard clinical care outside of this prevalence survey. Specifically, participants should be counselled on the benefits and risks of undergoing testing for these infections during pregnancy as part of the informed consent process. Participants should be counselled on the following: (1) the benefits of testing and treatment to prevent manifestations of untreated infection in mothers and infants; (2) risks associated with untreated chlamydia and gonorrhoea during pregnancy for both the mother and the infant; (3) potential emotional stress of being diagnosed with an STI; (4) the importance of treatment of sexual partners to avoid reinfection during pregnancy; and (5) the risk of disclosure to sexual partners of exposure to an STI with a resulting possibility of emotional, verbal or physical abuse, or abandonment during pregnancy. Participants should be made aware that while partner notification for treatment is important, partner notification is optional and should be considered by the patient/participant with the support of the clinic staff and according to standard clinical practice for maintaining the confidentiality of patients/participants.

3. Side-effects or adverse reactions can be experienced following antibiotic treatment for chlamydia and gonorrhoea. These are uncommon and would not be different from what might occur as part of standard clinical practice outside of the prevalence survey.

Data collection

Sociodemographic data elements

All data collected for the survey should be information that is routinely collected at the site – for example, during the registration process.

It is recommended to collect, at a minimum, the following data elements: age, education level, occupation, residence, gravidity, parity, ethnic group, and HIV and syphilis test results.

Countries may wish to include additional sociodemographic data elements (e.g. duration of stay at the present residence) on the basis of programme needs.

Sociodemographic data elements

Age (required). Prevalence trends should be monitored by age. Patients may not know their exact age, so an approximate age within a five-year range can be used. Use of a chronological list of important national and local events may aid in recall of birth dates.

Education level and occupation (optional). Education level and occupation may provide information that could be related to the use of STI services or with specific sexual risk behaviours.

Residence (required). Residence information will help to determine the catchment population at a given site (e.g. rural or urban) and will aid in the interpretation of prevalence trends.

Gravidity and parity (optional). Gravidity (total number of pregnancies) and parity (the number of full-term children borne by a woman, excluding miscarriages or abortions in early pregnancy but including stillbirths) are indicators for assessing the association between *NG* and *CT* infections and exposure to unprotected sex. For women who do not use contraceptives, the number of births tends to be a better measure of sexual exposure than a woman's age.⁷

Suggested Annex 6: Use the standard clinic protocol and add other necessary questions as needed.

Specimen collection, transport, storage and tracking

Collection

Specimens should be collected ideally following routine procedures currently implemented at the clinic site. Samples for the *NG* and *CT* diagnostic tests can be urine, or vaginal or endocervical material. To collect endocervical material, a speculum examination is necessary. Self-collected vaginal swabs are also an option. For details on sample collection, transportation and storage, see Tables 4 and 5.

Provider or self-collected vaginal swabs are the recommended specimen type for these prevalence assessments as sensitivity has been shown to be higher with this specimen type as compared to urine.

⁷ Zaba B, Boerma T, White R. Monitoring the AIDS epidemic using HIV prevalence data among young women attending antenatal clinics: prospects and problems. *AIDS*. 2000;14(11):1633–45.

Transport

Specimens not tested on site need to be transported (using recommended transport media according to sample type) to a regional or national laboratory for testing. Transport methods depend on a country's infrastructure. Frequently, field staff from the surveillance programme is responsible for transporting specimens from the local to the national level. Packaging procedures depend on the type of tests used. All biological samples should be handled using biosafety precautions (biosecurity measures).

Storage of samples

Long-term storage of biological samples is not recommended as part of this prevalence assessment. Thus, governance arrangements for biobanking and consent for long-term storage of specimens is not included as part of this protocol.

