STD Program Management

Surveillance & Epidemiology

Surveillance & Epidemiology Module Objectives
- Summarize the overall goals of STD surveillance systems
- Distinguish between the reporting and/or surveillance requirements for federal, state, providers, laboratories, and health care facilities.
- Describe common surveillance methods
- Describe the common pathway for STD case/lab reports to flow to the reporting authority
- Describe the basic components of STD surveillance systems
- Discuss the key attributes for successful STD surveillance systems

Surveillance & Epidemiology Module Objectives
- List the four criteria important to evaluating STD surveillance systems
- List fundamental goals of Epidemiology
- Briefly define incidence, prevalence, epidemic, pandemic, endemic.
- List questions that epidemiology can answer for STD programs
- List the four main epi functions that all STD program must be able to accomplish.
What is Public Health Surveillance?

Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health. (MMWR 2001;50)

Surveillance Systems...

- Provide timely, focused and relevant information upon which to base interventions for improving health
- Provide ongoing information for evaluating the success of public health interventions
- Provide evidence base for allocating resources for diagnosis, treatment and prevention of disease
Core Public Health Functions

- Assuranc
  - Link people to needed health services
  - Assure competent health care workforce
  - Inform, educate, and mobilize partnerships
- Policy Development
  - Policies supporting health goals
  - Laws and regulations protecting health
  - Research solutions to health issues
- Assessment
  - Monitor health status of communities
  - Investigate health problems and hazards
  - Evaluate population-based health services

The Bigger Picture

STIs Diagnosed → Data Management → Interpretation, Analysis & Dissemination → Disease Control & Prevention → Policy Development & Public Health Action

Goals of STD Surveillance Systems

- Understand the distribution and spread of sexually transmitted infections
- Identify outbreaks and clusters of cases to prioritize field investigations
- Inform health care policy and public health response in support of intervention and disease control planning efforts
- Evaluate disease control efforts and direct resources to most cost effective interventions
- Identify emergent issues impacting STD diagnosis and treatment
**Key Considerations for STD Surveillance**

- Public health importance of disease/condition
  - What are the consequences of infection?
- Costs
  - What resources – human and fiscal – are needed?
- Local context
  - Who are the stakeholders?
- Purpose
  - What will the information be used to accomplish?
- Actions
  - Are there specific actions that the surveillance data will inform?

**Legal Authority for Surveillance**

- Legally notifiable diseases/conditions are those for which regular, frequent and timely information on individual cases is considered a public health priority for prevention and control
- Legal authority resides at the state and territorial level (or at local level) for reporting with identifiers
- Providers, laboratories and other facilities may have different reporting requirements defined in statute or administrative code
- Nationally notifiable diseases/conditions are identified by the Council of State and Territorial Epidemiologists (CSTE) in collaboration with CDC and minimum data elements for national reporting suggested

**STIs on Nationally Notifiable Disease List**

- Chancroid
- Chlamydia
- Gonorrhea
- Syphilis and Congenital Syphilis
- HIV/AIDS
- States and territories may require additional conditions/diseases to be reported in their jurisdictions:
  - Herpes Genital Infections, Granuloma inguinale, NGU, etc.
  - LGV is subsumed under chlamydia reporting in some jurisdictions
  - PID is a clinical syndrome and is reportable in some jurisdictions when diagnosed in conjunction with a notifiable STD

* As of 2008
STI Case Definitions

- Case definitions direct surveillance activities and should provide operationally meaningful definitions:
  - Population of interest – for STDs this includes all sexually active persons
  - Places of interest – for STDs this includes all health care settings
  - Time period of interest – for STDs this includes all diagnosis regardless of the time frame of detection

- Case definitions often describe criteria for suspected, probable and confirmed cases
  - Laboratory confirmed cases are most relevant for STD surveillance

Chlamydia trachomatis, Genital Infections

**Clinical description**
Infection with Chlamydia trachomatis may result in urethritis, epididymitis, cervicitis, acute salpingitis, or other syndromes when sexually transmitted; however, the infection is often asymptomatic in women. Perinatal infections may result in inclusion conjunctivitis and pneumonia in newborns. Other syndromes caused by C. trachomatis include lymphogranuloma venereum (see Lymphogranuloma Venereum) and trachoma.

