

A Surveillance Model for Sexually Transmitted Infections in India

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Summary

The strategy for prevention and control of sexually transmitted infections (STIs) in India is based on syndromic case management delivered through designated STI/reproductive tract infection (RTI) centers (DSRCs) situated in medical colleges, district hospitals, and STI-clinics of targeted interventions programs. Laboratory tests for enhanced syndromic management are available at some sites. To ensure country-level planning and effective local implementation of STI services, reliable and consistent epidemiologic information is required on the distribution of STI cases, rate and trends of newly acquired infections, and STI prevalence in specific population groups. The present STI management information system is inadequate to meet these requirements because it is based on syndromic data and limited laboratory investigations on STIs reported passively by DSRCs and laboratories. Geographically representative information on the etiology of STI syndromes and antimicrobial susceptibility of STI pathogens although essential for optimizing available treatment options, is deficient. Surveillance must provide high quality information on: (a) prevalence of STIs such as syphilis, trichomoniasis, gonorrhea, and chlamydia among high-risk groups; syphilis in the general population and pregnant antenatal women; (b) demographic characteristics such as age, sex, new/recurrent episode, and type of syndromically diagnosed STI cases; (c) proportion of acute infections such as urethral discharge (UD) in men and nonherpetic genital ulcer disease (GUD) in men and women; (d) etiology of STI syndromes; and (e) gonococcal antimicrobial susceptibility. We describe here a framework for an STI sentinel surveillance system in India, building on the existing STI reporting systems and infrastructure, an overview of the components of the proposed surveillance system, and operational challenges in its implementation.

Keywords: Framework, India, sentinel surveillance, sexually transmitted disease (STD), sexually transmitted infection (STI)

Introduction

Why surveillance?

Surveillance denotes ongoing systematic collection, collation, analysis, and interpretation of output and outcome-specific data for the planning, implementation, evaluation, and improvement of public health practice.¹

The success of a surveillance system depends on timely dissemination of derived information to policymakers and program implementers to develop and implement evidence-based effective interventions.² Surveillance systems can provide information about time, place, and person distribution of all cases of disease diagnosed in any setting (universal surveillance) or from a sample thought to provide services for populations at high risk of disease (sentinel surveillance).³

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Why sexually transmitted infection surveillance?

Annually, as per the estimates of the World Health Organization (WHO) 498.9 million curable sexually transmitted infections (STIs) occur globally.⁴ Studies suggest that the population prevalence of STIs such as syphilis, gonorrhea, and chlamydia has a range of 0-3.9% in India but the STI burden is much higher among subpopulations practicing high-risk behavior.⁵ An efficient program management for STIs requires reliable and consistent information on the level and trends of recently acquired STI and prevalence of STI in different population groups that are at a higher risk of acquiring STI. Additionally, a good understanding of the etiological profile of the syndromes and patterns of antimicrobial susceptibility form the basis for updating STI treatment guidelines periodically.

International experience with surveillance for sexually transmitted infections

Various forms of surveillance strategies for STIs are practiced globally. Universal etiological case reporting in the United States of America captures all the diagnosed STI cases.⁶ In European countries such as Germany, France, and the United Kingdom, and KwaZulu Natal in South Africa, the STI surveillance system involves private practitioners and private laboratories.⁷⁻⁹ In China, human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), syphilis, and gonorrhea are reportable STIs to the national surveillance system by law¹⁰ although data are also collected on chlamydia, *condylomata acuminata*, and herpes simplex virus (HSV) infection.¹¹ In Brazil, epidemiological data on STIs are scarce but notification is mandatory for HIV/AIDS in pregnant women and exposed children as well as syphilis and urethral discharge syndrome in men.¹² Thailand has a robust universal etiological STI surveillance system, which is actively used for program planning.¹³

Description of STI reporting system of National AIDS Control Organization (NACO) in India