Table 4. Sample collection, transportation and storage

	Collection device	Sampling procedure	Transportation and storage
Endocervix	Swab/plastic OR endocervical brush OR assay-specific collection kit	Use a vaginal speculum and clean the ectocervix. Insert a swab 2–3 cm and rotate for 5–10 seconds.	Place into manufacturer's collection device. Transport and store according to manufacturer's instructions. If transport medium is not available from manufacturer, use appropriate transport medium to stabilize the nucleic acid, e.g. GeneLock tubes or Xpert CT/NG urine transport reagent tube).
Vagina	Swab/plastic OR assay-specific collection kit	Clinicians or patients can obtain samples. Rotate swab against posterior vaginal walls for 5 seconds.	
Urine (collected ≥1 hour after last void)	Sterile urine cup	Patient should not clean the genital area. Catch first-void urine (less than 25 mL in general).	

Tracking

To track specimens for the survey, surveillance staff should maintain a separate laboratory logbook at the testing laboratory. *NG* and *CT* test results should be recorded in this logbook by the corresponding survey code. The logbook should be accessible only to laboratory and surveillance staff, and should be secured in a locked drawer or cabinet when not in use to help ensure the confidentiality of test results.

Testing codes are linked to personal identifiers in order to facilitate the provision of test results and treatment. Strict measures must be followed so that such information is accessible only to laboratory and surveillance staff.

Laboratory testing

Testing options

The most appropriate type of test for *NG* and *CT* surveillance purposes is molecular detection of specific nucleic acid (DNA/RNA) sequences. Commercially available kits are qualitative in vitro real-time polymerase chain reaction (PCR) tests (Abbott RealTime CT/NG, Xpert CT/NG assay and Roche cobas CT/NG test) that detect both *N. gonorrhoeae* and *C. trachomatis* in the same kit and sometimes simultaneously, and often at little or no extra direct cost.

Nucleic acid amplification tests (NAATs) detect a region of the DNA or rRNA specific to *NG* or *CT*, and the region detected differs between kits (Table 5).⁸ The target sequence is amplified using a variety of methods to produce multiple copies that can be easily detected.⁹ NAATs are highly sensitive and specific (but specificity differs substantially between the various NAATs) and can be used with non-invasively taken specimens (e.g. urine in men and vaginal swabs or urine in women). This allows both a larger number of patients to be seen in a clinic or primary care setting as well as provides the prerequisites for effective screening.

Disadvantages of using NAATs include the cost of equipment and reagents, inability to perform antimicrobial susceptibility testing, and the suboptimal specificity of some NAAT assays. Despite these disadvantages, the use of appropriate NAATs is the recommended technique for *NG* and *CT* surveys. NAATs are more tolerant to inadequacies in collection, transportation and storage conditions. New NAAT assays are becoming available rapidly and it is important to continually assess the relevant literature for high-quality evaluations of new assays to determine the best fit for each laboratory.

Countries should select tests from among the recommended molecular methods according to the availability of the installed equipment and the cost of each test.

For details on the principles of molecular tests; media, reagents, diagnostics tests, stains and laboratory supplies, see:

Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Geneva: WHO; 2013 (http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf, accessed 24 August 2018).

Laboratory quality assurance

Tests with acceptable performance and operational characteristics, as specified by national and international organizations such as WHO or US CDC, should be prioritized for use (Table 5). Staff proficiency in performing the tests selected should be evaluated prior to the study. Laboratory information systems should be able to report positive and negative results back to the study coordinators. Laboratory quality assurance activities should be undertaken prior to the start of and during the prevalence study. These activities should include local laboratory verification of the performance of the testing methods.

Laboratories performing testing for chlamydia and gonorrhoea for these prevalence surveys should have national accreditation and should follow national/international standards for laboratory practices and quality assurance, including aspects of quality assurance processes such as ISO certification, and participation in quality assurance activities (<https://www.who.int/ihr/publications/lqms/en/>).

8 Papp JR, Schacter J, Gaydos CA, Van Der Pol B. Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Morbid Mortal Wkly Rep (MMWR). 2014;63(2):1–19.

9 Unemo M, Ballard R, Ison C, Lewis D, Ndowa F, Peeling R. Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Geneva: WHO; 2013 (http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf, accessed 24 August 2018).

