Introduction to HIV, AIDS and STI Surveillance

HIV Sero-surveillance

Participant Manual

August 2009
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Introduction

How to Study This Module

What you should know before the course

This course is meant primarily for district-level surveillance officers. As a participant, you should have a basic understanding of HIV/AIDS and public health surveillance before taking the course.

Module summary

This module is intended to train public health officers in how to develop and operate systems for second-generation HIV surveillance using sentinel surveillance techniques.

Module structure

The module is divided into units. The units are convenient blocks of material for a single study session. This module also can be used for self-study.

We begin each unit with some warm up questions. Some of the answers you may know. For other questions, your answer may just be a guess. Answer the questions as best you can.

You will keep the warm up questions in this manual. No one will see your answers but you. We will study and discuss the unit, and then you will have time to go back and change your warm up answers. At the end of the unit, the class will discuss the warm up questions. You can then check your work.

As you study this module, you may come across italicised terms that are unfamiliar. In Appendix B you will find a Glossary that defines these words. The Glossary also contains acronyms that you may not recognise.

Appendices

At the end of this module, more information is provided.

Appendix A, References and Further Reading Material
Appendix B, Glossary and Acronyms
Appendix C, Useful Links
Appendix D, Answers to Warm Up Questions and Case Studies
Additions, Corrections, Suggestions

Do you have changes to suggest for this module? Is there other information you’d like to see? Please email us. We will collect your emails and consider your comments in the next update to this module.

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Unit 1
Objectives and Approaches to HIV Surveillance

Overview

What this unit is about

This unit gives an overview of HIV surveillance and includes objectives and approaches to different kinds of HIV surveillance. This unit discusses the differences between HIV surveillance and HIV case reporting, describing the strengths and weaknesses of each.

Warm up questions

1. HIV sero-surveillance refers to the component of second-generation HIV surveillance that measures HIV________________.

2. Which of the following is one of the epidemiologic principles that guide HIV surveillance?
   a. HIV infections are not evenly distributed in a population.
   b. There are a limited number of ways that HIV can be transmitted.
   c. HIV infection enters different areas and populations at different times, and spreads at different rates.
   d. All of the above.

3. Blood donation is ideally voluntary and entails selecting donors at lowest risk of infection. HIV prevalence data from blood banks are likely to __________ true prevalence in the general population.
   a. Over-estimate
   b. Under-estimate

4. True or false? In low-level epidemics, HIV surveillance should primarily focus on measuring HIV prevalence in antenatal clinics.
   True False

5. True or false? Second-generation HIV surveillance is the only way to conduct HIV surveillance.
   True False
Warm up questions, continued

6. Which type of surveillance better shows the clinical disease burden of the HIV epidemic?
   a. HIV case reporting
   b. HIV sero-surveillance

7. Which of these is a goal of HIV surveillance?
   a. Identifying sub-groups at greater or lesser risk for infection
   b. Monitoring trends in the prevalence of infection over time
   c. Assessing risk factors of HIV transmission
   d. All of the above

8. True or false? Sentinel surveys are harder to do than population-based surveys and give a more accurate picture of the over-all HIV prevalence in a population.
   True  False

9. Selection bias is a big concern for _____ surveys. People who attend a particular facility may be different from those who do not use that site.
   a. Population-based
   b. Sentinel
Introduction

What you will learn

By the end of this unit, you should be able to:

- Define the terms HIV surveillance, second-generation HIV surveillance, HIV sero-surveillance and HIV sentinel surveillance
- Describe how epidemiologic principles and the state of the epidemic in a location guide HIV sero-surveillance
- Compare HIV case reporting and HIV sero-surveillance
  - Identify the strengths and weaknesses of each
  - Describe how the two are complementary
- Identify the main objectives of HIV sero-surveillance
- Describe the three main approaches to conducting HIV sero-surveillance
- Describe HIV incidence surveillance
- Identify other sources of HIV testing data that can be used for HIV surveillance in the context of second-generation HIV surveillance.

Terms and Definitions

HIV surveillance

HIV surveillance is the systematic and regular collection of information on the occurrence, distribution, and trends in HIV infection and factors associated with its transmission. It monitors the risk of infection among specific populations and is done ongoing for the purpose of public health action.

There are two general approaches to HIV surveillance, each of which is described in more detail below:

- HIV case reporting
- HIV sero-surveillance.

Case reporting

In many parts of the world, the primary HIV surveillance activity is sero-surveillance. We briefly describe HIV and advanced HIV disease case reporting below and then describe in detail HIV sero-surveillance.

- HIV infection case reporting is when you systematically identify and report all persons diagnosed with HIV, regardless of their clinical stage.
- Advanced HIV disease reporting is when you report all persons with clinical stages 3 and 4. In most countries, advanced HIV disease reporting will replace AIDS case reporting (reporting of persons with clinical stage 4).
HIV Sero-surveillance

Although HIV case reporting is an important surveillance tool in the Americas, Europe, and Asia, it has not been used in the African region. In 2006, the World Health Organization (WHO) revised the HIV clinical staging and surveillance case definitions, recommending that countries adopt case report of either all clinical stages of HIV or the reporting of persons with advanced HIV disease (WHO clinical stages 3 and 4).

**HIV sero-surveillance**

The term HIV sero-surveillance is used when you determine HIV prevalence by testing blood for HIV antibodies. Surveys that collect blood for HIV or other sexually transmitted infections (STIs, such as syphilis) are called sero-surveys. HIV sero-surveillance measures HIV prevalence in specific populations regularly. Data from HIV sero-surveillance helps you to learn which populations are most affected by the epidemic and to monitor trends over time.