**Laboratory criteria for diagnosis**
Isolation of C. trachomatis by culture or demonstration of C. trachomatis in a clinical specimen by detection of antigen or nucleic acid

**Case classification**
- Confirmed: a case that is laboratory confirmed
**Gonorrhea**

**Clinical description**
A sexually transmitted infection commonly manifested by urethritis, cervicitis, or salpingitis. Infection may be asymptomatic.

**Laboratory criteria for diagnosis**
Isolation of typical gram-negative, oxidase-positive diplococci (presumptive Neisseria gonorrhoeae) from a clinical specimen, or
Demonstration of N. gonorrhoeae in a clinical specimen by detection of antigen or nucleic acid, or
Observation of gram-negative intracellular diplococci in a urethral smear obtained from a male

**Case classification**
Probable: a demonstration of gram-negative intracellular diplococci in an endocervical smear obtained from a female or b) a written morbidity report of gonorrhea submitted by a physician
Confirmed: a case that is laboratory confirmed

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**Syphilis**

**Primary syphilis**

**Clinical description**
A stage of infection with Treponema pallidum characterized by one or more chancres (ulcers); chancres might differ considerably in clinical appearance.

**Laboratory criteria for diagnosis**
Demonstration of T. pallidum in clinical specimens by darkfield microscopy, direct fluorescent antibody (DFA-TP), or equivalent methods.

**Case classification**
Probable: a clinically compatible case with one or more ulcers (chancres) consistent with primary syphilis; and a reactive serologic test (nontreponemal: Venereal Disease Research Laboratory (VDRL) or rapid plasma reagin (RPR); treponemal: fluorescent treponemal antibody absorbed [FTA-ABS] or microhemagglutination assay for antibody to T. pallidum [MHA-TP])
Confirmed: a clinically compatible case that is laboratory confirmed

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**Secondary syphilis**

**Clinical description**
A stage of infection caused by T. pallidum and characterized by localized or diffuse mucocutaneous lesions, often with generalized lymphadenopathy. The primary chancre may still be present.

**Laboratory criteria for diagnosis**
DFA-TP, or equivalent methods. Demonstration of T. pallidum in clinical specimens by darkfield microscopy, direct fluorescent antibody

**Case classification**
Probable: a clinically compatible case with a nontreponemal (VDRL or RPR) titer greater than or equal to 4
Confirmed: a clinically compatible case that is laboratory confirmed
Minimum data elements

- The minimum data required for national reporting through NETSS includes:
  - Reporting state
  - Unique case number
  - Patient DOB (age)
  - Patient race & Hispanic ethnicity
  - County of residence
  - Zip code
  - Case report date
  - Diagnosis code
  - Specimen collection date
  - Provider type

Many states and jurisdictions also require reporting of additional data elements at the local level.

Surveillance Methods

- Passive versus Active
  - Passive methods are commonly employed for STD surveillance
  - Active case finding is less common, except for HIV/AIDS

- Sentinel vs. Population-based
  - Most STD programs employ population-based case reporting
  - Special settings, such as STD clinics, can be sentinel sites for special surveillance (resistance monitoring, GISP)

- Syndromic
  - Syndromic surveillance is not relevant to STD programs in the U.S. because STDs have specific laboratory confirmation

Sentinel Surveillance

- Sentinel surveillance activities monitor defined populations or specific settings for events of interest
  - Gonococcal Isolate Surveillance Project (GISP) is an example of sentinel surveillance
  - A distinguishing characteristic of sentinel surveillance in STD programs is that these activities are almost exclusively clinic-based and for specific purposes
  - Sentinel surveillance activities often provide early evidence of changing risk behaviors, emergent disease trends or new risk factors for disease
Prevalence Monitoring

- STI programs monitor results of laboratory tests for chlamydia and gonorrhea conducted through reproductive health and other settings through the Infertility Prevention Project (IPP).

