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Guidelines for Sexually Transmitted Infections Surveillance

UNAIDS/WHO Working Group on Global HIV/AIDS/STI Surveillance

World Health Organization

Communicable Disease Surveillance and Response

Surveillance of the global epidemic of HIV/AIDS and sexually transmitted infections is conducted as a joint effort by UNAIDS and WHO.

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1. INTRODUCTION

Sexually transmitted infections (STIs) are a major global cause of acute illness, infertility, long-term disability and death, with severe medical and psychological consequences for millions of men, women and infants. The impact of these diseases is magnified by their potential to facilitate the spread of HIV infection. These guidelines for improving surveillance of sexually transmitted infections (STIs) are intended to assist in the world-wide effort to prevent them. STI surveillance data should actively be used to improve the quality and effectiveness of STI and HIV prevention programmes and programmes of sexual and reproductive health. STI surveillance is considered by WHO/UNAIDS to be a key component of second-generation HIV/AIDS surveillance systems.

This report focuses primarily on those curable conditions and pathogens that are the main focus of STI control programmes: syphilis, chancroid, gonorrhoea, chlamydial infection, trichomoniasis, and the syndromes that they cause. Although viral infections that are often sexually transmitted (including hepatitis viruses, herpes simplex viruses [HSV], and human papillomaviruses [HPV]) are also of major importance, they are not currently a central focus of most STI control programmes, and are mentioned only briefly in this document.

This document is intended to provide practical guidance for ministries of health to obtain surveillance data on STIs to directly facilitate disease control efforts at national, regional and local levels. As such, this document emphasises the timely collection, analysis, dissemination, and use of data that can be routinely collected on the general population and on defined subpopulations within a country. Although data obtained through routine public health surveillance activities need to be interpreted in view of their biases and limitations, they can provide valuable information on disease burden and aspects of programme services. The strengthening of STI surveillance systems should be viewed as a central component of the global effort to strengthen all countries' STI/HIV prevention programmes.

2. STI SURVEILLANCE COMPONENTS

The five components of STI surveillance that are necessary for effective control programmes are the following:

- < case reporting
- < prevalence assessment and monitoring
- < assessment of STI syndrome etiologies
- < antimicrobial resistance monitoring
- < special studies

Each of these components is discussed in detail in this document. These are complementary activities, with their utility differing for different aspects of STI control. The ways in which each of these activities are performed will depend on the existing STI surveillance infrastructure, particularly the extent to which

laboratory testing is available for routine clinical care, and on the structure of systems that are already in place for reporting of other communicable diseases. The HIV epidemic state in a country (low grade, concentrated, or generalised) also has implications for STI surveillance activities and priorities (Section 8).

There exists no single model for a STI surveillance system that is ideal for all countries. However, the five basic components listed above provide a framework for STI surveillance that can be adapted for use in most countries.

3. CASE REPORTING

Case reporting is the process of reporting cases of notifiable diseases from health care providers or laboratories to public health authorities.

3.1 Objectives of case reporting

Case reporting has several purposes and uses:

- assess disease burden, by providing an indicator of minimum incidence of recently acquired infections
- monitor trends in incidence of recently acquired infections.
- provide information required for management of patients and their sex partners
- provide information on which providers in the health care system are diagnosing and reporting the major STIs, to assist in planning and managing programme efforts
- provide other data necessary for managing health services (e.g., pharmaceutical distribution)

Box 1

Incidence

Incidence of disease is defined as the number of new cases of disease occurring in a population during a defined time interval.

STIs may be reported either syndromically or etiologically, depending on the availability of laboratory tests in clinical care settings. In most developing countries, syndromic case reporting is the only option.

3.2 Syndromic case reporting

Syndromic case reports require no laboratory diagnostic tests. The following case definitions are primarily for surveillance purposes, and not intended to be comprehensive from the perspective of providing clinical care.

Box 2

Selected STI syndromic case definitions

Genital ulcer syndrome - non-vesicular
Ulcer on penis, scrotum, or rectum in men and on labia, vagina, or rectum in women, with or without inguinal adenopathy. (This syndrome can be caused by syphilis, chancroid, lymphogranuloma venereum, granuloma inguinale, or atypical cases of genital herpes.)

Genital ulcer syndrome - vesicular
Genital or anal vesicles in men or women. (This syndrome is typically caused by genital HSV infection.)

Urethral discharge syndrome
Urethral discharge in men with or without dysuria. (This syndrome is most commonly caused by *Neisseria gonorrhoeae* and *Chlamydia trachomatis*; other infectious agents associated with urethral discharge include *Trichomonas vaginalis*, *Ureaplasma urealyticum*, and *Mycoplasma* spp.)

Vaginal discharge syndrome
Abnormal vaginal discharge (indicated by amount, colour and odour) with or without lower abdominal pain or specific symptoms or specific risk factors. (This syndrome is most commonly caused by bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis; it is less frequently caused by gonococcal or chlamydial infection.)

Lower abdominal pain in women
Symptoms of lower abdominal pain and pain during sexual intercourse with examination showing vaginal discharge, lower abdominal tenderness on palpation, or temperature >38 C. (This syndrome, which is suggestive of pelvic inflammatory disease, may be caused by gonococcal, chlamydial, or anaerobic infection.)

STI syndromic case reports have important limitations:

< *Only urethral discharge and genital ulcer disease (non-vesicular) are potentially useful for monitoring trends in STI incidence*. These syndromes usually represent recently acquired sexually transmitted infections. In contrast, usually a high proportion of vaginal discharge cases are not caused by STIs, nor are a substantial proportion of cases of lower abdominal pain in women, or of clinically apparent cervicitis. Vesicular ulcers, an indication of genital HSV infection, are usually a recurrence of a herpes infection that was acquired years before. Many cases of genital warts also represent a symptomatic

recurrence of a persistent infection.

- *Use of syndromic reports provides a poor assessment of disease burden and trends in women compared with men*. This is because a high proportion of STI infections in women cause no symptoms. In women, STI prevalence assessment and monitoring are essential, even in resource-poor settings (section 4).
- *These syndromes are not pathogen-specific*. Studies of syndrome etiology also must be periodically performed to guide therapy (section 5).

Reporting of vaginal discharge syndrome, lower abdominal pain in women, vesicular genital ulcers, genital warts and cervicitis is useful only if it contributes to management of health services by providing information on the number of cases seen and assists with the allocation of pharmaceuticals. They are not reliable for assessment of STI incidence or prevalence or to measure the impact of STI/HIV prevention programmes.

While all clinicians who provide STI care should be able to treat the common causes of vaginal discharge, two major causes of vaginal discharge, bacterial vaginosis (BV) and vulvovaginal candidiasis, are not considered to be STIs in the same way as other conditions. Furthermore, treatment of sex partners of women with BV and candidiasis have not been shown to prevent reinfection of the index patients. The control of these two conditions has not generally been the focus of STI control programmes, nor of systematic STI surveillance efforts. However, new evidence for the effectiveness of treatment of bacterial vaginosis among pregnant women in decreasing pre-term delivery, and on the possible role of this condition in facilitating transmission of HIV infection, has resulted in increased attention being given to the diagnosis and treatment of this condition; however, related surveillance measures have not yet been evaluated.

It will only be possible to use case reports of STI syndromes (i.e. genital ulcer disease and urethral discharge) for monitoring trends in incidence when the structure and functioning of health services are stable and when reporting practices are consistent over time. Even with significant under-detection and underreporting, if the system is consistent the trends in reported incidence will likely reflect trends in actual incidence. Special studies to assess the proportion of cases seeking by health-care workers and being reported may be used to estimate the extent of underreporting.