**Second-generation surveillance**

As the HIV/AIDS epidemic is becoming larger and more complex, surveillance efforts must become more sophisticated if they are to be effective. Recognising this, WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have developed second-generation HIV surveillance.

Second-generation HIV surveillance is not a single method of conducting HIV surveillance but consists of an integrated group of goals and principles for tracking the epidemic, including:

- A focus on trends of the epidemic over time
- A better understanding of the behaviours that drive the epidemic
- Emphasis on the sub-populations at highest risk for infection
- Better use of existing data
- Flexibility to the states of the epidemic.

**Overview of HIV Case Reporting**

Because HIV case reporting and HIV sero-surveillance are two core activities in second-generation surveillance, it is important to distinguish their strengths and weaknesses. Although different, information gathered from each is complementary.

- HIV case reporting refers to reporting all persons diagnosed with any clinical stage of HIV disease. Countries may only report persons with advanced HIV disease (WHO clinical stages 3 and 4).
Overview of HIV Case Reporting, continued

- HIV case reporting is based upon HIV testing and diagnosis. If few at-risk persons get HIV tested, then HIV case reporting will underestimate HIV prevalence.
- In resource-limited settings, HIV cases may not be reported due to a lack of access to healthcare and HIV testing (where HIV testing is part of the case definition). They may not be reported because of logistical difficulties, or due to a lack of training of healthcare staff.
- One approach to disease reporting is Integrated Disease Surveillance (IDS), a system whereby all priority communicable diseases are reported together using the same form.

Case-based and aggregate case reporting

In many developing countries, individual-level information is collected at health facilities using a single form for each individual or a line register where each line is dedicated to one individual. Each facility sends the forms/line register to the next level—that is, to the district or province. At the district/province level, the data are aggregated (that is, a single form summarises all of the patients who were diagnosed with the condition at all the health facilities in the district in a given time period). The data are aggregated by demographic characteristics, risk profile, clinical characteristics, etc. Such an approach is called aggregate case reporting and is often simpler than case-based reporting. It is not as flexible, however, as it does not allow data to be analysed in ways that are not pre-determined.

In contrast, in a case-based reporting system, each person diagnosed with the condition is reported using a separate case report form. In this way, information that pertains to that patient specifically is collected and forwarded to the health authorities all the way up to a level where data are computerised. Case-based reporting allows for analysis of surveillance data in a variety of ways. As countries adopt patient-level monitoring of ART, HIV case-based surveillance systems should also be scaled up.

Overview of HIV Sero-surveillance

HIV sero-surveillance uses

The specific uses of HIV sero-surveillance are to:

- Assess the prevalence of HIV infection in population sub-groups; for example, by person and place
- Monitor trends in the prevalence (defined below) of HIV infection over time
- Identify behaviours and risk factors (a characteristic associated with an increased occurrence of disease) for HIV transmission
HIV Sero-surveillance

HIV sero-surveillance uses, continued

- Provide data to assist with making public health decisions, including:
  - Advocacy
  - Targeting and prioritising prevention and care programmes
  - Monitoring and evaluating prevention and care programmes
  - Resource allocation and programme planning
  - Mobilisation of political commitment
- Educate the public on HIV
- Guide scientific research
- Make estimates and projections for new and total HIV infections, AIDS cases, AIDS deaths, HIV-positive pregnancies and births, and number of orphans.

Epidemiologic principles that underlie HIV sero-surveillance include the following:

- HIV infections are not uniformly distributed in a population. The distribution depends on the prevalence of behavioural and biological risk factors associated with an increased risk for HIV transmission.
- There are a limited number of modes of HIV transmission. These include:
  - Sexual transmission, through vaginal and anal intercourse
  - Parenteral transmission, through contact with blood, blood products, or equipment contaminated by infected blood
  - from mother to child during pregnancy, birth, or breastfeeding
- HIV infection enters different geographic areas and populations at different times and spreads at different rates.

To most accurately measure HIV prevalence, surveillance data focus primarily on three variables:

- Person (for example, young women vs. older men)
- Place (for example, urban vs. rural health district)
- Time (for example, an increase or decrease in infections over years).

Monitoring trends in HIV infection over person, place, and time requires that surveillance must be conducted in the same manner and in the same population groups each time it is done.

Types of sero-surveys

Clinic-based sero-surveys are designed to gather HIV prevalence in clinic attendees for the purpose of measuring prevalence either in the general population or in high-risk groups.

- Clinic-based surveys measure HIV prevalence in blood that is drawn for other purposes, such as syphilis testing of pregnant women at antenatal clinics (ANCs).
Types of sero-surveys, continued

- Clinic-based surveys also measure HIV prevalence in blood drawn for the purpose of HIV testing, such as HIV tests drawn at sexually transmitted infection (STI) clinics or voluntary counselling and testing (VCT) clinics.

Population-based sero-surveys are designed to measure HIV prevalence in the general population directly.

- Population-based surveys use a probability sample of a population defined by geographic boundaries, such as villages or provinces.
- In a probability survey, each person in that population has an equal or known probability of being selected in the sample.
- An example is the Demographic and Health Survey Plus (DHS+) that combines a behavioural risk factor survey and a sero-survey.
- These surveys are complex and costly, yet, periodic population-based sero-surveys may be needed to give a full picture of sentinel surveillance data in a region. It is important to consider if prevalence measured at the sentinel sites over- or under-estimate the true prevalence of HIV in the population.

Community-based sero-surveys are useful in reaching difficult-to-reach populations who are not seen at clinics.