At present, the National AIDS control program of India (NACP) implemented by NACO collects service statistics on STI syndromes and syphilis screening among STI and antenatal clinic attendees through the computerized management information system (CMIS). The reporting units include designated STI/RTI clinics (DSRCs) and STI clinics of targeted interventions (TIs). The latter provides on-site services to high-risk

groups such as men who have sex with men (MSM), female sex workers (FSWs), injecting drug users (IDU), transgenders, long-distance truckers, and male migrants.¹⁴ Between 2007 and 2012, 34.9 million (range 2.6-10 million per year) episodes of STI and RTI have been treated at the STI clinics managed by NACO.¹⁵ In addition, seven regional STI training, reference, and research centers provide information on etiologic diagnoses and gonococcal antimicrobial susceptibility. Recently, NACO has also initiated reporting of STI syndromes at subdistrict levels through the Health Management Information System (HMIS) of the National Rural Health Mission (NRHM).

Strengths and limitations of the existing National AIDS Control Organization surveillance mechanism and infrastructure

There are challenges in interpreting information on STI that emerge from the service facilities due to incompleteness and/or inconsistent reporting. The information are a mix of syndromic and etiologic case reporting.¹⁶ There is nonuniformity in data due to suboptimal adherence to NACO's STI syndromic case definitions and national guidelines for data collection and reporting mechanisms by the staff responsible for data collection and reporting. Additionally inadequate syphilis posttest reporting and follow-up and operational problems such as the lack of explicit guidelines for reporting STI cases attending other departments (most importantly those attending the outpatient gynecology department also contribute to incompleteness of reported data. The present STI reporting system is restricted to symptomatic cases who attend health care facilities.¹⁴ Thus, information on asymptomatic infections particularly among women are not captured. Similarly, symptomatic patients seeking care at facilities other than the government clinics or alternative systems of medicine also remain unreported. Data derived from STI prevalence studies show wide variations in methodology for laboratory diagnosis, clinic based risk-group investigations, and geographical areas.⁵

Initiating "sentinel" surveillance for sexually transmitted infection in India

For various reasons mentioned above, India needs a STI sentinel surveillance system that is accurate, adequate, and uniform and hence, should include a limited number of purposively selected sites and population groups. The "sentinel" nature would help ensure greater supervisory

support and regular monitoring to maintain a high level of data quality that is strikingly deficient in the present system.^{2,7} Additional in-depth qualitative information on few key risk behaviors could also be collected from a subsample. The data on prevalence and syndromic etiology obtained from the sentinel surveillance system should be used in conjunction with the management information system (MIS) data to describe the national burden of STI.^{5,16} It is essential that syndromic approach, which is the mainstay of STI case management in India, is validated regularly. Sentinel STI surveillance system would provide a good platform for this purpose. Systematically and timely collected accurate and detailed STI surveillance data from different population groups and geographical areas are needed to monitor the trends in incidence, prevalence, STI etiology, antimicrobial susceptibility, and risk behaviors of STI among different population subgroups and to decide on treatment guidelines. This would help to appropriately plan resources and improve patient management. This article suggests a framework for STI surveillance in India that will build on the STI reporting systems and infrastructure that are already in place.

Methods

Core components

The following core components are being proposed to achieve the abovementioned objectives. The rationale for each of the core components is summarized in Table 1.

Core component #1: To estimate the magnitude of sexually transmitted infection syndromes and to estimate the proportion of new infections

Inferential and analytical strengths of syndromic diagnosis will be provided by supplementing this data with demographic details on age, sex, and place of residence. The presenting syndrome will be characterized as a new or recurrent episode. The STI program in India partly collects and reports some findings based on elements captured through 1,100 STI¹⁵ reporting units. Information on STI syndromes would help monitor the distribution of STI disaggregated by age group, sex, geographical area (place of residence), etc. Additionally, data on the number of attendees at a clinic would be helpful in planning appropriate treatment and follow-up services based on estimated STI disease burden at the clinic.