3.3 Etiologic case reporting

Etiologic case reporting requires diagnosis based on laboratory testing and can be performed in settings where well-developed systems of laboratory diagnosis are incorporated into routine STI clinical care. For certain STIs (e.g. syphilis), stage of disease is defined by clinical findings and history, while etiology is diagnosed by laboratory tests.

STI etiologic case definitions that can be used for surveillance purposes are listed below. Depending on the clinical specimen tested and the specificity of the test used, the case may be considered probable or confirmed; all probable and confirmed cases should be reported. In some instances, the surveillance criteria for reporting a case as confirmed may be less stringent than laboratory criteria (e.g., Gram stain

diagnosis of gonococcal infection in men).

Box 3

Selected STI etiologic case definitions

Syphilis, primary and secondary
Probable: an illness with ulcers (primary) or mucocutaneous lesions (secondary) and a reactive serologic test (non-treponemal or treponemal).
Confirmed: demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy, DFA-TP, nucleic acid test, or equivalent methods.

Syphilis, latent
Probable: no clinical signs or symptoms of syphilis and 1) a reactive nontreponemal and treponemal test in a patient with no prior syphilis diagnosis; or 2) a nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer in a patient with a prior syphilis diagnosis.

Latent syphilis may be further characterised as early latent, if there is evidence that the infection was acquired within the previous 24 (or 12) months, and late latent, if there is evidence that the infection was acquired earlier.

Chancroid
Probable: an illness with genital or anal ulcers with 1) no evidence of *T. pallidum* infection by darkfield examination of ulcer exudate or by a serologic test for syphilis performed $\geq$ 7 days after ulcer onset, and 2) a negative test for HSV on ulcer exudate.
Confirmed: identification of *Haemophilus ducreyi* by culture or nucleic acid test in ulcer exudate.

Chlamydia
Confirmed: a positive culture, direct fluorescent antibody test, antigen detection test, or nucleic acid-based test for *C. trachomatis*.

Gonorrhoea
Confirmed: 1) isolation of typical gram-negative, oxidase-positive diplococci (presumptive *Neisseria gonorrhoeae)* from a clinical specimen, 2) demonstration of *Neisseria gonorrhoeae* in a clinical specimen by a nucleic acid-based test, or 3) observation of gram-negative intracellular diplococci in a urethral smear obtained from a man. (For assessment of antimicrobial susceptibility, culture is required; see Section 6).

An advantage of etiologic case reporting is that specificity for STI agents is high, providing a highly credible assessment of the minimum disease burden and facilitating efforts at counselling and treating

patients and their sex partners.

Etiologic STI case reports have important limitations:

- *Primary and secondary syphilis in men and women, and gonorrhoea in symptomatic men, are the etiologic diagnoses that are most useful for monitoring trends in incidence; many other STIs are not useful for this purpose*. Recently detected latent syphilis in men and women, or chlamydia, gonorrhoea, and trichomonasis in women usually reflect infections that were acquired at an unknown time before. (High quality diagnostic testing is usually not available for chancroid, otherwise etiologic case reporting for this condition might also be used to reliably monitor trends in incidence).
- *Etiologic case reports are generally more useful for monitoring trends in STI incidence in men than in women*. As for syndromic case reports, this is because a higher proportion of infections in men are symptomatic.
- *Sensitivity of diagnostic tests is often substantially <100%*. Etiologic reporting does not include syndromes (e.g., genital ulcers) that test negative for a specific pathogen, even though the patient may actually be infected.
- *The availability of diagnostic tests does not assure their quality.* Quality assurance procedures for specimen collection and diagnostic testing must be in place for diagnostic tests to provide consistent, reliable results.

Most developing countries do not have sufficient laboratory infrastructure for routine etiologic case reporting; however, understanding the requirements of etiologic case definitions can contribute to an understanding of the importance of syndromic case reporting in countries without adequate laboratory capacity.

Etiologic case reporting based on clinical impressions alone, without the use of laboratory diagnostic testing, is not reliable, results in wide variation in reporting practices, and makes any STI surveillance data difficult to interpret. For this reason, all etiologic case reports require laboratory testing to establish the diagnosis. *In the absence of routinely available, high quality laboratory diagnostic testing, case reporting should be based on syndromes.*

In countries where substantial clinical diagnosis is performed both syndromically and etiologically, some experts believe that a combined system of syndromic and etiologic case reporting may be used, although care should be taken that STI cases occurring in individual patients not be reported to both systems. In countries where etiologic diagnosis is performed, multiple infections in the same person can be reported separately (e.g., gonorrhoea and chlamydia).

Box 4

Sensitivity and specificity

Sensitivity: The proportion (%) of truly infected persons who are identified by a diagnostic test or algorithm as infected [true positives(true positives plus false negatives)].

Specificity: The proportion (%) of truly uninfected persons who are identified by a diagnostic test or algorithm as uninfected [true negativesrue negatives plus false positives)].

3.4 Reporting perinatally-acquired STIs

Perinatal infection is a devastating consequence of certain STIs. Measuring the number of these infections and their rates (number of infections per number of live births) are important STI surveillance activities. The most common perinatally-acquired STIs in most countries are congenital syphilis and ophthalmia neonatorum. Surveillance case definitions for each of these are shown in Box 5.

Box 5

Case definitions for congenital syphilis and ophthalmia neonatorum

Congenital syphilis

Probable: 1) an infant whose mother had untreated or inadequately treated syphilis during pregnancy (regardless of signs in the infant), or 2) an infant or child with a reactive treponemal test and any one of the following: evidence of congenital syphilis on physical examination, long bone x-rays compatible with congenital syphilis, a reactive VDRL-CSF, an elevated CSF cell count or protein (without other cause), a reactive FTA-ABS 19S-IgM antibody test, a reactive IgM ELISA, or a reactive IgM treponemal Western blot.

Confirmed: demonstration of *T. pallidum* by darkfield microscopy, fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord or autopsy material.

Stillbirth: a foetal death that occurs after a 20 week gestation or in which the foetus weighs >500 g and the mother had untreated or inadequately treated syphilis at delivery.

Ophthalmia neonatorum

Probable: Conjunctivitis in a new-born who has not received ocular prophylaxis, occurring within two weeks of delivery.

Confirmed: Conjunctivitis in a new-born (≤ 30 days old), with an ocular specimen that tests positive for *N. gonorrhoeae* or *C. trachomatis*.

Diagnosis of each of these conditions can be difficult. Diagnosis of congenital syphilis is problematic because not all mothers with untreated or inadequately treated infection will pass the infection to their infants and serologic tests for evaluating actual infection of the infant are not widely available. Even more problematic is that it is often difficult to determine if a mother who has a reactive syphilis serologic test has untreated syphilis, or if she has received adequate treatment. Syphilis in the mother cannot be confirmed without the use of treponemal tests (MHA-TP or FTA-ABS), and these tests are not routinely available in many developing countries.

Surveillance for ophthalmia neonatorum can be difficult even for infants born in hospitals because most infections appear after the infant has left the hospital. Gonococcal ophthalmia neonatorum usually occurs during the week after birth. Chlamydial ophthalmia usually occurs 7-14 days after birth and may occur up to 30 days after birth, making identification of cases particularly difficult, and increasing the probability of confusing chlamydial ophthalmia with other etiologies of conjunctivitis.

Other perinatally acquired STIs can also result in substantial neonatal morbidity, including chlamydia pneumonia and neonatal HSV infection. In countries with adequate diagnostic capacity, these cases may also be reported through the notifiable disease surveillance system.

3.5 Data elements

Core data elements that are essential to reporting a case should routinely be collected on clinic logs and reporting forms. Additional data elements may be collected at some sites, which can provide more detail on patient demographics, risk characteristics and treatment. The selection of additional data elements will depend on the specific purposes for which the data will be used.