- You may conduct community-based surveys to reach populations at high risk for HIV infection.
- In sub-Saharan Africa, you may want to conduct such surveys among sex workers, truck drivers, men who have sex with men, or factory or mine workers. In Asia these surveys may be conducted among sex workers, truck drivers, or injection drug users.

Table 1.1 presents a structured way to think about the types of sero-surveys.

Comparing types of sero-surveys

<table>
<thead>
<tr>
<th>Persons being surveyed</th>
<th>Clinic-based</th>
<th>Not clinic-based</th>
</tr>
</thead>
<tbody>
<tr>
<td>General population (such as pregnant women)</td>
<td>ANCs</td>
<td>Population-based surveys of general population such as DHS+</td>
</tr>
<tr>
<td>High-risk groups (such as sex workers, STI patients, and truck drivers)</td>
<td>STI clinics</td>
<td>Community-based survey of commercial sex workers and truck drivers at a border truck stop</td>
</tr>
</tbody>
</table>
Discussing the table

Looking at Table 1.1 on the previous page, answer the following questions:

a. In what clinic can you conduct clinic-based surveys of high-risk groups? Can you think of other types of clinics, not listed in the table, where these can be conducted?

b. Which options do you have for surveying the general population?

**HIV Sentinel Surveillance**

The main activity in HIV sero-surveillance is conducting *sentinel surveillance*. Sentinel surveillance is the collection of high-quality data from a sample of specially selected *sentinel sites*. HIV sentinel surveillance is comprised of the following parts:

- Measuring the prevalence of HIV infection in a selected population. It measures this in regular *cross-sectional surveys*. Cross-sectional surveys ideally use a sample that is representative of a whole population to be surveyed. These surveys are done regularly and the same way each time.

- Collecting and testing blood for HIV *antibodies*. Antibodies are molecules in the blood or secretory fluids that the body produces in response to infection. Antibodies tag, destroy, or neutralise bacteria, viruses, or other harmful toxins.

- Collecting *demographic* characteristics (personal qualities such as age or sex) and some data on *high-risk behaviours*. High-risk behaviours are actions that increase the risk that a person will contract a disease.

**Sentinel sites**

The populations selected for HIV sentinel surveillance include persons who are regularly seen in defined locations called sentinel sites. They are usually clinics. Sentinel sites may be selected to represent the general population. Alternatively, sentinel sites may represent persons at high risk of HIV infection. The steps for setting up HIV sentinel sero-surveys are presented in Annex 1.1. A template for a survey protocol is presented in Annex 1.2. Table 1.2 on the following page lists possible sentinel sites for the general population and for persons at high risk of HIV infection.
Sentinel sites, continued

Table 1.2. Examples of possible sentinel sites.

<table>
<thead>
<tr>
<th>Sentinel sites representing the general population</th>
<th>Sentinel sites representing persons at high risk of HIV infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANCs</td>
<td>STI clinics</td>
</tr>
<tr>
<td>Military conscription health intake centres</td>
<td>Drug treatment centres</td>
</tr>
<tr>
<td></td>
<td>Jails</td>
</tr>
<tr>
<td></td>
<td>Tuberculosis (TB) clinics</td>
</tr>
<tr>
<td></td>
<td>Hospital wards</td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 1.2 above, answer the following questions:

a. What sort of sentinel sites would you use if you wanted to measure HIV prevalence in the general population?

b. What sort of sentinel sites would you use if you wanted to measure HIV prevalence in high-risk populations?

HIV incidence and prevalence

Understanding the differences between HIV incidence and prevalence is important in interpreting surveillance data. These terms are defined in Table 1.3 below.

Table 1.3. Comparing incidence and prevalence.

<table>
<thead>
<tr>
<th>Type of measure</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence</td>
<td>▪ A measure of the number of newly acquired HIV infections in a specific time period</td>
</tr>
<tr>
<td></td>
<td>▪ Influenced by levels of infection and risky behaviours</td>
</tr>
<tr>
<td></td>
<td>▪ Indicates where HIV prevention is needed</td>
</tr>
<tr>
<td></td>
<td>▪ Indicates where current and future care is needed</td>
</tr>
<tr>
<td>Prevalence</td>
<td>▪ Proportion of persons with HIV infection at a given time</td>
</tr>
<tr>
<td></td>
<td>▪ Influenced by both the rate of new infections (incidence) and the rate that infected people leave the population for reasons such as death or migration</td>
</tr>
<tr>
<td></td>
<td>▪ Indicates where HIV prevention is needed</td>
</tr>
<tr>
<td></td>
<td>▪ Indicates where current and future care is needed</td>
</tr>
</tbody>
</table>
Looking at Table 1.3 on the previous page, answer the following questions:

a. Which measure (incidence, prevalence, or both) indicates the need for prevention in a certain population?

b. Which measure indicates the future need for care?

c. What factors influence incidence? Prevalence?

Trends in HIV prevalence are measured by HIV sero-surveillance activities. Early in epidemics, trends in HIV prevalence may reflect trends in HIV incidence because most infections are new infections. In mature epidemics, however, an increasing number of infections may be old infections, so most HIV cases measured are pre-existing (HIV prevalence). In order to measure HIV incidence in mature epidemics, a direct measure is needed. Examples of direct measures of HIV incidence are discussed below.

Measuring HIV incidence

Direct measures of HIV incidence are logistically difficult and costly to obtain. The following list outlines several methods to measure or estimate HIV incidence.