- Usefulness of these data may be limited by changes in the population being screened; caution should be exercised in interpreting test positivity (proportion of all tests that are positive) through the IPP.

Flow of Information

Many states and territories do not have an infrastructure for local health authority; reporting requirements compel reporting only to a single, central authority, usually the state STD program.

Flow of Information

In some states, providers, facilities and labs report to local county health departments – some jurisdictions may make no distinction between facilities and providers.
Basic Components of STD Surveillance

Provider-based and laboratory reporting are core activities of most STD surveillance systems.

Provider reporting can provide valuable demographic and behavioral information on patients being diagnosed but has the disadvantage of reliance on a large number of providers.

Laboratory reporting may be more complete but often lacks important information about patients and their characteristics.

Prevalence Monitoring

Prevalence monitoring collects data on tests performed in a defined population and monitors the proportion of positive tests over time.

Infertility Prevention Project (IPP) is an example of prevalence monitoring.

"Prevalence" and "Positivity" are often used interchangeably but there is an important distinction between the two. Prevalence refers to persons infected in a specific time frame whereas positivity refers to positive tests detected.

Enhanced STD Surveillance

Enhanced surveillance projects collect additional lab, behavioral, clinical or patient outcome data.

Enhanced surveillance data may help address information gaps in existing surveillance systems.
Components of STD Surveillance

- Surveillance Monitoring
- Laboratory Reporting
- Provider-based Reporting
- Enhanced Surveillance Projects
- Prevalence Monitoring
- Prevalence Monitoring

Key Attributes of Surveillance Systems
- Simple
- Acceptable
- Sensitive
- Specific
- Timely
- Flexible
- Representative

Costs must be balanced against utility of information.

Keeping it Simple
- For many STDs (such as chlamydia) a single surveillance method will suffice to provide meaningful information
  - Provider OR laboratory reporting
- Overly complex systems may strain limited resources and impede analyses, interpretation and dissemination
Stakeholders

- Programs should know who will be using the information provided by the surveillance system
  - Community partners such as Planned Parenthood use STD surveillance data to advocate for programs
- Members of the at-risk population should be informed of surveillance activities
  - For STD surveillance, general educational materials often suffice to inform at-risk populations and affected communities
- Clinics, labs and facilities should be aware of reporting requirements
- Policy-makers should be educated on the public health importance of the diseases
  - Surveillance reports and presentations to various decision-makers are an important STD Program activity

Sensitivity

- Is the ability of a STD surveillance systems to detect all diagnosed cases
  - Sensitivity of surveillance system is a function of multiple factors:
    - Case definitions for STIs
    - Ease of diagnosis and presence of symptoms
    - Availability of laboratory tests (CT, GC and Syphilis)
    - Efficiency of information flow
    - Broad dissemination of reporting requirements
  - Sensitivity can be enhanced by broad case definitions

Specificity

- The ability of the surveillance system to exclude persons without a confirmed diagnosis
  - Clear and concise case definitions help maximize specificity, including a requirement for laboratory confirmation of CT or GC
  - A comprehensive reactor grid for syphilis serologies enhances specificity by ruling out previously treated cases and prioritizing case investigations
  - Efforts to identify biologic false positive results enhance specificity
  - Consideration of positive predictive value of widespread screening in low prevalence populations can also be important in detecting false positives
Surveillance and Epidemiology

Timeliness
- Cases of disease should be detected early enough to for disease control efforts to be successful
- Many factors can have an impact on timeliness of reporting:
  - Each step in the data flow should be examined for reporting delays
    - Provider to local health authorities
    - Laboratories to local/state authorities
    - Local health to state STD program
    - State program to CDC
- Surveillance data should also be analyzed, interpreted and presented to stakeholders in sufficient time to inform policy-making

Flexibility
- STI surveillance systems may be re-directed to new or emerging diseases
  - HSV, HPV, etc.
  - Chlamydia reporting only recently added
- Can additional patient or pathogen-specific information be collected easily?
- Can new sources of information be added (i.e. Lab or EMR data)?