Box 6

Data elements

Core data elements

- Diagnosis
- Reporting site
- Date of visit
- Gender
- Age group, age or date of birth (see below)

Additional data elements

- Residence
- Education or socio-economic status
- Syndrome (for etiologic reporting)
- Anatomic site of infection
- Date of symptom onset
- Risk behaviours (see below)
- Pregnancy
- History of STI
- Treatment

One challenge in reporting STIs through the universal reporting system in developing countries is that the age groups that are often used in aggregate reporting forms (e.g., <5 years, ≥5 years) make it impossible to identify how much disease is occurring among adolescents and young adults. Detailed age categories are desirable, especially for the younger age groups (e.g., 10-14, 15-19, 20-24, 25-29, etc.). *At minimum, the age categories of 15-24 and ≥25 years should be used for reporting STI diagnoses*.

For countries that are unable to include such age categories in their routine reporting forms, an alternative is to collect more detailed age data on a sample of patients, which can then be used to estimate the proportion of all case reports that fall into these categories. However, this can result in a greater effort than simply including appropriate age categories in the case reporting system.

For STIs, reporting of risk behaviours has generally been done less systematically than it has in HIV/AIDS case reports. If feasible, questions used to obtain risk information on STI patients can be comparable to those used for HIV/AIDS case reporting, if those data have been gathered in a systematic fashion, or comparable to questions used on behavioural surveillance surveys. These questions may include the following: number of sex partners in the past 90 days (or 12 months); new

sex partner in the past 90 days; gender of sex partners in the past 12 months (or sexual orientation); condom use at last sexual intercourse; drug use in the past 12 months; and giving or receiving money or drugs for sex in the past 12 months.

In those countries where health departments routinely assess adequacy of therapy for individual patients, details of treatment (e.g, specific drugs used and dates of therapy) may be obtained.
In countries where data from the patient interview are used to confidentially identify, counsel and treat sex partners of patients with STIs, personal identifying information about those sex partners may also be obtained.

3.6 Reporting formats

For case reporting, hand-tabulated aggregate reports are sufficient for most purposes. The capacity to enter these aggregate reports into a computerised database at the central level facilitates the analysis of these data by health district, type of reporting site, sex and age, and may make it easier to monitor which sites are reporting consistently. An example of aggregate reporting formats is shown in Annex 1.

Computerised line-listed data provide more flexibility than aggregate reports, and allow for more rapid and sophisticated analysis, but the data entry requirements are beyond the scope of all but a few programmes.

There is no advantage to computerisation if a system becomes overly complex and unwieldy either because of the complexity of the system relative to the level of training of personnel available to manage the system, or because the volume of data exceeds the capacity of available hardware and software to easily manage it.

3.7 Universal versus sentinel-site case reporting

In countries where a national reporting system for notifiable infectious diseases exists, STI case reporting should be incorporated into the national health information system wherever possible, with input provided by the STI programme into reporting and analysis of STI data. The major advantages of including STI case reporting in the universal reporting system are the following:

- When the structure of health care services and patterns of health care seeking behaviour and reporting are consistent, trends in notifiable STI syndromes (e.g., urethral discharge in men and genital ulcer disease in men and women) will reflect trends in STI incidence in the population.

- Universal reporting systems can be used to provide a *minimum* estimate of population-based STI incidence throughout the country.

An important role of universal case reporting systems is to provide ongoing information on the capacity of health care providers throughout a country to report STIs. Sites that are not reporting, or where

reporting has suddenly declined, should be contacted to determine if the decline is due to lack of drug availability, lack of trained personnel available to diagnosis STIs, or if it is a problem of preparing and submitting case reporting forms. The universal case reporting system should be viewed as an important programme management tool.

A major limitation of universal case reporting systems is that in some countries they are used as the only mechanism to obtain data on the burden of STIs in the population, even though other sources of data are usually necessary to help characterise disease burden (e.g., prevalence assessment and monitoring; see Section 4).

In countries where no universal reporting system exists, or where STI case reporting cannot be incorporated into the national health information system, a case reporting system may be instituted at specially designated "sentinel" or "enhanced surveillance" sites. If sentinel-site STI case reporting is established, the purposes of the system must be clearly defined.

Potential purposes of sentinel site case reporting include the following:

- Assess the proportion of clinic attendees with STIs compared with other conditions (if a denominator for total patient visits per site is available),
- Among patients with STIs, determine the distribution of types that are seen at the clinic.
- Determine characteristics of STI patients who attend the sentinel sites.
- Assess trends in numbers of cases at sentinel sites, as a possible indication of trends in disease burden in the community (although many factors, in addition to morbidity, may affect case numbers).

The major potential advantage of sentinel site case reporting is the opportunity to obtain higher quality data on case reports than may be obtained through a system of universal reporting, particularly if staff at the sentinel reporting sites receive special training, and if a data system can be established to improve quality and use of these data. Also, more detailed data may be obtained on patients than could be obtained through a universal system.

However, sentinel-site case reporting also has limitations. Since staff at sentinel reporting sites often receive special training and resources, in most countries these clinics cannot be considered representative of other clinics. To the extent that quality of care and availability of drugs are differentially improved at sentinel sites and not more broadly at all primary health care and reproductive health clinics, efforts to integrate quality STI care into primary care may suffer. Another limitation of sentinel-site case reporting, whether syndromic or etiologic, is that it cannot be used to provide even minimum population-based rates of disease.

Another option is to perform universal case reporting in sentinel districts; that is, to select specific geographic areas where reporting from all facilities will be standardised. This may make it possible to generate minimum population-based rates of disease for those areas under surveillance.

A country may seek to establish sentinel site case reporting (or universal case reporting within sentinel

geographic districts) as the beginning of an effort to phase in a system with broader coverage. If a decision is made to institute sentinel site case reporting, the selection of sentinel sites should be based on the country's structure of health care delivery, the extent to which STI care is incorporated into primary health care, and the specific purposes of establishing the system. In settings where STIs are cared for mostly in primary health care settings, sentinel sites should be sites of primary health care, rather than categorical STI clinics; a minimum suitable number of reporting sites would be about one per administrative public health unit (e.g., health district).

Sentinel-site case reporting should not be confused with other STI surveillance activities that can be performed at "sentinel sites," "enhanced surveillance sites," specialised STI clinics, or among "sentinel populations," including assessment of STI prevalence and syndrome etiologies, antimicrobial resistance monitoring, and special studies, as discussed below. The term "sentinel surveillance" has frequently been used to refer to any or all of these activities, without clarifying the objectives and methods for each.

3.8 Private sector and laboratory-based case reporting

Among the most difficult challenges for any STI surveillance system is to encourage case reporting from the private sector. The extent to which this is a priority will depend in large part on the structure of health care delivery and on the extent to which care is provided by the private sector. In those countries where laboratories routinely perform STI diagnostic tests, it may be possible to encourage laboratories to report results more easily than clinicians.

In countries where private sector reporting is a priority, the STI programme should have a written plan that states in detail the responsibilities of health care providers (and, if relevant, laboratories) for reporting, and the STI programme's procedures for working with these groups. A registry of providers and laboratories should be maintained and updated at regular intervals.

Methods to encourage reporting may include site visits, training courses, and the distribution of written materials with updated information on STI diagnosis and treatment. Interactions with providers and laboratories should focus on providing them with useful information; case reporting should be presented in this context as one aspect of appropriate STI care. The dissemination of STI surveillance data to individuals responsible for reporting can also be helpful in encouraging persons to report (Section 10).