- **Cohort studies**: This is the traditional method to measure HIV incidence. Subjects are periodically tested for HIV, for instance, annually, to measure the incidence of new infection. Incident cases are those whose HIV antibody tests changed from negative to positive (known as *sero-conversion*). Examples of cohort studies in sub-Saharan Africa include those done in Mwanza, Tanzania, and the Rakai and Masaka districts in Uganda.

- **Laboratory-based methods**: Several laboratory tests can identify persons in the early period of HIV infection. The *BED assay* is a technique to measure HIV incidence in a single blood specimen. The BED assay identifies persons who were infected in the last 160 days or nearly six months.

- **Repeat testers**: HIV incidence can be calculated from persons who are repeatedly tested for HIV at VCT sites or through repeated testing at STI clinics. New infections are identified by persons who tested negative at one visit and later test positive at another.
Measuring HIV incidence, continued

- **Mathematical modelling:** Various mathematical models to estimate HIV incidence have been developed, based on a variety of data and assumptions. These assumptions include HIV prevalence by age groups and survival, the chance of transmission through certain behaviours and back-calculation from AIDS cases.

- **HIV prevalence in young age groups:** HIV incidence can be crudely estimated from the HIV prevalence among the youngest individuals, such as 15- to 24-year-old women in ANC surveys. Because they have not been sexually active for very long, their infections are likely to be relatively new.

Until there is further validation of methods to directly measure HIV incidence, you should use trends in HIV prevalence among 15- to 24-year-olds as a practical proxy measure for trends in HIV incidence, because this young age group most likely represents new infections.

Sources of HIV prevalence data

HIV testing is done in a large number of programmes and settings. Testing in these sites usually is not conducted for surveillance reasons, but the data from these sites may be used to enhance HIV sero-surveillance activities. The data, however, must be interpreted cautiously. The following list outlines the five general types of HIV testing programmes.

1. **VCT programmes:** Persons may seek HIV testing to be counselled on their care and treatment options and to reduce their risk for acquiring and transmitting infection. To the extent that persons who suspect they are infected seek out HIV testing, using HIV prevalence data from voluntary testing programmes may over-estimate the true prevalence in a population. Over time, however, the proportion of persons infected in a population who already know they are infected will not seek out testing. In this situation, VCT data may under-estimate HIV prevalence.

2. **Routine HIV testing:** In some settings, HIV testing is routinely offered and done as part of standard health care. Many ANCs in sub-Saharan Africa are scaling up programmes that involve routine antenatal testing to prevent mother-to-child transmission of HIV. As the percentage of women tested increases, data will provide an approximate measure of prevalence. STI and TB clinics are other settings where routine or universal HIV testing of patients is conducted. In these settings, HIV prevalence data are likely to over-estimate the true prevalence in a population because persons with STI and TB are more likely to be infected.
Sources of HIV prevalence data, continued

3. **Blood transfusion safety**: To prevent transmission of HIV from transfusion of blood and blood products, all blood donations are tested for HIV. Ideally, blood donation is voluntary. Measures to select donors at the lowest risk of infection should be in place. Thus, HIV prevalence data from blood banks are likely to underestimate the true prevalence in a population.

4. **Scientific research**: HIV testing often is done in the context of scientific research. The purpose of such research may range from epidemiologic surveys to characterise populations at high risk to prevention interventions to reduce risk. HIV prevalence data from studies must be interpreted in the context of the objectives of the research and the study subjects included.

5. **Screening of persons entering the military or seeking employment other benefits**: Sometimes, persons are routinely tested for HIV for a particular reason, such as entering the military, going to prison, or getting health insurance. HIV prevalence data from these sources may be biased by self-selection. Data from screening in the military, for example, may be more representative of the young adult male population, if there is universal conscription. It is less representative if based on voluntary service or if there are many restrictions on who may enlist. HIV prevalence data from prisoners, especially female prisoners who may have been arrested for sex work, may over-estimate HIV prevalence.

While HIV testing data collected for purposes other than surveillance may under- or over-estimate true population prevalence, they still are a potential source of information regarding HIV prevalence in different populations. However, it is important to consider the possible biases when interpreting data from these sources.

**Second-Generation HIV Surveillance**

**Components of second-generation surveillance**

One of the core activities of second-generation surveillance is HIV sero-surveillance. In addition to HIV sero-surveillance, other data sources that are used in second-generation surveillance to obtain a more integrated view of the HIV epidemic include:

- *Behavioural surveillance*, which involves asking a sample of people about their sexual and, sometimes, their drug-injecting behaviours
- HIV case reporting
- Death registries
- STI surveillance
- TB surveillance.
Components of second-generation surveillance, continued

These additional data sources can provide a more comprehensive understanding of trends in the epidemic and an indication of the effectiveness of control and prevention programmes. Figure 1.1 illustrates the primary components of second-generation HIV surveillance.

Figure 1.1. Primary components of second-generation HIV surveillance.

Discussion the figure

Looking at Figure 1.1, answer the following questions:

a. Is STI surveillance a component of second-generation HIV surveillance?

b. What are some other data sources that might be used for second-generation HIV surveillance? You can look at the paragraph before the figure for ideas.
Comparing HIV case reporting and HIV sero-surveillance

As illustrated in Table 1.4, in contrast to case reporting, HIV sero-surveillance describes current levels of HIV infection in defined populations. If done regularly, it also represents recent trends in the HIV epidemic. HIV sero-surveys identify persons with HIV infection regardless of their symptoms. By conducting sero-surveys in defined populations, you can determine HIV prevalence with more certainty. Still, as current infections may have been acquired years prior to testing, changes in HIV transmission patterns (rising, declining, or change in person and place) may take years to be detected.