An estimate of newly acquired infections will be derived from acutely presenting syndromes. These include urethral discharge (UD) in men and nonherpetic genital ulcer disease (GUD) among men and women.¹⁷ STI surveillance is a component of second generation HIV surveillance.¹⁸ STIs are considered as markers of unprotected sexual intercourse and ongoing high-risk sexual activity. Hence, surveillance for newly acquired STI will potentially provide warning signals for HIV transmission through the sexual route. This information will be especially useful in low HIV prevalence areas to monitor HIV transmission.¹⁹

Core component #2: To assess specific etiologies for presenting syndromes periodically

The etiologies of syndromes will be determined to estimate the burden of specific pathogens and to update treatment guidelines to update treatment guidelines. The etiologies of common syndromes such as UD among men, GUD among men and women and vaginal discharge among women will be assessed every 2-3 years. A recent study from India assessed the etiologies among men with complaints of genital ulcer; based on high detection rates for *Treponema Pallidum*, the study suggested a revision of existing national STI treatment guidelines in India to include treatment of syphilis for all GUD patients.²⁰ Thus, periodic monitoring for the changing spectrum of etiologies would guide STI syndromic treatment.

Core component #3: To determine prevalence of sexually transmitted infections in different population groups and identify their demographic determinants

Cross-sectional surveys will be conducted to monitor STI prevalence in both the general population and among subgroups that are at a higher risk of acquiring STI. STI control programs need prevalence data to monitor their trends and to understand which population groups are at a greater risk for infection. These prevalence surveys would determine what percentage of people has STI. Over the years, this would enable observing prevalence trends to assess the efficacy of interventions. Prevalence data are required for estimating the burden of STI, prioritizing funding and resource allocation, identifying population groups at high risk of HIV, and helping to monitor the effectiveness of prevention programs for HIV/STI. Various population categories such as sexually active groups (FSW and MSM), pregnant women, and family planning clinic attendees are to be assessed for

Table 1: Gap analysis of the present surveillance system for STI in India

Objective	Source	Why	Indicators required	Current status in India	Laboratory facility requirement	Major challenge	Additional requirement for surveillance	Frequency of data collection
To provide information on STI cases	Syndrome case reports	Distribution of STI* by age, sex, To inform needs for manpower, treatment kits, etc.	Number of people attending, no. and types of syndromes, disaggregated by gender, age, place of residence	Reported through the SMIS	None	Incompleteness, inconsistency, misclassification, erroneous reporting	Reporting would be strengthened at sentinel sites	Regular at sentinel sites
To estimate proportion of acute infections	Syndrome Case reports	Indicator of burden, Early warning for HIV** sexual transmission in low HIV prevalence areas	Number of and proportion of syndromes with UD*** (males), GUD*** (males and females)	Reported through the SMIS	None	Incompleteness, inconsistency, misclassification, erroneous reporting	Reporting would be strengthened at sentinel sites	Regular at sentinel sites
To document prevalence of STIs	Prevalence surveys	Indicator of burden in specific population groups, tool for program management, evaluation of STI and HIV prevention programs	Proportion positive for specific etiologic agent	Not being done, apart from one community-based study, and IBBA* in selected districts and other local studies	Yes	Survey-based Would require laboratory set up, SOPs, quality assurance of labs, sample transport mechanism, adequacy of specimens	Periodic assessments needed among HRGT (FSW [†] ; MSM [†]), Among ANCs* for syphilis at sentinel sites	Every 5 years
To assess etiologies of syndrome	Etiological assessment of reported syndromes	Crucial for updating treatment guidelines	Proportion of specific pathogen for STI syndrome mainly for UD, GUD, and vaginal discharge	Not existent	Yes	Would require linkage of the proposed sentinel clinic with laboratories	Periodic etiological assessments to be included at DSRCs	Every 2-3 years
To assess anti-microbial resistance	Monitoring of antibiotic resistance pattern against <i>Neisseria gonorrhoea</i>	Necessary for optimization of treatment regimens	Limited data, available mainly from northern India	Yes	Yes			

*STI = Sexually transmitted infection, **HIV = Human immunodeficiency virus, ***UD = Urethral discharge, ****GUD = Genital ulcer disease, \$SOPs = Standard operative procedures, †HRG = High-risk group, †FSW = Female sex worker, †MSM = Men who have sex with men, †ANCs = Antenatal clinics, †IBBA = Integrated biological and behavioral assessment, SMIS = Strategic management information system

syphilis, trichomoniasis, gonorrhea, and chlamydia. Recruitment of subjects for such surveys can be done at sentinel sites that could be either facility based such as antenatal and family planning clinics or drop-in centers at a TI site [for high-risk group (HRG) populations]. With appropriate operational adjustments, these surveys can also be combined, along with bio-behavioral surveys or HIV sentinel surveillance.