Efforts to improve STI case detection and reporting should extend beyond those providers who have traditionally treated patients with symptomatic STIs. In particular, clinicians in public and private sectors that provide family planning services and gynaecological care should be encouraged to report cases of STIs. In countries where laboratory services are readily available, clinicians may be able to routinely screen asymptomatic patients using diagnostic tests. The selection and use of screening tests will depend on the local prevalence of disease and the cost of diagnostic testing.

In many countries, patients with STIs may seek to obtain medications directly from pharmacies, without first consulting a clinician. The extent of underreporting due to this and other reasons may be assessed through special studies (Section 7).

3.9 Data quality

STI surveillance programmes should establish standards for quality of data in case reports. Three critical components of data quality are completeness (the proportion of reported cases with complete information), validity (among reported cases, the proportion of each data element that is reported correctly), and timeliness (the time intervals between the steps in surveillance).

These aspects of data quality do not address the sensitivity or representativeness of the surveillance system, or the accuracy of self-reported demographic and behavioural data. These may be evaluated through special studies (Section 7).

Data quality can be improved through use of computerised systems that have built-in error checks and that can generate standard reports to highlight missing data and frequency distributions. However, even in the absence of computerised systems, quality of data can be assessed through periodic examination of reporting forms and site visits during which local clinic logs and reported data can be compared.

3.10 Confidentiality of STI surveillance data

All STI surveillance programmes should have policies that protect the privacy of patients and the confidentiality of disease control data; that ensure the integrity of these data (i.e., that prevent unauthorised modification); and, that provide access only to persons who are authorised to have these data for purposes of disease control.

Unauthorised disclosure of personal identifying information on patients with STIs and other diseases under public health surveillance can result in severe personal consequences for the individuals involved, result in a loss of confidence in the basic systems of disease control, and thereby jeopardise all disease control activities. In most countries, personal identifying information is maintained at the local reporting site or local jurisdiction where access to the data is highly restricted. Personal identifying information need not be (and is usually not) reported at the national level.

3.11 Analysis and interpretation of case reports

STI case reporting data should be analysed at quarterly and annual intervals. Quarterly analysis may consist of the following:

- Comparison of the most recent quarterly number of case reports with the same quarter during the previous year.
- Examination of quarterly trends in the number of reported cases and prevalence for the past 1-2 years, overall, and by the following categories:
    - geographic area
    - gender
    - age group

- provider type (e.g., primary care, family planning, STI clinic)
- reporting site

Additionally, annual analysis may include the following:

< Case reports annually, stratified by the five categories listed above

< Annual trend in overall population-based rates of reported cases, using available census data or population estimates, and stratified by basic demographic categories (geographic area, gender, and age group), depending on availability of population-level data.

In those situations where STI syndromes or etiologies are reported through the universal case reporting system, it may often seem that data are inconsistently collected, that timeliness is poor and that categories available for analysis (especially age categories) are inadequate. However, interpretation may be substantially improved by clarifying the objectives of the analysis, and by comparing case reporting data with other sources of data (e.g., prevalence assessments).

In any system of case reporting, it is to be expected that as the system improves, the number of cases reported will increase. This demonstrates the impact of the programme on improved case-finding and reporting, and in many cases, may also represent improved diagnosis and treatment by health care providers. Once the system stabilises, trends in case numbers will likely reflect trends in incidence. If the STI control programme is effective, a decline in cases will likely occur, representing a true decline in incidence.

However, trends in case reports should not be interpreted outside of the context of ongoing changes in the STI programme or health care system. Site-specific declines in case reports may be due to a lack of persons seeking care (for example, if drug supply is interrupted), or a failure of reporting mechanisms. Unexpected declines or increases in case reports should be investigated to determine the probable explanation. Thus, variation in case reporting should not be interpreted as a weakness of the surveillance system, but as one way to obtain information on how the system of STI care and reporting is functioning.

To improve monitoring of STI incidence trends in a universal case reporting system, it may be possible to selectively analyse data from reporting sites that provide consistent, high quality data, in a timely fashion. These data also may be compared with case reports of non-STI conditions from the same sites to provide an estimate of the proportional morbidity caused by STIs, in relation to other causes of morbidity over time.

4. PREVALENCE ASSESSMENT AND MONITORING

A second major component of STI surveillance is prevalence assessment and monitoring.

Box 7

Prevalence

Prevalence of a disease or infection is defined as the proportion of persons in a population who have that disease or infection at a specified point in time.

Prevalence assessment is the determination of prevalence among persons screened in defined populations.

Prevalence monitoring is the monitoring of trends in prevalence over time.

4.1 Objectives of STI prevalence assessment and monitoring

The primary purposes of STI prevalence assessment and monitoring are the following:
- Identify population subgroups with high prevalence of STIs
- Monitor trends in STI prevalence among defined populations.

In many situations, STI prevalence is monitored in defined populations that are routinely screened, for example, women who are routinely screened for syphilis during antenatal care or at delivery; thus the primary purpose of testing is detection and treatment of STIs rather than determination of prevalence. However, prevalence assessment may also be performed as part of studies that are specifically designed to obtain data for purposes of programme planning.
Prevalence data are of great use in STI programme planning, management, and evaluation because they can be used to:
- Identify population subgroups at high risk for HIV infection (as evidenced by high rates of STIs)
- Guide funding and resource allocation for STI and HIV prevention programmes
- Monitor effectiveness of STI and HIV prevention programmes
- Develop national estimates of STIs

An important limitation of STI prevalence data is that it has no role in the management of individual patients or their sex partners. For those purposes case reports are required.

4.2 Assessing prevalence of symptomatic versus asymptomatic STIs

Prevalence of STIs that are often asymptomatic (e.g., chlamydia and gonorrhoea in women; syphilis, determined through serologic testing) may provide insight into the disease burden in the population from which those attending the clinic is drawn. Asymptomatic patients are usually seeking services for reasons that are unrelated to STI (for example, family planning clinic clients and women seeking antenatal care). In contrast, prevalence of symptomatic disease (i.e., STI syndromes) in clinical care settings will be heavily biased compared with community disease rates, because these patients are presenting for care.

In settings where all patients may be examined without relation to symptoms (e.g., entry into detention facilities, military recruitment, routine sex worker examinations), STI syndromes may serve as useful indicators of prevalence, because the bias introduced by care-seeking is less than in settings where patients are seeking care for symptoms. In these situations, it is possible that genital ulcer disease and urethral discharge may assist in assessing prevalence, particularly in settings where incidence of these diseases is high. However, even these few syndromic measures of disease burden should be considered substantial underestimates. Recent data using highly sensitive nucleic acid amplification tests suggest that substantially more cases of gonococcal and chlamydial infections in men are asymptomatic than previously thought.

Tests that do not require gynaecological or genital examinations can facilitate screening (and prevalence assessment) outside of clinic settings. Urine tests for gonorrhoea and chlamydia based on nucleic acid amplification methods can be used for this purpose, although their cost may limit their use. The leukocyte esterase test can be used for screening men for presence of urethritis, but the sensitivity and specificity of this test varies considerably depending on the population screened and the competence of the individuals performing the test.

Box 8

STIs that are most useful for prevalence assessment and monitoring*

Settings where patients are seen	
All settings	without relation to symptoms†
Syphilis (m, f)	Syphilis (m, f)
Gonorrhoea (f)	Gonorrhoea (m, f)
Chlamydia (f)	Chlamydia (m, f)
Trichomoniasis (f)	Trichomoniasis (f)
	Genital ulcer disease (m, f)
	Urethral discharge (m)

*This table focuses on the major curable STIs that can be diagnosed by standard diagnostic tests or physical examination. Serologic tests for viral infections (e.g., HSV-2 and hepatitis viruses) can also be used as measures of prevalence in all settings. Serologic testing for chancroid is available in some specialised laboratories.
†Examples include detention facilities, military recruitment, routine sex worker examinations, and women at delivery.