Table 1.4. Comparison of HIV case reporting and HIV sero-surveillance.

<table>
<thead>
<tr>
<th>HIV Case Reporting</th>
<th>HIV Sero-surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usually passively reported by care providers at healthcare facilities</td>
<td>Usually actively implemented by public health surveillance departments</td>
</tr>
<tr>
<td>Under-reporting by providers may be severe</td>
<td>Under-reporting not an issue</td>
</tr>
<tr>
<td>Measures morbidity or clinical disease burden</td>
<td>Usually collects no information on morbidity</td>
</tr>
<tr>
<td>Does not accurately indicate prevalence of HIV infection in population groups</td>
<td>Measures levels and trends in HIV prevalence in population groups</td>
</tr>
<tr>
<td>Does not measure incidence of HIV infection</td>
<td>Does not measure incidence of HIV infection, although sero-prevalence in younger age groups may approximate incidence</td>
</tr>
</tbody>
</table>

Discussing the table

Look at Table 1.4 to answer the following questions:

a. Which type of surveillance more accurately measures trends in HIV prevalence?

b. If you wanted to avoid problems of under-reporting, which surveillance method would you choose?
Epidemic classification

To choose the most appropriate elements for an HIV surveillance system, UNAIDS and WHO suggest a classification that describes the HIV epidemic by its current state: low-level, concentrated, or generalised. Epidemics may shift from one state to another over time, but such a shift is not inevitable. Although the issues for planning HIV surveillance are similar for each state of epidemic, the actual surveillance needs will differ. The three classifications are described in Table 1.5 below.

Table 1.5. States of the HIV epidemic and relevant information for sero-surveillance.

<table>
<thead>
<tr>
<th>State of the Epidemic</th>
<th>Associated HIV Prevalence</th>
<th>Description</th>
</tr>
</thead>
</table>
| Low-level             | HIV prevalence has not consistently exceeded 5% in any defined sub-population and remains below 1% in pregnant women in urban areas. | ▪ Sero-surveys are usually targeted to the populations at highest risk where HIV infection may appear first and spread fastest.  
▪ These populations may include sex workers, truck drivers, *tuberculosis* (TB), or STI clinic patients. A prevalence of 5% or greater in any of these populations should trigger consideration of sero-surveys in ANCs.  
▪ Behavioural surveys and understanding the geography and social networks of high-risk populations are of paramount importance in low-level epidemic. |
| Concentrated          | HIV prevalence is consistently over 5% in at least one defined sub-population but below 1% in pregnant women in urban areas. | ▪ Sero-surveys should remain focused on high-risk populations, such as STI clinics, sex workers, IDUs.  
▪ Measuring HIV prevalence in ANCs is also recommended, to detect bridging of infection to the general population. |
| Generalised           | HIV prevalence is consistently over 1% in pregnant women. | ▪ Sero-surveys are largely conducted in ANCs to track an epidemic fast spreading in the general population. |

Discussing
Looking at Table 1.5 on the previous page, answer the following questions:

a. In which epidemic state(s) should you undertake sero-surveys in ANCs?

b. If the prevalence of HIV is greater than 1% in pregnant women, what is the state of the epidemic?

State of the global epidemic

Generalised epidemics prevail in most of sub-Saharan Africa. Sero-surveys are therefore primarily directed at women who attend ANCs and are between the ages of 15 and 49 years, with special emphasis on women 15 to 24 years old, to assess characteristics of recently-infected women in this age group. In countries with concentrated epidemics, as in Asia and Eastern Europe, sero-surveys are primarily directed at the populations that drive the epidemic. Figure 1.2 below illustrates the state of the global HIV epidemic.

Figure 1.2. A Global View of HIV Infection

Source: UNAIDS, 2009
Discussing the figure

Looking at Figure 1.2 on the previous page, answer the following questions:

a. Which epidemic state are most WHO-AFRO countries experiencing?

b. Which epidemic state characterises the fewest WHO-AFRO countries?

c. Which epidemic state are most WHO-SEARO countries experiencing?

d. Which epidemic state characterises the fewest WHO-SEARO countries?

Summary

For sub-Saharan Africa, the recommended approach to HIV surveillance is to conduct sentinel sero-surveys of pregnant women in ANCs in addition to HIV case reporting. If resources permit, you may complement these basic surveillance activities with:

- Periodic population-based sero-surveys
- Clinic-based and community-based sentinel sero-surveys of selected groups that may be at higher risk of HIV infection, including:
  - Sex workers
  - Mobile populations, such as truck drivers, military personnel and refugees
  - Prisoners.
Unit 1 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. List all of the groups usually tested for HIV in your district or province.

2. For what reasons is testing being conducted in each group?

3. Can you suggest groups in which HIV sero-surveys might be useful in your district or province?

4. What methods have been used to assess HIV prevalence and monitor trends in your district or province?

5. To what extent are the above objectives for HIV sentinel surveillance applicable to the HIV sentinel surveillance system in your country? List which ones need improvement.
You have recently assumed the position of surveillance officer for the Inyo District of the Yolo Republic. You are charged with determining the surveillance activities for the district. The district conducted HIV seroprevalence surveys two years ago among women attending ANCs in two urban areas of the district. The average seroprevalence from these sites was 2%. Five years ago, there was a country-wide Demographic Health Survey that collected blood for HIV testing (DHS+) and your district was included. The HIV prevalence was found to be 1%.

a. What type of surveillance do you think should be undertaken at this point and why?

You conduct sero-surveys in the two urban areas in which the earlier surveys were conducted and find that the prevalence is now 2.5%.

b. What other information can you use from this survey to help you understand what is happening with the epidemic in Inyo District?