Representativeness
- Does the surveillance system capture information from all populations at risk for infection?
  - Categorical STD clinics
  - Private providers diagnosing STIs
  - Reproductive health settings – Planned Parenthood
  - Other facilities such as school-based or military
- Categorical or integrated surveillance?
  - System limited to a single disease or group of related conditions?
Evaluation of Surveillance Systems

- Sensitivity
  - Are all cases being detected?

- Timeliness
  - Are cases being reported in a timely fashion?

- Representativeness
  - Are all at-risk populations covered?

- CDC provides extensive guidance on evaluating surveillance systems
  - MMWR Recommendations and Reports

Limitations of surveillance systems

- Limitations of surveillance systems must be taken into consideration when interpreting trends in disease incidence and prevalence

STI Epidemiology
A working definition

- **Epidemiology:**
  - The study of the **distribution** and **determinants** of disease

  - **Distribution:**
    - Time, place and populations
  - **Determinants:**
    - Physical, biological, social, cultural, geographic and behavioral factors

  *From ancient Greek:*
  *Epi* – upon, among; *demos* – people, districts; *logos* – study, discourse

Goals

There are several fundamental goals of epidemiology in public health directly relevant to STD Programs

1) Interpret and report on general trends in the distribution of STDs in communities and populations

2) Identify and investigate clusters/outbreaks

3) Identify hazards and exposure risks for STDs to guide disease control and prevention efforts

Sources of Information

- Your surveillance system should provide the case data needed for analyses of disease incidence and prevalence

- Additional information about the populations and communities in your area will also be needed and can be obtained from census data

- Many states have a population center or agency where additional local information can be obtained
A Few Definitions

- **Incidence:**
  - Number of events (cases) occurring in a specified time period

- **Prevalence:**
  - Proportion (or number) of persons infected/affected at a given point in time or within a specified time period

Prevalence and incidence are often presented as a standardized "rate" to allow for comparison between groups or places. Rates are usually expressed as a ratio of cases to a specific population standard.

And more definitions

- **Epidemic:**
  - Cases of disease occurring in a given population and over a given time period in excess of those 'normally' expected

- **Pandemic:**
  - Epidemic of disease among people globally or over a very wide distribution of populations and places simultaneously

- **Endemic:**
  - Constant prevalence or incidence of disease/infection within a specific population or geographic area

Basic Reproductive Rate

The basic reproductive rate of an STD describes mathematically the likelihood of new infections and predicts whether transmission will increase, decrease or remain steady in a population over time:

\[ R_0 = \beta \times C \times D \]

- \( \beta \) = probability of transmission per exposure
- \( C \) = Number of exposures per unit time
- \( D \) = Duration of infectiousness

- Values greater than one indicate a growing epidemic
- Values less than one indicate that the disease is decreasing
- Values close to one indicate steady incidence or an endemic state
Incidence and Prevalence Rates

'Rate per 100,000' is calculated by:

\[
\text{Rate per 100,000} = \left( \frac{\text{Number of Cases}}{\text{Population}} \right) \times 100,000
\]

Rate per 100,000 is the convention for presenting STD incidence & prevalence data but rates can also be expressed in other conventions:

- Gonorrhea incidence in 2009 was 34 cases per 100,000
- There were 1.2 cases of neonatal herpes per 10,000 live births in 2005
- 6% of tests performed through the IPP were positive for CT in 2008

Person, Place & Time

- The most meaningful information epidemiology can provide for STD programs will answer the following questions:
  - Who is being infected?
  - What diseases are they being infected with?
  - When are people being diagnosed?
    - Is incidence changing over time?
  - Where are infected people...
    - ...living when they are diagnosed?
    - ...being diagnosed?
  - How are people becoming infected?