4.3 Laboratory requirements

Because assessment of prevalence necessarily focuses in most settings on diseases that are asymptomatic and persistent, reporting of prevalence based on laboratory diagnosis is necessary. This means that syphilis serologic testing and testing for genital chlamydial and gonococcal infection must be performed.

Diagnostic tests are more useful for assessing prevalence when the test results are specific for active infection. For example, while cervical gonococcal and chlamydial testing is specific for active infection, non-treponemal syphilis serologic testing is not, unless titers are examined in relation to a reliable treatment history (in most developing country settings, such data are not available). Treponemal tests alone (which usually remain reactive for life) are of no use in distinguishing adequately treated syphilis from active syphilis infection. Use of a non-treponemal test titre cut-off (e.g., 1:4 or 1:8) may assist in monitoring trends in prevalence of active syphilis infection.

Prevalence studies can only be performed when local laboratory infrastructure exists or when a site without laboratory infrastructure can collaborate with a site that has resources. Quality control is an important issue, and quality of specimen collection and local testing can never be taken for granted. It is often the case that specimen collection and testing sensitivity improve with experience, and it is

important not to confuse improved testing with increasing prevalence of disease. Where feasible, specimen adequacy should be monitored periodically. An independent measure of quality of laboratory testing through a system of proficiency testing established by a reference laboratory is also essential.

4.4 Selection of populations and frequency

In all countries it is essential to assess prevalence among persons who by their risk behaviour are likely to have high rates of disease (for example, female sex workers); the feasibility of doing this will depend in large part on the extent to which such populations are identifiable and accessible. A period of formative behavioural assessment may be needed to learn how to best access these persons, for reasons of monitoring disease burden, and more importantly, for providing STI care and HIV prevention services.

At a minimum, the assessment of STI prevalence in persons at high risk should be performed in major cities; once this has been achieved, the effort can be extended to smaller cities where identifiable persons engaging in high risk behaviour reside.

The minimum assessment of STI prevalence among women at high risk for infection should include syphilis, gonorrhoea, chlamydia, and genital ulcers (by examination). Depending on the rates of disease, these data should be used to guide programmatic interventions, and disease rates periodically reassessed, at least annually when prevalence has been found to be high.

In some countries, it may be possible to include screening as part of the ongoing programmatic intervention. For example, if adequate infrastructure exists, it may be possible to routinely screen each client (treating those who are infected) at a regular interval (e.g., every three months), recording and reporting the prevalence of STIs found through screening.

Even in settings where laboratory testing is not available to provide periodic screening, monitoring prevalence of genital ulcer disease can be useful for assessing the impact of programmatic interventions. However, trends in prevalence of genital ulcer disease must be interpreted cautiously in populations with high HIV seroprevalence. Immuno-compromised persons with HSV infection can have frequent and severe recurrences that are atypical and easily confused with bacterial causes of genital ulcers.

STI data from clinics attended by the general population can also be useful for establishing STI programme priorities, determining the need for ongoing services, and targeting HIV prevention interventions. At a minimum, countries should perform an assessment of syphilis seroreactivity among antenatal or parturient women in one or more large facilities at least once every two years.
Another potentially important source of syphilis seroprevalence data in many countries is blood donors. These screening data are often available, but STI programmes often do not receive, organise, or report these data. Despite the limitations of these data, they can be especially useful in those countries where few other data on STI prevalence have been obtained and reported.

In settings where prevalence data are not generally available, even for syphilis serologic testing on

antenatal or parturient women, it may be useful to designate some sites as sentinel sites where this activity of collecting and reporting prevalence data can be initiated. However, to the extent possible, the monitoring of prevalence should be integrated into the routine of large institutions that are already testing patients, and, if data quality is adequate, those data can be routinely reported to the STI programme.

4.5 Sample size

The minimum acceptable sample size for assessing prevalence depends primarily on the expected prevalence of the disease in the population, and on whether or not it is intended to monitor trends in prevalence over time. Sample size requirements are substantially larger when the intention is to monitor trends over time. These requirements are described in Annex 2.

4.6 Data elements and reporting formats

Data elements for monitoring prevalence are the same as those for aggregate case reports; the only difference is that denominators are also recorded. Use of the additional data elements is also feasible if line-listed data on persons testing positive and negative are entered into a computer.

For monitoring prevalence, hand-tabulated aggregate numbers of numerators and denominators may have to be based on simple breakdowns by gender; certain sites may also be able to report prevalence by age categories (see Annex 1, Example 4).

The data collection and management demands of prevalence data are more complex than case reporting data because it is necessary to document denominators as well as numerators for each stratum, and large numbers of patients without disease are included in these denominators. The capacity to obtain line-listed data on positives and negatives from a relatively small number of enhanced surveillance sites makes it possible to perform more detailed analyses, including analyses that may assist in identifying subgroups with particularly high prevalence of disease, and in performing analyses for screening criteria (mentioned in Section 7). Where data on symptoms are also obtained, it may be possible to use these data to examine syndrome etiologies and evaluate syndromic management algorithms.

4.7 Positivity versus prevalence

Whereas prevalence of infection is based on a single test result on individuals at a specified point in time (for example, pregnant women at their first prenatal visit or at delivery, military recruitment examinations, etc.), test *positivity* is defined as the number of positive tests divided by the number of valid test results during a specified time period. The distinction between positivity and prevalence is more important for a population that is screened repeatedly (for example, sex workers who may be tested quarterly for syphilis), and less important in settings where patients are usually tested no more than once a year (for example, women at delivery, military recruitment, etc.). In many settings, particularly those where repeat testing is minimal, test positivity can be used as a surrogate for prevalence.

In settings where patients are screened repeatedly, the options are to shorten the time periods over which positivity is calculated (which minimises repeat test results within that time period), or, if unique patient identifiers are available, prevalence can be defined as the proportion of positive tests among persons tested the first time (and who have valid test results) in a specified time period.

4.8 Unlinked versus confidential assessment of STI prevalence, and linkage with HIV seroprevalence surveys

Unlike HIV seroprevalence studies, for which testing has often been performed in an unlinked fashion, testing for STIs is usually performed confidentially so that the results can then be used for treating and counselling patients. When interpreting data on STI prevalence, biases may be substantial if many patients decline testing; however, when the circumstances and setting are appropriate, adequate education and counselling are provided (for example, in many family planning clinics, antenatal clinics, and STI clinics), and if costs are not prohibitive, many clients will consent to testing. Adequate therapy must be available to persons found to be infected.

In settings where data on HIV seroprevalence are sought for surveillance purposes, unlinked HIV testing can be performed on leftover sera collected for syphilis serological testing. (The protocols and procedures for performing unlinked HIV testing are beyond the scope of this document.) When such leftover sera are used in this way, the syphilis seroprevalence should also be recorded and reported; in the past, this potentially important source of data has been under-utilised.

4.9 Analysis and interpretation of prevalence data

Analysis of routinely collected prevalence data (for example, those data obtained from routine screening of women in antenatal care) can follow the outline for analysis of case reporting data described above (Section 3.9). Quarterly and annual trends in prevalence should be analysed, overall, and stratified by basic categories (geographic area, age group, provider type, and provider site/laboratory).

Trends in prevalence may be altered substantially by changes in the population being screened because of changes in the characteristics of the clinic, in the population's patterns of health care-seeking, or criteria used to select persons for screening. Any such changes should be recorded and taken into account in the interpretation of trend data. Changes in diagnostic tests, which often vary in sensitivity and specificity, in the use of confirmatory tests, and in the type of specimen collected (e.g., endocervical swab versus urine) should also be recorded and considered when interpreting these data.