You notice that the sero-prevalence among the youngest women is 2.8%.

c. What is a possible interpretation of this finding?

d. What additional information might be helpful to you to understand the epidemic?

Results from the DHS+ show a slight increase in sero-prevalence. The sero-prevalence among truck drivers and commercial sex workers is higher than the prevalence from the DHS and from ANCs. Among truck drivers the prevalence is 2.6% and among commercial sex workers it is 3%.

e. What can you do with the information you have from these surveys?
Notes
Annex 1.1. Setting Up HIV Sentinel Sero-surveys

Before an HIV sentinel surveillance system is set up or expanded to a province or area in which one does not already exist, you should take the following steps as part of a strategic plan. You should develop these steps in a surveillance protocol.

**Background preparation**
- Review the existing epidemiologic situation and need for HIV surveillance.
- Assess current HIV surveillance activities at the national, provincial, and district level.
- Review additional, existing sources of HIV prevalence data.

**General survey methods**
- Select sentinel populations.
- Select sites for sentinel surveillance.
- Select inclusion criteria for the sample.
- Review methods for collecting blood samples for HIV testing.
- Review procedures for ensuring that HIV test results are anonymous.
- Determine data to be collected with blood samples.
- Determine methods for compiling, analysing, presenting and disseminating data at the national, provincial, and district levels.

**Sampling methods**
- Determine the over-all sample size.
- Determine the frequency of sampling.
- Determine the duration of sampling.
- Determine the minimum sample size per sentinel site.

**Laboratory testing**
- Review the recommended Joint United Nations Programme on AIDS (UNAIDS)/WHO HIV testing strategy.
- Select HIV tests to be used for surveillance specimens.
- Develop HIV testing operations manual for local and national use.
- Develop quality assurance plans for laboratory HIV testing.

**Training**
- Provide training for surveillance personnel.
- Provide training for sentinel site staff.
- Provide training for laboratory staff.
- Provide training for supervisory personnel.
- Provide training for data management and analysis personnel.
HIV Sero-surveillance

**Surveillance system supervision**
- Develop a plan for supervision at sentinel sites.
- Be sure supervisory plans include district, regional and national staff.

**Personnel requirements**
- Identify personnel requirements for data collection and specimen processing.
- Identify personnel requirements for transport of specimens to the laboratory.
- Identify personnel requirements for HIV testing.
- Identify personnel requirements for data compilation, analysis, presentation, and interpretation.
- Identify personnel requirements for district, provincial and national supervision.

**Equipment needs**
- Identify laboratory equipment needs for specimen collection, serum separation, storage and transport.
- Identify laboratory equipment needs for HIV testing.
- Identify equipment needs for data compilation, analysis, and presentation.
- Identify general office equipment and space.

**Budget**
- Determine cost of identified required personnel and equipment.

**Dissemination and presentation**
Plan dissemination and presentation of results to audiences including:
- National AIDS Committee
- Ministry of Health, other government ministries
- Media and general public
- Sentinel sites/districts/provinces
- General public and civil society.

**Finalisation**
Compile these elements into a plan of action and timeline for implementation of HIV sentinel surveillance protocol.
Annex 1.2. Outline of a Survey Protocol

I. Introduction
   a. Types of HIV surveillance (biological, behavioural, etc.)
   b. Modes of blood collection for HIV testing (with/without informed consent, linked/unlinked/confidential anonymous)

II. Sampling, blood and data collection
   a. Sentinel population: Describe ANC population, eligibility and ineligibility requirements
   b. Sampling frame
   c. Sample size (per site), sampling period, possibly by type of site (rural/urban)
   d. Blood and data collection at site: Describe methods step by step; highlight which steps are to take place in the ANC room (nurse/midwife), and which in the laboratory (laboratory technician)
      i. Tally sheet to count eligible women
      ii. Routine blood draw for syphilis
      iii. Filling in of laboratory request form
      iv. Filling in of surveillance questionnaire
      v. Syphilis testing
      vi. Removing an aliquot of blood and unlinking the specimen
      vii. Labelling of surveillance questionnaire and specimen
      viii. HIV testing at site
      ix. Hands-on demonstration of activities
   e. Overview: data and specimen flow chart to central/national office
   f. Forms and file keeping
      i. list forms to be used
      ii. describe purpose of each form
      iii. state who is to fill in form
      iv. describe how to fill in form
   g. Specimen storage (temperature recording form)
   h. Specimen transport.

III. Syphilis testing
   a. Introduction
   b. Serologic testing
      i. Introduction
      ii. Immunology of syphilis infection
      iii. Test principles
      iv. Interpretation of results of test used
      v. Recording of syphilis results, unlinking
      vi. Treatment of syphilis
      vii. Handling of blood taken for syphilis testing.
IV. HIV testing  
   a. Type of HIV test(s) used  
   b. Testing algorithm  
   c. Protocol for conducting testing (if done at site).

V. Supervision  
   a. Outline who supervises site staff, how, and when.  
   b. Explain how findings of supervision are forwarded to regional/national level.

VI. Roles and responsibilities during the surveillance round  
   a. Ministry of health  
   b. Regional level  
   c. Health centre  
      i. Health centre co-ordinator or manager  
      ii. Health centre laboratory technician  
      iii. Midwife/nurse.