Core component #4: To determine antimicrobial susceptibility

Optimum treatment of *Neisseria gonorrhoeae* (NG) infection is necessary to achieve microbiological cure, along with a relief of the signs and symptoms of infection and prevention of serious complications. Emerging antibiotic resistant strains of NG is a worldwide concern. Decreased susceptibility of NG to tetracycline was reported as early as 1971 from India.²¹ Recently, resistance to oral third-generation cephalosporins such as cefixime and ceftibuten has been reported from Japan, Hong Kong, and Taiwan.²² In view of the elevated minimum inhibitory concentrations (MICs) for cefixime, the Centers for Disease Control and Prevention (CDC) 2010 treatment guidelines does not recommend cefixime as a first-line regimen for treatment of gonococcal infections.²³ Thus, monitoring of antibiotic resistance pattern against NG is a core component of STI surveillance activity that would provide necessary information for the optimization of treatment regimens. Majority of the studies on antimicrobial resistance for gonorrhea in India have been conducted at tertiary referral care centers, mostly from Northern India.⁵ Therefore, to determine the extent and distribution of antimicrobial susceptibility to common antibiotics used in the treatment of STI in the country, testing will be done periodically in different geographical areas.

STI sentinel surveillance mechanism

What should be the sentinel units?

Given the heterogeneity in the country, we propose to consider a district as a sentinel unit, within which selected (sentinel) DSRCs, TIs, and (if present) private practitioner clinics would function as sentinel reporting sites. Initially, a convenience sample of the desired number of districts with a large population of HRGs, high-risk behavior of key population groups, documented high prevalence of STI, and evidence of substantial population migration will be selected. To enable etiologic diagnosis, availability of specimen transport facilities and access to laboratories would also be considered.

Surveillance platform

The basic platform for the surveillance system will consist of STI or gynecology clinics, TI clinics, or private STI clinics. The selection of TI clinics would be a purposive sampling dependent upon their performance, ability to handle data management, possession of data quality practices, and the willingness to participate in such a surveillance system. A presurveillance feasibility assessment of the sentinel reporting sites will be made for the assessment of client turnover, presence of essential infrastructure, and willingness of staff and laboratory facilities (at places where etiologic tests would be performed).

Types of surveillance

Syndromic core surveillance will be carried out routinely and all through the year to track the burden and trends of various syndromes, whereas etiologic surveillance for STI will be periodically attempted with strong laboratory testing support to track the transmission patterns of STI pathogens. Prevalence surveys will be conducted among specific population groups in these districts. For conservation of resources, the possibility of combining STI prevalence surveys with HIV bio-behavioral surveys will be explored.

The sentinel populations

There is a need to capture STI data from different population groups, namely, populations with high-risk behaviors, bridge populations, and the general population.¹⁶ We have already proposed that sexually active groups (FSW and MSM), pregnant women, and family planning clinic attendees could be the populations initially targeted for inclusion in sentinel surveillance. Standard case definitions (based on syndromic or etiologic diagnosis) will be used [Table 2]. For etiologic diagnosis, the infrastructure of STI laboratory facilities set up by NACO should be utilized. This includes the seven regional STD laboratories (RSLs) and the state reference centers (SRCs). The SRCs would perform the first-level tests and store the samples, which would be shipped periodically to the RSLs for evaluation and validation of results. The RSLs would be responsible for training, quality assurance and the management of the SRCs.