Who?

- Attributes of persons being infected:
  - Gender
  - Age
  - Race
  - Hispanic Ethnicity
  - Socioeconomic position
  - Behavioral factors
    - Gender of sex partners
    - Drug use
    - Number of partners
  - What are the differences in disease incidence between categories?
Race & Ethnicity

Gonorrhea Cases by Race and Hispanic Ethnicity, Washington State, 2007

Race and Hispanic ethnicity is often missing for a significant fraction of cases.

Missing cases may be redistributed by the proportion of known cases if there is no reason to suspect that there is bias in reporting.

Race Hispanic Ethnicity

- AI/AN: 2.2%
- BLACK: 22.7%
- MULTI/OTHER: 4.4%
- NH/OPI: 0.5%
- WHITE: 40.4%
- ASIAN: 1.9%
- UNKNOWN: 27.7%
- HISPANIC: 10.0%
- NON-HISPANIC: 54.4%
- UNKNOWN: 35.6%

* Cases diagnosed in 2007

Health Inequalities

Graphing incidence rates by race and ethnicity may reveal significant inequalities in disease incidence not revealed by charting just the proportion of cases from each group.

Comparing incidence rates for race/ethnic groups to the proportion of people in the population in each group is also crucial to identifying inequities in disease burden.

Behavioral Characteristics

Information may be available from case reporting or enhanced surveillance activities on risk behaviors - such as gender of sex partners – to help understand disease incidence and inform prevention activities.

Disease interventions for MSM may be quite different from those targeting primarily heterosexuals.
Where?

- Knowing about the distribution of cases across jurisdictions is essential to help direct prevention resources appropriately.

Gonorrhea Incidence Rate Per 100,000 by County, Washington State 2007

Location, location, location...

- For purposes of assigning morbidity, the residence of the patient should be used.
- If residence of the patient is not known, location of the provider is second best for morbidity.

Other locations of interest may be useful in planning interventions:

- Clinics
- Pharmacies
- Labs
- Hospitals
- Commercial sex venues

Geographic Information Systems

- Geographic Information Systems (GIS) provide new tools for programs to assign incident cases to the appropriate jurisdiction and to create useful maps displaying disease incidence information.

The core of GIS applications are tools that can reliably match address information on case reports and assign additional geographic information to the case like census tract, block group or neighborhood.
When?

- Changes in disease incidence over time are crucial to understanding epidemics and to public health planning.

Gonorrhea Incidence Rate in the United States, 1941 - 2005

Time Trends

- Trends are often presented by year of diagnosis but other time scales may be more useful.

Cases can also be analyzed by date of report, but date of diagnosis is more meaningful for understanding disease trends.

Is It Real?

Changes in surveillance methods, such as case definitions, as well as clinic and laboratory practices may effect the epidemic curve:

- Chlamydia — Rates: Total and by sex, United States, 1990-2007
- Chlamydia — Percent of tests that were nucleic acid amplification tests (NAATs) in family planning clinics among 15- to 24-year-old women by HHS region, 2003-2007
- Gonorrhea — Rates, 1941-2005

Screened For CT Infection, Washington State, 2002 - 2006
Is It Real II - Significance

- Confidence intervals may help evaluate whether a difference between times, groups or places is 'real'

Other tests of significance include:
- Chi Square test of trend
- Chi Square for bivariate analyses

Just because a difference is 'significant' does not always mean that it is necessarily meaningful!

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Epi Capacity for STD Programs

- At a minimum STD Programs should be able to:
  - Calculate incidence rates and graphically represent changes in incidence over time
  - Understand how changes to surveillance methods may affect reporting and incidence rates
  - Be able to compare incidence rates between demographic groups and by geographic regions in their jurisdiction
  - Be able to successfully interpret disease trends and inequalities to policy-makers and stakeholders

- Not all programs will have resources to hire full or part-time epidemiologists dedicated to STDs but should consider borrowing capacity from other programs (such as HIV/AIDS)