Table 5. (US) Food and Drug Administration-cleared specimen types and requirements for the transport and storage of specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by nucleic acid amplification test (NAAT) type

FDA-cleared* NAAT	FDA-cleared* specimen types	Specimen transport and storage conditions
Abbott RealTime CT/NG (Abbott Molecular Inc, Des Plaines, IL)	Asymptomatic women: clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, and urine Asymptomatic men: urine Symptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, and urine Symptomatic men: urethral swab and urine	≤14 days at 2 to 30°C ≤90 days at -10°C or lower Thaw frozen specimens at 2 to 30°C Specimens must not undergo more than four freeze/thaw cycles
APTIMA COMBO 2 [®] Assay APTIMA [®] CT Assay APTIMA [®] GC Assay (Gen-Probe Incorporated, San Diego, CA)	Asymptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, gynaecological specimens collected in PreservCyt [™] solution and urine Asymptomatic men: urethral swab and urine Symptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, gynaecological specimens collected in PreservCyt [™] solution and urine Symptomatic men: urethral swab and urine	≤24 hours at 2 to 30°C (urine specimen in primary cup) ≤30 days at 2 to 30°C (urine specimen in Aptima urine transport tube) ≤60 days at 2 to 30°C (swab in Aptima swab transport tube) ≤12 months at -20 to -70°C (urine specimen and swab specimens in respective Aptima transport tubes)
BD ProbeTec [™] ET CT/GC Amplified DNA Assay (Becton Dickinson and Company, Sparks, MD)	Asymptomatic women: endocervical swab and urine Asymptomatic men: urethral swab and urine Symptomatic women: endocervical swab and urine Symptomatic men: urethral swab and urine	≤30 hours at 2 to 30°C (urine specimen in primary cup) ≤7 days at 2 to 8°C (urine specimen in primary cup) ≤30 days at 2 to 30°C (urine specimen in urine processing tube) ≤60 days at -20°C or lower (neat urine specimen or urine in urine processing tube) ≤6 days at 2 to 27°C (swab specimens) ≤30 days at 2 to 8°C (swab specimens)

FDA-cleared* NAAT	FDA-cleared* specimen types	Specimen transport and storage conditions
BD ProbeTec™ QX CT Amplified DNA Assay BD ProbeTec™ QX GC Amplified DNA Assay (Becton Dickinson and Company, Sparks, MD)	Asymptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, gynaecological specimens collected in BDSurePath™ or PreservCyt™ solution and urine Asymptomatic men: urethral swab and urine Symptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, gynaecological specimens collected in BDSurePath™ or PreservCyt™ solution and urine Symptomatic men: urethral swab and urine	≤30 hours at 2 to 30°C (urine specimen in primary cup) ≤7 days at 2 to 8°C (urine specimen in primary cup) ≤30 days at 2 to 30°C (urine specimen in urine processing tube) ≤180 days at -20°C or lower (neat urine specimen or urine in urine processing tube) ≤30 days at 2 to 30°C (endocervical and urethral swab specimens) ≤180 days at -20°C or lower (endocervical and urethral swab specimens) ≤14 days at 2 to 30°C (dry vaginal swab specimens) ≤30 days at 2 to 30°C (expressed vaginal swab specimens) ≤180 days at -20°C or lower (dry or expressed vaginal swab specimens)
Xpert® CT/NG Assay (Cepheid, Sunnyvale, CA)	Asymptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, and urine Asymptomatic men: urine Symptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, and urine Symptomatic men: urine	≤24 hours at room temperature (female urine specimen in primary cup) ≤3 days at room temperature (male urine specimen in primary cup) ≤8 days at 4°C (female and male urine specimen in primary cup) ≤3 days at 15 to 30°C (female urine specimen in Xpert CT/NG Urine Transport Reagent tube) ≤45 days at 2 to 15°C (female urine specimen in Xpert CT/NG Urine Transport Reagent tube) ≤45 days at 2 to 30°C (male urine specimen in Xpert CT/NG Urine Transport Reagent tube) ≤45 days at 2 to 30°C (swab in Xpert CT/NG Swab Transport Reagent tube)
cobas® CT/NG test (Roche Diagnostics, Indianapolis, IN)	Asymptomatic women: patient-collected vaginal swab in a clinical setting Asymptomatic men: urine Symptomatic women: self-collected vaginal swab in a clinical setting Symptomatic men: urine	≤1 year at 2 to 30°C (swab or urine specimen in cobas PCR media) 24 hours at 2 to 30°C (neat male urine specimen prior to addition to cobas PCR media)

* FDA-cleared NAATs and specimen types as of 1 May 2013

Source: Adapted from Papp JR, Schacter J, Gaydos CA, Van Der Pol B. Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Morbid Mortal Wkly Rep (MMWR). 2014;63(2):1–19.