Sampling and sample size

The routine core surveillance will cover all the clinic attendees but care will be taken to ensure that no participant is included in the survey for more than

Table 2: Collected data and analysis of different core components

Core component	Data collection	Data analysis
STI syndrome	Required: Age, sex, place of residence, syndromic diagnosis Others: Education, new/recurrent episode, treatment received	Describe the number of attendees and number of syndromes by age, sex, residence, new/recurrent STI* infections, risk behavior Description of place of residence would indicate if there are geographic clustering of cases Trends to be plotted, by sentinel sites
Newly acquired STIs	Required: Age, sex, place of residence, syndromic diagnosis Others: Education, new/recurrent episode, treatment received	Proportion of men diagnosed with UD [‡] Proportion of men and women diagnosed with nonherpetic GUD [†] Trends to be plotted, by geographical areas
Prevalence surveys	Required: Age, sex, place of residence, syndromic diagnosis Others: Education, new/recurrent episode, treatment received, risk behavior Sample size: As per estimate of STI prevalence in population, feasibility, budget Sampling strategy: Consecutive or random (if line list available)	Proportion positive for a STI pathogen, by age, sex, geographical area Trends to be plotted for consistent sites over the years
Etiology of syndromes	Required: Age, sex, place of residence, etiological diagnosis, Others: Education, new/recurrent episode, treatment received, date of specimen collection, Sample size: Minimum sample of 100 specimens ²⁴ Sampling strategy: Swabs would be collected from consecutive men and women presenting with a visible urethral discharge and cervical discharge, respectively	Proportion of specific organisms, by age, sex, geographical area
AMR	Required: Age, sex, place of residence, etiological diagnosis Others: Education, new/recurrent episode, treatment received, date of specimen collection, adherence to medication Sample size: Minimum 100 ²⁴ Swabs would be collected from consecutive men and women presenting with a visible urethral discharge and cervical discharge, respectively	Description of specific resistance type, by age, sex, geographical area

*STI = Sexually transmitted infection, [‡]UD = Urethral discharge, [†]GUD = Genital ulcer disease

once every year. The sample size for etiological survey would depend on the specific etiology and its anticipated prevalence. However, a minimum sample size of 100 specimens from consecutive patients with the specified syndrome will provide preliminary information for analysis.²⁵ Consecutive sampling may be considered as a type of systematic random sampling where the sampling interval is zero. For the antimicrobial susceptibility surveys, a sample size of around 100 is targeted.²⁵ Swabs would be collected from consecutive men and women presenting with a visible urethral discharge and cervical discharge, respectively.

Data management

Computerized data management for surveillance for STIs would greatly help in automated data transfer, data validation, and timely customized report generation. Data should therefore, be entered in standard data formats at the source, in software capable of handling multilevel entries and validation.

Training and support activities

The operational guidelines, training manuals, and job-aids will be developed for providing guidance on case definitions for syndromes/etiologies to be reported; the roles and responsibilities of the staff; steps for data entry and troubleshooting; eligibility criteria, steps for specimen collection for prevalence surveys; standard operating procedures (SOPs) for laboratory procedures, etc. Surveillance output would be dependent on the quality of training of the surveillance staff. To ensure uniform standards across sentinel sites, modular training using a standardized training manual will be utilized.

Coordination

Such a large scale activity would require the presence of a coordination team that would contribute to the finalization of surveillance design, selection of the sentinel units, meeting regularly to review progress, and the addressing of challenges. The regional centers for STIs, being the centers of excellence, may be imparted regional

responsibility for periodic presurveillance assessment of sentinel reporting units, trainings for surveillance, monitoring, supervision, quality control, data entry, data analyses, coordination between sentinel districts and the central nodal agency, and regional trouble shooting.

Monitoring will assess the adequacy of sentinel clinic infrastructure for data and sample collection; presence of trained staff (medical officer, laboratory technician); adherence to surveillance protocol, measures of confidentiality, guidelines for sample collection and processing; presence of adequate laboratory as well as nonlaboratory consumables and checks for data quality using a specially developed and uniformly adopted checklist.