5. ASSESSMENT OF SYNDROME ETIOLOGIES

Periodic assessment of etiologies of STI syndromes (e.g., urethral discharge, genital ulcer disease, vaginal discharge) should be considered a core STI surveillance activity, especially in countries where STI syndromic management and case reporting are routinely performed.

5.1 Objectives of assessing syndrome etiologies

The primary purposes of assessing syndrome etiologies are to:

< Provide data for guiding STI syndromic management
< Assist in the interpretation of syndromic case reports, and the assessment of disease burden due to specific pathogens.

These data also may be used to evaluate syndromic management algorithms for urethral discharge and genital ulcers. (However, for assessment of sensitivity and positive predictive value of vaginal discharge algorithms for chlamydia and gonorrhoea, testing of women without symptoms who are seen in the same settings is also required).

5.2 Laboratory requirements

Laboratory protocols for assessing syndrome etiologies should be developed in consultation with a microbiologist experienced in STI diagnostic tests; details of diagnostic testing are beyond the scope of this document. The range of diagnostic tests that may be used is broad, many new tests are being developed, and selection will depend upon local availability and resources. The general types of laboratory tests that may be used for assessing syndrome etiologies are the following:

< Urethral discharge
  - Microscopy (Gram stain of urethral exudate to identify gram-negative diplococci)
  - Gonorrhoea and chlamydia testing available in some settings; these may include culture for *N. gonorrhoeae*, DFA for *C. trachomatis*, and EIA, amplified, and non-amplified nucleic-acid based tests for both pathogens.
< Genital ulcer disease
  - Syphilis serologic testing (non-treponemal and treponemal).
  - Dark field, direct fluorescent antibody test, culture for *Haemophilus ducreyi*, HSV culture or antigen detection test, and polymerase chain reaction (PCR) for *T. pallidum*, *H. ducreyi*, and HSV available in some settings.
< Vaginal discharge syndrome
  - Wet mount microscopy (*T. vaginalis*, clue cells, yeast).
  - Culture for *T. vaginalis* and *Candida* sp, dry chemistry for bacterial vaginosis, and chlamydia and gonorrhoea testing available in some settings

5.3 Selection of populations and frequency

Selection of populations for assessing syndrome etiologies depends on the number of cases available for examination at a single site. Ideally, syndrome etiologies should be assessed in different types of populations with high and low rates of disease, geographically distributed.

As a practical matter, for countries that have minimal infrastructure it is useful to begin with assessment

of etiology of urethral discharge and genital ulcer disease at a single specialised STI clinic that has good quality Gram stain microscopy and that can perform syphilis serologic testing. In most such countries, reliable dark field microscopy is usually unavailable.

Collaboration with a well-equipped laboratory can help to further assess the contribution of chlamydial infection to urethral discharge, and chancroid and herpes to genital ulcer disease. Syphilis serologic testing alone provides an incomplete assessment of genital ulcer etiology because many patients with ulcers due to chancroid and HSV can have reactive syphilis serologic tests from previously treated or untreated (latent) infections, and a substantial proportion of patients with primary syphilis (10%-30%) will not yet have developed a serologic response to infection.

In each country where patients are managed syndromically, and where syndromic STI case reporting is used, syndrome etiologies should be reassessed about once every two to three years or more frequently if the need arises (for example, in a setting with a new outbreak of genital ulcer disease).

5.4 Sample size

Sample size depends on the specific etiology and the expected prevalence of pathogens. For most purposes, a minimum sample size of 50 or 100 specimens from consecutive patients with the specified syndrome (or other type of systematic sample) will provide adequate information for useful analyses.

5.5 Data analysis and interpretation

Interpretation of diagnostic test results should be done in collaboration with microbiologists who are familiar with the sensitivity and specificity of each of the tests used for diagnosis.

Data on syndrome etiologies are important for interpreting STI syndromic case reporting data, and in particular, for estimating the burden of disease by pathogen. The data from the assessment of syndrome etiologies should be reported along with case reporting data to provide ongoing support for syndromic management algorithms. These data can be especially useful for supporting recommendations for treatment of urethral discharge for both gonorrhoea and chlamydia, for treatment of genital ulcers for both syphilis and chancroid, and for providing counselling for patients likely to have genital herpes.

6. MONITORING ANTIMICROBIAL RESISTANCE

In view of the substantial use of drugs for treatment of gonococcal infections and increasing rates of resistance world-wide, it is important for each country to monitor antimicrobial resistance in *Neisseria gonorrhoeae* as a core component of STI surveillance. Appropriate therapy of gonococcal infection is necessary to achieve microbiologic cure, relieve signs and symptoms of infection, prevent complications (which include pelvic inflammatory disease, chronic pelvic pain, and infertility in women), and interrupt transmission. In men infected with HIV, treatment of gonococcal infection substantially reduces HIV in semen, providing a mechanism for reducing the risk of HIV transmission.

Antimicrobial susceptibility testing for *Haemophilus ducreyi* is more difficult than for *N. gonorrhoeae*. However, in countries where rates of chancroid are high, studies to assess antimicrobial resistance in *H. ducreyi* may be performed with the assistance of a specialised reference laboratory (a discussion of susceptibility testing for *H. ducreyi* is beyond the scope of this document).

6.1 Objectives of monitoring antimicrobial resistance in *Neisseria gonorrhoeae*

The principal objective of monitoring antimicrobial resistance in *N. gonorrhoeae* is to obtain data necessary for developing guidelines for treatment. A second objective is to detect newly emerging resistance.

Demographic and risk information obtained through a sentinel system for monitoring antimicrobial resistance in *N. gonorrhoeae* may also be used to further characterise risk factors for resistance and the local epidemiology of this disease.

6.2 Laboratory requirements

Optimally, a laboratory performing susceptibility testing for *N. gonorrhoeae* should be able to culture the organism, to perform biochemical and serologic confirmatory tests, and to perform minimum inhibitory concentration (MIC) agar dilution testing of antimicrobial agents. If the national reference laboratory does not have this capacity, it may send isolates to a regional laboratory in another country that does.

Alternatively, until capacity for MIC testing is available locally, susceptibility testing may be performed using disk diffusion or the E-test. In some studies, the E-test has compared favourably with MIC agar dilution. In all laboratories that are able to culture *N. gonorrhoeae*, testing for plasmid-mediated resistance to penicillin is feasible using nitrocefin impregnated disks; this is an important option in those countries where penicillin is still in widespread use for treatment of gonococcal infections.

In selecting antimicrobials for susceptibility testing, priority should be given to those drugs commonly used for treating gonococcal infections.

Regional networks for antimicrobial susceptibility testing for *N. gonorrhoeae*, supported by WHO Collaborating Centres, have been established in several WHO regions. National reference laboratories are encouraged by WHO/UNAIDS to participate in these Centres' programmes of quality control and assessment.

6.3 Selection of gonococcal isolates

A sentinel site system for collection of gonococcal isolates should include coverage of major regions in the country; usually urban clinics that have capacity for culture are used as sentinel sites.

Isolates may be collected as a systematic sample from patients seen in any clinic setting where culture can be performed, and it is generally desirable to obtain isolates from both women and men. Culture testing of women is necessary to detect and treat asymptomatic infections and to monitor prevalence (See Section 4); where prevalence is high the yield may be sufficient to obtain an adequate number of isolates for antimicrobial susceptibility testing. In settings where men with urethral discharge are managed syndromically, gonorrhoea culture is not necessary for clinical management; however, isolates for susceptibility testing can be obtained by culturing men who have urethral discharge and a Gram stain that shows Gram negative intracellular diplococci. Because the yield of culture from these patients will be high, this method of selecting the sample can be an important option where laboratory resources are scarce.