Assessing prevalence based on test performance

The prevalence of *NG* and *CT* in the population being tested must be considered together with the sensitivity and specificity of the NAAT being used, as this will affect the positive predictive value (PPV) of the test and hence the number of false-positive results obtained (see Table 6). A PPV of >90% (using a single NAAT or screening NAAT plus supplementary NAAT with a different target) has been suggested as a minimum when using NAATs to detect *NG*.

It should be noted that, even when the sensitivity and specificity of a NAAT is above 95%, the PPV in a population with both 1% and 5% prevalence is, for most NAATs, still less than 90%, whereas at a prevalence of 10%, the PPV of most (but not all) NAATs is greater than 90%. This is particularly important for dual NAATs that detect both *NG* and *CT* because the prevalence of these two infections can differ markedly. In many countries, chlamydial infection is commonly detected at a considerably higher prevalence than gonorrhoea, and the algorithm for testing for both infections together may not need a supplementary test for detection of *CT*, but will require testing with a second NAAT (another target sequence) for those with positive results to *NG* to obtain acceptable PPVs. This is the case for clinical management and may not be necessary for the purpose of this survey.

NAATs may require more technical expertise; however, the sensitivity and specificity of these tests can be high. Multiplex PCR assays detecting, for example, *N. gonorrhoeae*, *C. trachomatis*, *Mycoplasma genitalium* and *Trichomonas vaginalis* have also been developed; however, these need further evaluation of their performance characteristics.

Table 6. Effect of prevalence on positive predictive value (PPV) for single tests

Tests		A	B	C
Sensitivity		97.8%	96.4%	98.0%
Specificity		99.2%	97.9%	99.7%
PPV	10% prevalence	93%	84%	97%
	5% prevalence	87%	73%	95%
	1% prevalence	55%	35%	77%

Source: Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Geneva: WHO; 2003.

Clinical care and case reporting

In this survey, test results are linked to the participants in order to deliver the appropriate treatment to those with positive results. Treatment, and all standard practice to detect participants who have positive test results, should follow national or WHO treatment guidelines for gonorrhoea and chlamydia.^{10,11}

Testing

Laboratory screening for chlamydia and gonorrhoea during ANC will be undertaken through collection of clinical specimens appropriate for the test type used and according to the package insert of the chosen test kit.

Due to the ease of collection of urine or vaginal swabs (provider- or patient-collected) as specimens for testing for chlamydia and gonorrhoea using PCR-based testing methods, it is not recommended that patients undergo a speculum examination as part of this prevalence survey. The sensitivity of

10 WHO guidelines for the treatment of *Neisseria gonorrhoeae*. Geneva: WHO; 2016 (<http://www.who.int/reproductivehealth/publications/rtis/gonorrhoea-treatment-guidelines/en/>, accessed 25 August 2018).

11 WHO guidelines for the treatment of *Chlamydia trachomatis*. Geneva: WHO; 2016 (<http://www.who.int/reproductivehealth/publications/rtis/chlamydia-treatment-guidelines/en/>, accessed 25 August 2018).

DNA-based tests for *NG* and *CT* has been shown to be higher with the use of a vaginal or cervical swab as compared to a urine specimen among women.

Confidential delivery of results of chlamydia and gonorrhoea testing

Patients testing positive for chlamydia or gonorrhoea should be confidentially notified of this result by the study staff. Patients should be asked to provide an acceptable method of contact for the confidential receipt of test results following consent and prior to testing. Study staff will ensure confidentiality by requiring patients to provide proof of identification before delivering the test results. Patients with positive test results can be notified by phone and asked to return to the clinic for results and further treatment. Study staff can provide positive results of chlamydia and gonorrhoea tests by phone or in-person once the patient has been positively identified and confidentiality assured through verification of personally identifiable information, including, but not limited to, date of birth, address, date of clinic visit and patient ID number. A private room should be used to deliver in-person test results.