VII. Other  
   a. Required materials and equipment for each sentinel site  
   b. Checklist for trainers.
Unit 2
Selection of Sentinel Populations and Sentinel Sites

Overview

What this unit is about

This unit will describe selection of populations for HIV sentinel sero-surveys using the local epidemiology of HIV. It provides the rationale for using women who use ANC's as the most suitable sentinel population for sub-Saharan Africa. This unit also describes the criteria for selecting sites to carry out the HIV sentinel surveillance and gives recommendations for the number and distribution of sites to be selected.

Warm up questions

1. True or false? In generalised HIV epidemics, surveillance activities should focus only on groups that have high-risk behaviours.

   True       False

2. Which of the following is a key consideration for selecting a sentinel population for HIV surveillance purposes?

   a. The local epidemiology of HIV and the major risk factors that drive HIV transmission
   b. The state of the epidemic
   c. Both of the above

3. True or false? In a concentrated epidemic, voluntary blood donors are an ideal sentinel population.

   True       False

4. Since the epidemic in sub-Saharan Africa is generalised, the ideal sentinel population would be:

   a. Attendees at STI clinics
   b. Pregnant women visiting ANC's
   c. Men who have sex with men
   d. All of the above
Warm up questions, continued

5. True or false? When selecting sites for sentinel surveillance, the sites should be located in geographically diverse areas, both inside and outside major cities and towns.

   True    False

6. True or false? Provincial- or district-level staff should make decisions about the number and location of sentinel sites.

   True    False
Introduction

What you will learn

By the end of this unit you should be able to:

- Identify the primary way that HIV is transmitted in Sub-Saharan Africa
- List the considerations for selecting sentinel populations
- Identify specific groups that would be ideal sentinel populations
- Define criteria for selection of sentinel sites
- Identify sites in your district that fit the selection criteria.

Selection of Sentinel Populations

Factors to consider

The key considerations in selecting sentinel populations for HIV sentinel surveillance are the local epidemiology of HIV and the major risk behaviours for HIV transmission.

As summarized in Table 2.1 on the next page, the state of the epidemic guides the selection of sentinel populations as follows:

- In low-level epidemics, HIV prevalence has never been above 5% in any high-risk population. Populations selected for sentinel sero-surveys should be those where HIV prevalence is expected to appear first and be highest. These populations include:
  - Sex workers
  - Voluntary mobile populations, such as truck drivers and miners
  - Involuntary mobile populations, including refugees and displaced persons
  - Uniformed personnel, such as the members of the military or police
  - Patients with other sexually transmitted infections (STIs)
  - Prisoners
  - Men who have sex with men (MSM)
  - Injection drug users (IDUs).

- In concentrated epidemics, HIV prevalence is consistently higher than 5% in at least one high-risk population. Populations to be included in sentinel sero-surveys in this instance should include both persons from high-risk groups and at least some women at antenatal clinics (ANCs) in urban areas to track the spread from high-risk groups to the general population.
Factors to consider, continued

- In generalised epidemics, where HIV prevalence among women in ANCs in urban areas is consistently above 1%. Sentinel sero-prevalence survey populations should be primarily women at ANCs in both urban and rural areas.

Sentinel populations must be selected on the basis of risk for heterosexual exposure to HIV. This is because generalised epidemics are only sustained when the majority of transmission occurs through heterosexual sex, regardless of the contributions of other modes of transmission.

Access to Sentinel Populations

Access to high-risk populations is challenging. For some high-risk populations such as sex workers, MSM, and IDUs, behaviours that lead to HIV infection may be illegal or highly stigmatized.

Three general approaches are used to access high-risk populations. Each is discussed below.

Facilities

High-risk populations are often concentrated in certain facilities. These are usually health care facilities such as STI clinics or de-addiction centres. Table 2.2 below presents potential facilities for accessing high-risk populations. Facility-based HIV sentinel surveillance, the most common approach, is the focus of the remainder of this training module.
Table 2.2. Potential access to high-risk populations for HIV sentinel surveillance.

<table>
<thead>
<tr>
<th>High-risk population</th>
<th>Facilities or methods of access</th>
</tr>
</thead>
<tbody>
<tr>
<td>STI clinic attendees</td>
<td>STI clinics</td>
</tr>
<tr>
<td>Female sex workers</td>
<td>STI clinics, Detention centres, Targeted interventions, Special surveys</td>
</tr>
<tr>
<td>Male partners of female sex workers</td>
<td>STI clinics, Targeted interventions</td>
</tr>
<tr>
<td>IDUs</td>
<td>De-addiction centres, Methadone clinics, Detention centres, Targeted interventions, Special surveys</td>
</tr>
<tr>
<td>MSM</td>
<td>STI clinics, Targeted interventions, Special surveys</td>
</tr>
<tr>
<td>Truck drivers</td>
<td>STI clinics, Occupational health clinics, Targeted interventions, borders, truck stops, Special surveys</td>
</tr>
<tr>
<td>Prisoners</td>
<td>Detention centre intake examinations, Detention centre clinics</td>
</tr>
<tr>
<td>Military, uniformed personnel</td>
<td>Military recruitment centres, Military health clinics</td>
</tr>
<tr>
<td>Voluntary migrant</td>
<td>STI clinics, Occupational health clinics</td>
</tr>
<tr>
<td>Involuntary migrants</td>
<td>Refugee and IDP health clinics, Border area health clinics</td>
</tr>
</tbody>
</table>

**Targeted interventions**

Often high-risk populations do not attend particular fixed facilities or do not identify themselves at such facilities, but are served by non-governmental or community-based organizations (NGOs or CBOs). Sentinel surveillance activities can be done in collaboration with such organizations.