6.4 Sample size and frequency

A sample of about 100 isolates per sentinel site during a defined time interval (e.g., quarter or year) is usually sufficient to provide an approximate characterisation of local patterns of resistance during that interval. A finding of zero cases of resistant isolates among 100 isolates tested provides a probability of 0.95 that on the average the true proportion of resistant isolates is <5% (if a random sample of isolates is tested). Although a true random sample of gonococcal isolates is usually difficult to obtain in most clinic settings, a systematic sample may be adequately representative.

A sample of 200 or more isolates collected during a defined time interval will make possible a more detailed analysis, including an opportunity to examine more closely risk factors for resistance and the local epidemiology of gonococcal infection. Confidence limits based on these and other sample sizes are shown in Annex 2, Statistical table 1.

The assessment of antimicrobial resistance should be performed at least annually. When feasible, it is advantageous to sample isolates on an ongoing basis rather than during only one month or quarter per year (e.g., testing 20 isolates per month at each sentinel site throughout the year). Ongoing sampling makes it more likely that newly emerging resistance or large changes in patterns of resistance will be detected early.

If trends in susceptibility are to be reliably monitored over time, variations in the sentinel sites and sampling procedures should be minimised, to the extent possible.

6.5 Data analysis and interpretation

It is helpful to review the results of resistance testing each quarter, even if the sample size per quarter is small, to see if data are complete and patterns are generally consistent from quarter to quarter. Any large changes noted on a quarterly review of data should be investigated to determine if they are due to real shifts in resistance patterns or to problems in the laboratory. When such changes are noted, it

may be useful to expand the sample beyond the numbers described above (Section 6.4), and to increase the number of sites where susceptibility testing is performed, until the problem can be accurately characterised for purposes of disease control and updating treatment recommendations.

Data on gonococcal resistance should be disseminated nationally at least annually. Reports should summarise resistance by antibiotic overall and for each sentinel site. They should also include mention of the gender of patients, the clinic setting where they were tested (e.g., antenatal clinic, STI clinic, or clinic for female sex workers), and any substantive changes that have occurred in the sentinel sites over time. This information can assist in the interpretation of test results, particularly if certain of these sites are commonly attended by patients who have failed previous therapy, and thus who are more likely to have resistant strains. Where it is possible to systematically collect demographic and behavioural data on patients in the sample, it may be possible to provide a detailed description of the characteristics of infected patients.

Data on resistance should be reviewed carefully in preparing updated treatment guidelines and in revising the country's list of essential drugs.

The appearance of new resistant strains should be reported as soon as possible to a WHO Collaborating Centre, which can assist in confirming the finding. Intensive investigation of newly emerging resistance, in collaboration with WHO and other public health agencies, may be warranted.

7. SPECIAL STUDIES AS A COMPONENT OF STI SURVEILLANCE

Periodically, public health personnel or university collaborators may perform special studies to address important STI surveillance issues that are not part of routine case reporting or prevalence assessments. Surveillance-related studies that have been found to be useful in many countries are listed below (Box 9). The need for these studies and their frequency will vary. In some countries, certain of these activities are considered an essential part of a comprehensive STI surveillance programme, while in others the cost and complexity of these activities is prohibitive, and more emphasis is placed in strengthening routine surveillance. For countries with limited resources, certain of these activities will require collaboration with specialised laboratories.

Box 9

Special studies

- < Outbreak investigations
- < Evaluation of STI syndromic management algorithms
- < Rapid assessment of STI prevalence in defined populations using new diagnostic tests (e.g., urine PCR and ligase chain reaction (LCR) tests for chlamydia and gonorrhoea; PCR testing of genital ulcer specimens for chancroid, syphilis, and herpes)
- < National probability sample survey of STI prevalence using serologic tests for syphilis (and other STIs) and urine tests for chlamydia and gonorrhoea.
- < Assessment of antimicrobial resistance in *Haemophilus ducreyi*
- < Incidence and prevalence of STI-related complications:
  - PID
  - Ectopic pregnancy
  - Cervical cancer
- < Prevalence of viral STIs (e.g., HSV-2, human papillomavirus [HPV], and hepatitis viruses)
- < Prevalence of bacterial vaginosis and associated sequelae in defined populations
- < Assessment of STI incidence and prevalence among persons who are HIV-positive, and of HIV prevalence among persons with other STIs
- < Development and evaluation of STI screening criteria
- < Assessment of health care-seeking behaviour and its relationship to underdetection and underreporting of STIs
- < Public and private sector STI screening and reporting practices
- < Country-specific estimates of incidence and prevalence of STIs
- < Estimation of economic costs of STIs

8. BASIC AND ADVANCED STI SURVEILLANCE AND THE CLASSIFICATION OF HIV/AIDS EPIDEMICS

The STI surveillance system should be designed considering current systems of STI care, including the availability of diagnostic tests. The HIV epidemic state can also have implications for STI programme development and surveillance priorities. The options for STI surveillance based on these considerations are outlined below.

8.1 Basic and advanced STI surveillance activities

A *basic* level of STI surveillance activities should be instituted in those countries with minimal resources. These include the following:

- < Case reporting
  - Syndromic reporting of urethral discharge (in males) and genital ulcers (in males and

females) through sentinel sites or a system of universal reporting, and using minimum data elements
    - Universal reporting of congenital syphilis cases. (The feasibility and utility of routine reporting of neonatal conjunctivitis/ophthalmia neonatorum has not been fully evaluated)
< STI prevalence assessment and monitoring
    - Periodic prevalence assessments in vulnerable populations (e.g., female sex workers), which includes syphilis serologic testing, gonorrhoea testing, chlamydia testing, and examination for genital ulcer disease; and assessment of syphilis seroreactivity among antenatal or parturient women.
< Antimicrobial resistance monitoring
    - N. gonorrhoeae, annually
< Assessment of syndrome etiologies
    - Genital ulcer disease, urethral discharge, and vaginal discharge, about every three years
< Special studies
    - Evaluation of STI syndromic management algorithms, about every three years.

An *advanced* level of STI surveillance activities can be performed in countries with more capacity and well-developed systems of clinical laboratory testing. Some of these activities may be more appropriate for some countries than others:

< Case reporting
    - Etiologic case reporting of syphilis (by stage), gonorrhoea, chlamydia, and congenital syphilis.
< Prevalence assessment and monitoring
    - Periodic or ongoing prevalence assessments in vulnerable populations (e.g., female sex workers) and the general population (e.g., women attending family planning clinics, antenatal and parturient women, military recruits), which includes syphilis serologic testing, testing for gonorrhoea, chlamydia, and trichomoniasis and examination for genital ulcer disease in some populations.
< Antimicrobial resistance monitoring
    - N. gonorrhoeae
< Assessment of syndrome etiologies
    - Genital ulcer disease, at least every three years (urethral discharge and vaginal discharge are usually adequately assessed by routine laboratory tests, but because of the difficulties of accurate laboratory diagnosis of primary syphilis and chancroid, genital ulcer disease may often be misdiagnosed and under reported)
< Special studies
    - Special studies related to STI surveillance activities are listed in Box 10. Of particular importance are investigations of outbreaks of diseases in countries where the incidence is low (e.g., syphilis and chancroid in most industrialised countries). Data on seroprevalence of HSV-2 through a population-based serosurvey or serosurveys of specific sub-populations can be useful, especially for countries beginning to consider HSV-2 prevention programmes. Some prevalence data on HPV in defined populations,

for subtypes associated with cervical neoplasia, may also be of interest. Knowledge of prevalence of bacterial vaginosis in some groups of pregnant women may assist in supporting recommendations for screening for this condition in women at risk for pre-term delivery.