Treatment

Participants diagnosed with chlamydia and gonorrhoea will undergo follow-up evaluation by clinic staff for treatment. This participant follow up will require that the patients are confidentially notified of their positive test results and asked to return to the clinic for treatment. Efforts to maintain confidentiality should be prioritized (see the next section on Confidentiality). Participants should receive treatment for chlamydia and gonorrhoea according to the national or WHO STI treatment guidelines.

Suggested Annex 7: **Insert national gonorrhoea and chlamydia standards of care, including treatment.**

Case reporting to nationally notifiable disease registries

Positive cases of chlamydia or gonorrhoea should be confidentially reported to nationally notifiable disease registries or surveillance programmes. Forms for this reporting purpose should be obtained from the national surveillance programme.

Summary



WHO recommends routine STI prevalence surveys among general populations such as pregnant women as part of national-level STI surveillance programming. This protocol serves to guide national programmes in the planning and processes needed to conduct these assessments. Country and regional programmes are encouraged to review additional WHO guidance on national STI surveillance and laboratory STI testing to fully inform activities to strengthen STI surveillance and evaluate trends.¹²

¹² Sexual and reproductive health. In: World Health Organization Human Reproduction Programme [website] (<http://www.who.int/reproductivehealth/topics/rtis/en/>, accessed 27 August 2018).

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Annex 1.

Example of a budget

Suggested Annex 8: **Sample study budget for local use**

Example of study budget		
Category	Item	Estimated cost (US\$)
<i>Study team</i>	Principal investigator and Technical Advisory Group: costs associated with meetings, planning, implementing survey – telephone/fax/stationery	5 000
<i>Data management</i>	Database development, questionnaire preparation (5 hours); entry (30 hours); analysis (5 hours)	500
	Equipment: computer, printer, software	800
	Survey report: writing, printing, dissemination	1 500
<i>Staff</i>	Training – study protocol, clinical and laboratory training, data management skills	2 000
	Office (data entry, analysis, questionnaire preparation, collation of results)	2 000
	Clinic staff (nurse practitioners, doctors, receptionist)	5 000
	Laboratory (technicians, senior scientists)	2 000
<i>Transportation</i>	Laboratory specimens (200 specimens)	NA
<i>Laboratory</i>	Specimen collection kits, test reagents, culture medium, pipettes (200 tests)	1 000
	Equipment (e.g. microscope, incubator, refrigerator, centrifuge)	NA
	Specimen collection (transport media, swabs, serum tubes, urine jars)	1 000
	Testing for <i>NG</i> and <i>CT</i> (200 tests)	3 000
<i>Clinic</i>	Study support material (data forms, consent forms, study registers, study protocol)	1 000
	Equipment for examination	NA
	Blood and specimen collection instruments (speculum, syringes, needles, labels, swabs, antiseptic)	1 000
	Medications for treatment	200
Total		26 000

Annex 2. Sample Patient consent form for prevalence survey

A. Purpose of the study. Chlamydia and gonorrhoea are infections caused by bacteria that are transmitted by sexual intercourse. In women, this infection can cause pelvic pain and, in the long term, increase the risk of infertility. Infections during pregnancy can cause adverse birth outcomes. Furthermore, during unprotected sexual intercourse with a man infected with the AIDS virus (HIV), a woman with these infections will have a higher risk of acquiring HIV than a woman who is not infected. The main purpose of this study is to assess the prevalence of chlamydia and gonorrhoea among pregnant women for use in estimating the national burden of these sexually transmitted infections.

B. Procedures to be followed. If you agree to participate in the study, you will be assigned a study number. The doctor or nurse will give you a physical examination and ask you some questions according to standard clinic procedure. He/she will take up to n samples, other than the ones that are potentially needed for your regular tests, from your urine, cervix or vagina. Your name will not appear on any of the samples or on the questionnaire. All the samples will be destroyed at the end of the study.