Ethical aspects

Stigma and the resultant discrimination of the people who have STI has been one of the reasons for the lack of complete and reliable STI/RTI data in India.²⁶ Confidentiality of client information will be preserved by the delinking of personal identifiers, development of appropriate guidelines, and training of clinic/laboratory staff involved in surveillance. A decision to communicate to the client the results of antimicrobial susceptibility tests, otherwise valid only at the population level, would depend upon assessing the benefits for the management of individual patients.

Results and Discussion

The objectives of this paper was to propose a framework for STI surveillance in India so as to improve STI program planning and management by estimating the magnitude of STI syndromes, deciding the etiology, describing the distribution in different subpopulations and geographical areas by various population characteristics, and monitoring the trends over time. It will also contribute in ensuring a uniform reporting of STI syndromes and improving patient care by suggesting appropriate treatment algorithms for common STI syndromes based on the observed antimicrobial susceptibility patterns.

It is anticipated that with serious emphasis on establishing the STI sentinel surveillance, giving adequate emphasis on quality management at high levels, this network will be able to meet its objectives. STI case reporting will be etiologic as well as syndromic. Data should be analyzed at each stratum (district, state, and national) for enabling appropriate programmatic actions [Table 2]. Increase, decrease, or other unusual findings will have to be adequately investigated.

Simplicity, timeliness, and data quality will be the most essential attributes of the STI sentinel surveillance program. No new data variable is being proposed. While syndromic reporting is proposed to be a regular feature (monthly reporting as is being done currently), etiological reporting if conducted once in 2 years will suffice. Additional effort would be only in terms of computing individual case based data entry so as to enable cross-tabulation of diagnoses with other variables. Data forms for private practitioners should be simple, straight-forward, and with minimum variables to be reported. Simplicity of data forms, standardized and uniform training, and regular supervision would help to ensure quality of the reported data. *Sensitivity and representativeness*: Sensitivity of a surveillance system can be defined either as the proportion of cases detected by the surveillance out of all who are infected or by the completeness of case-reporting. Sensitivity could be affected by the probability that a person with STI seeks care at a health facility, which is a sentinel site; the syndrome is correctly diagnosed by the physician (physician skill-dependent upon training) or the etiology is correctly picked up by the laboratory test (depends upon various laboratory factors); the STI syndrome/etiology is reported after the diagnosis is made (responsibility of the clinic counselor or laboratory technician for reporting dependent upon training). According to the model we propose, all DSRCs in the sentinel district would report the syndromes diagnosed. Assuming that reported cases are correctly diagnosed, (i.e., there is no misclassification), this model is expected to pick the proportion of STI cases who would be reporting to government health care facilities. As per the national Behaviour Surveillance Survey (BSS) among the general population, self-reported health care seeking for STI symptoms was 25.7% for government facilities (43.6% did not seek any care).²⁴ Hence, by involving high turnover private practitioners to the reporting network as per our model, this proportion would be higher. Around 29% of the general population respondents in the BSS 2006 had reported preferring a private practitioner for a future episode of STI.²⁴

A detailed plan of dissemination should include the steps, timeline, and people identified for performing quality checks, data validation, preparation of data tables, making the data available for data analysis, analysis of the data, interpretation of the findings, preparation of customized reports for national, state, district, and sentinel site/clinic levels, and its systematic dissemination. Targeted training of the hierarchy of

the staff identified should be a prerequisite. End-user experience of STI surveillance information could be enhanced by representing spatial relation between risk factor/demographics and outcome of interest such as case distribution mapping.²⁷

Conclusion

We have described the framework to initiate a surveillance system for STI in India where STIs have been recognized as a major public health problem. In a resource-limited setting, a mixed approach of passive and active surveillances is more appropriate because a newly initiated surveillance system would take time to get established, reach adequate coverage levels, and be able to generate consistent and reliable data. Hence, efforts should continue to strengthen the current routinely and passively collected STI information. Reliable data on the core components of STI surveillance would enable measuring the success of these important efforts and would assist program managers in evidence-based future planning. We have not attempted an economic evaluation of the proposed surveillance system. However, if the proposed model is considered to have scientific merit, financial implications of its implementation may be carefully considered.

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Conflicts of interest

There are no conflicts of interest.

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