8.2 Implications of the classification of HIV/AIDS epidemics for STI surveillance activities

UNAIDS/WHO has developed a classification of HIV/AIDS epidemic states, similar to a typology previously developed by the World Bank (Box 10). In general, the STI surveillance activities that are recommended above pertain to countries at all stages of the HIV epidemic. However, this classification of epidemic states has two implications for *basic* STI surveillance activities that go beyond those described above:

- In countries with generalised epidemics, prevalence assessment and monitoring in general population groups (antenatal and parturient women, family planning attendees) should also include chlamydia and gonorrhoea.
- Whereas basic prevalence assessment activities in countries with low grade epidemics can focus (at least initially) on urban areas, in countries with concentrated and generalised epidemics, they should be extended to include rural populations as quickly as possible.

These recommendations support extending STI prevalence assessment and monitoring activities in countries with high HIV prevalence to include more STIs and broader geographic coverage than listed under the basic activities described above. In such countries (even those with limited resources), these data are needed to assist in setting programme priorities, and thus to improve targeting and evaluation of STI control and HIV prevention efforts.

Box 10

Classification of HIV/AIDS Epidemics

Low grade

Principle: Although HIV infection may have existed for many years, it has never spread to significant levels in any sub-population. Recorded infection is largely confined to individuals with higher risk behaviour: e.g. sex workers, drug injectors and men having sex with other men. This epidemic state suggests that networks of risk are rather diffuse (with low levels of partner exchange or sharing of drug injecting equipment), or that the virus is only very recently introduced. *Numerical proxy*: HIV prevalence has not exceeded five percent in any defined sub-population.

Concentrated

Principle: HIV has spread rapidly in a defined sub-population, but is not well established in the general population. This epidemic state suggests active networks of risk within the sub-population. The future course of the epidemic is determined by the frequency and nature of links between highly infected sub-populations and the general population. *Numerical proxy*: HIV prevalence over five percent in at least one defined sub-population. HIV prevalence below one percent in pregnant women

Generalised

Principle: In generalised epidemics, HIV is firmly established in the general population. Although sub-populations at high risk may continue to contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain an epidemic independent of sub-populations at higher risk of infection. *Numerical proxy:* HIV prevalence over one percent in pregnant women.

9. DISSEMINATING, COMMUNICATING, AND USING STI SURVEILLANCE DATA

Dissemination of STI surveillance data to health centres, clinicians, and laboratories who have reported the data can help to increase timely, valid and complete reporting. National STI programme managers should use STI surveillance data to guide, target, evaluate and demonstrate the need for programmes of STI and HIV prevention.

National STI programmes should develop and implement a plan to effectively communicate the analysis and interpretation of STI surveillance data to national AIDS programme directors, district medical officers, health care providers, non-governmental organisations, donors and other public health agencies. To the extent possible, persons experienced in health communications should assist in the design of materials that will concisely summarise and effectively communicate the data to each of these groups.

When communicating surveillance data, STI programmes should consider using the following types of reports:

- Annual report, *with case numbers, rates, and trends by geographic area and demographic variables, and prevalence data by population.*
- Fact sheets *with tables and graphs that can be posted at health department offices and clinics, and provided in response to ad hoc inquiries.*
- Newsletters *for clinicians, laboratory personnel, and others; these may include brief reports of surveillance data, along with updated information on patient management.*
- Press releases *which highlight disease burden and trends, and which can be used as part of public information campaigns.*

10. EVALUATION OF STI SURVEILLANCE SYSTEMS

Evaluation of STI surveillance systems should be performed every two years within the framework of the WHO "Protocol for the Evaluation of Epidemiological Surveillance Systems". In these evaluations, there are several considerations specific to STI surveillance systems that need to be addressed. These are listed on next page.

Box 11

Key points for evaluating STI surveillance systems

- The evaluation should begin with identification of all STI surveillance activities, categorising them by component (e.g., case reporting, prevalence assessment and monitoring, assessment of syndromes etiologies, antimicrobial resistance monitoring, and special studies) and by syndrome or disease.
- Initially, each component (case reporting, etc.) should be evaluated separately, and within each component, separate attention given to each reported syndrome or disease.
- After evaluating each component, an overall assessment should be performed that identifies components that need to be strengthened, gaps, areas of duplication and activities that can be dropped.

Following the surveillance evaluation, a plan for strengthening STI surveillance should be developed that identifies priorities within the context of the country's comprehensive STI/HIV prevention plan.

ANNEXES

Annex 1: Summary reporting formats

Example 1: Syndromic case reports by gender and age

Date: _____

Reporting site (or jurisdiction):_____
Month/year: ____/_____

Age[1]	Genital ulcers		Urethral discharge
	Male	Female	Male
15-24			
≥25			
Other/unknown			
Total			

1. Alternatively, age may be coded by additional 5-year groups, e.g., 10-14, 15-19, 20- 24, ≥25 (or 25-29, etc.)

Example 2: Etiologic case reports by gender and age

Reporting site or jurisdiction:_____

Month/year: ____/_____

Age[1]	Primary/secondary syphilis[2]		Latent syphilis		Gonorrhoea		Chlamydia		Chancroid	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
10-14										
15-19										
20-24										
25-29										
30-34										
35-39										
40-44										
45-49										
50-54										
55-64										
65+										
Unknown										
Total										

Notes:

1. Age categories should include at a minimum 15-24 and ≥25.
2. Syphilis may be further categorised as primary, secondary, early latent, late latent, latent of unknown duration. Congenital syphilis is not included in this example.

Example 3: Case reports of perinatally-acquired STIs*

Date: _____

Reporting site (or jurisdiction):_____
Month/year: ____/_____

Congenital syphilis			Ophthalmia neonatorum	
Probable	Confirmed	Stillbirth	Probable	Confirmed

*Surveillance case definitions for these conditions are described in Section 3.4

Example 4: Prevalence assessment/monitoring by category[1]

Reporting site (or jurisdiction):_____

Month/year: ____/_____

	Syphilis (RPR or VDRL)		Gonorrhoea		Chlamydia	
	Positive	Negative	Positive	Negative	Positive	Negative
Prenatal						
Delivery						
Sex workers (f)						
Other female[2]						
Male[3]						

1. May further categorise by age (e.g., <25 years; ≥25 years)
2. May further categorise by testing site or population screened (e.g., blood donors, family planning, STI, etc.)

2. May further categorise by testing site or population screened (e.g., blood donors, STI clinic). Gonorrhoea and chlamydia screening of asymptomatic men can be performed using urine tests (LCR or PCR), but these are not routinely available in many countries.

ANNEX 2: STATISTICAL TABLES

Statistical table 1: 95% confidence intervals for observed prevalence by sample size, based on the binomial distribution

Sample size

Prevalence (%)	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

Source: Fleiss JL. Statistical Methods for Rates and Proportions, 2nd edition. New York: John Wiley & Sons, 1981; and Snedecor GW, Cochran WG. Statistical Methods. Ames, Iowa: Iowa State University Press, 1967.

Statistical table 2: Sample size required for determining a significant ($p < 0.05$) decline between two proportions, with a power of 0.8, by baseline prevalence and proportional decline.

Proportional decline compared with baseline prevalence (%)

Baseline prevalence (%)	10	20	30	40	50	60	70	80	90
1	145,800	34,000	14,000	7290	4280	3000	2070	1459	1060
5	28,000	6550	2800	1500	903	585	400	282	204
10	13,300	3200	1350	718	432	280	190	135	97
15	8500	2030	850	457	275	178	122	86	62
20	6000	1425	612	326	197	128	87	61	44
25	4500	1090	463	247	149	97	66	46	33

Note: Sample size requirements for determining significance of trends based on more than two observations may be larger or smaller, depending on the values of the intervening proportions.

Source: Snedecor GW, Cochran WG. Statistical Methods. Ames, Iowa: Iowa State University Press, 1967.

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