C. Voluntary participation. A decision not to participate or to withdraw from participation will not affect the care you will receive at the clinic in any way. Even if you do agree to become a study participant, you can withdraw from the study at any time (verbally). During the interview, you can choose not to answer any particular question.

D. Discomfort and risks. You may feel a small amount of discomfort in the vagina during specimen collection. There is a risk of emotional stress if you are diagnosed with chlamydia or gonorrhoea. If you are diagnosed with chlamydia or gonorrhoea, it is important that your sexual partners receive treatment so that you do not become reinfected. Notification of your sexual partners is voluntary. For some patients, notifying a sexual partner of exposure to an STI could put them at risk for emotional, verbal or physical abuse during pregnancy. This risk should be considered.

E. Benefits. You will be provided with treatment if your chlamydia or gonorrhoea test returns a positive result. There are risks associated with untreated chlamydia and gonorrhoea infection during pregnancy, which include transmission of these infections to your baby. Testing and treatment for these infections can prevent the complications of infection with chlamydia (eye and lung infection) and gonorrhoea (eye infection) in your baby.

F. Compensation. There will be no monetary compensation for this study, but routine medical consultation and appropriate referral services are available.

G. Confidentiality statement. The records concerning your participation will be used only for the purpose of this research project. Your name will not be used on any study form or label on laboratory specimens or in any report resulting from this study. At the beginning of the study, we will give you a study identification number and this number will be used on the forms and on the laboratory specimens. Any information obtained in connection with this study will be kept strictly confidential. Only members of the study team (doctors, nurses) will have access to information linking your name with your study number. If, at any time during your gynaecological examination, the doctor doesn't diagnose cervical infection (and hence doesn't give you specific antibiotics) but the laboratory test detects any of these infections, we will treat you when you come back to the clinic to get your results. If you do not come back to the clinic within the following 10 days, a field worker will notify you to come back to the clinic.

H. 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 clinic.

You may contact any of the study physicians if you have questions about the research.

You may speak with the staff at the clinic (name _____).

You can also call the clinic during working hours at tel.: _____.

I. Publication of results: Data from the study will be kept for a minimum of 1 year after publication of the results. When the researchers have analysed the data, the summary prevalence results and the explanation of the implications related to the burden of these infections will be posted at the clinic.

J. 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 study 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

Name of volunteer

Signature (or thumb print or cross) of volunteer

Date

Name of witness

Signature of witness

K. Investigator's statement. I, the undersigned, have defined and explained to the volunteer in a language she understands the procedures of this study, its aims, and the risks and benefits associated with her participation. I have informed the volunteer that confidentiality will be preserved, and that she is free to withdraw from the study at any time without affecting the care she will receive at the clinic.

Following my definitions and explanations, the volunteer agrees to participate in this study.

Date:

Name of investigator who gave the information about the study:

Signature:

Appendix 3. Sample Clinic data collection form

1. Name of clinic/location: _____
2. Participant ID number: _____
3. Date of specimen collection (day/month/year): _____/_____/_____
4. Age or Date of birth (day/month/year): _____/_____/_____ (_____ age in years)
5. Duration of gestation: _____ weeks
6. Total number of pregnancies: _____
7. Total number of term deliveries: _____
8. Place of residence: Urban or rural (circle one)
9. Education level (optional)
 - No education
 - Some primary education
 - Completed primary education
 - Some college or university
 - Completed university

Appendix 4. Sample Laboratory data collection form

Laboratory name: _____

Name of test: _____

Manufacturer: _____

Lot number: _____

Expiry date (day/month/year): ____/____/____

Results read by: Staff Name 1 _____ Staff Name 2 _____

Participant number	Clinic Name	Date of specimen (day/month/year)	Lab results	
			Chlamydia	Gonorrhoea
		/ /		
		/ /		
		/ /		
		/ /		
		/ /		
		/ /		
		/ /		
		/ /		
		/ /		

P = positive; N = negative; I = invalid (A test with an invalid result should be repeated with a new test and the result will be recorded as "invalid" if the result of a repeated test is still invalid).



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