An example of sentinel surveillance conducted through a targeted intervention program is provided at the end of the unit. While a large number of sentinel surveillance efforts in Asia are conducted with targeted interventions, the procedures vary according to the nature of the activities and NGO collaborations.
At times, the high-risk population cannot be found at fixed facilities nor are they adequately served by outreach activities. In such instances, sentinel surveillance may require special epidemiological surveys.

Methods such as *time-location Sampling* (TLS) and *respondent-driven sampling* (RDS) can be used for sentinel surveillance. These approaches are described in other training modules.

**Antenatal Clinics**

Since most countries in sub-Saharan Africa have had generalised HIV epidemics for many years, the majority of sentinel surveillance activities should focus on pregnant women attending ANCs. Although the epidemic in Asia is different from sub-Saharan Africa, HIV sentinel surveillance systems in Asia do include ANC clinics.

**Advantages and disadvantages of ANC surveillance**

Table 2.3 on the next page summarises the advantages and disadvantages of using ANC attendees as an HIV sentinel population.
Advantages and disadvantages of ANC surveillance, continued

Table 2.3. Advantages and disadvantages of using women at ANCs as sentinel populations for HIV surveillance.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ ANC's see sexually active women from around 15 to 49 years old, the age range of most sexual transmission of HIV.</td>
<td>▪ ANC's do not include infertile women, women whose pregnancies end in abortion or women on contraceptives.</td>
</tr>
<tr>
<td>▪ ANC's are attended by a large proportion of the adult female population in many countries.</td>
<td>▪ HIV infection may decrease fertility and women's desire for more children; therefore, HIV-infected women will be under-represented at ANC clinics.</td>
</tr>
<tr>
<td>▪ HIV testing can be done anonymously because blood specimens are taken for other purposes, such as haemoglobin testing, blood typing or syphilis screening.</td>
<td>▪ HIV prevalence in pregnant women aged 15 to 19 years is likely an overestimate of the general population because there may be a substantial proportion of 15- to 19-year-old women who are not sexually active.</td>
</tr>
<tr>
<td>▪ HIV prevalence among pregnant women can be used to estimate the potential for mother-to-child transmission of HIV, the second most common mode of transmission in sub-Saharan Africa.</td>
<td>▪ ANC's may under-estimate HIV prevalence in older age groups because older HIV-infected women are less likely to get pregnant or come to clinics if they are pregnant.</td>
</tr>
<tr>
<td>▪ ANC's are the most common sentinel surveillance sites in the developing world; they therefore provide a basis to compare districts, countries and regions.</td>
<td>▪ ANC attendance may vary by the number of pregnancies a woman has had and quality of care provided; in general, women with more pregnancies are less likely to attend ANC's.</td>
</tr>
<tr>
<td>▪ ANC-based sentinel surveillance does not directly measure HIV prevalence in men.</td>
<td>▪ ANC's may not include or be able to identify the women at highest risk for infection, such as sex workers.</td>
</tr>
</tbody>
</table>
Discussing the table

Look at Table 2.3 on the previous page, and then answer these questions:

a. What kind(s) of selection bias(es) might potentially influence sentinel surveillance data at ANCs?

b. Do ANCs include all sexually active women aged 15 to 49 years?

Selecting ANC patients

When choosing the patients to select at ANC sites, it is important to standardise the selection criteria. Clear inclusion and exclusion criteria must be established. As an example, to minimise multiple sampling of the same woman attending an ANC, the sampling scheme could do either of the following:

- Include only women attending the ANC for current pregnancy for the first time. This typically is when blood is drawn for prenatal purposes.
- Include women who are being tested for syphilis, where syphilis screening is done only once during pregnancy.

Exclusion criteria might include repeat ANC visits or referrals from other ANCs.

STI Clinics

Patients of STI clinics are an easily identifiable and readily accessible group at high risk for acquiring HIV infection through sexual intercourse. Sentinel surveillance among STI patients is a key component of HIV surveillance in low-level and concentrated epidemics. Table 2.4 on the following page lists the advantages and disadvantages of using STI clinic patients as a sentinel population.
Table 2.4. Advantages and disadvantages of using STI clinic patients as a sentinel population.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>STI clinics include large numbers of sexually active men and women.</td>
<td>Only patients with STI symptoms will seek care, and some STIs, such as chlamydia, often do not cause symptoms, especially in women.</td>
</tr>
<tr>
<td>STI clinics include persons at high risk for HIV as a result of their sexual behaviour and the co-factor effect of STI enhancing HIV transmission</td>
<td>Many persons with STI seek care outside government clinics; for example, going to private clinics, pharmacies, or traditional health care providers, or accessing antibiotics on the street.</td>
</tr>
<tr>
<td>STI clinics often include diverse hard to reach populations such as female sex workers, their male partners, and MSM</td>
<td>High-risk populations, such as sex workers or MSM, may not identify themselves at STI clinics.</td>
</tr>
<tr>
<td>STI clinics may be able to provide HIV voluntary counselling and testing as well as referral to HIV care</td>
<td>Many STI clinic patients may be repeat visits for the same STI episode.</td>
</tr>
<tr>
<td>STI clinics routinely collect demographic and sexual risk behaviour information</td>
<td>STI clinics may not include persons at risk for HIV through injection drug use or other modes of transmission.</td>
</tr>
<tr>
<td>HIV testing can be accomplished on an unlinked, anonymous basis as blood specimens are taken for other purposes such as syphilis screening</td>
<td>It is unclear how representative the STI clinic population is of the general population or all persons with STIs.</td>
</tr>
</tbody>
</table>

**Discussing the table**

Looking at Table 2.4, answer the following questions:

a. Are STI clinics a good place to survey HIV prevalence among men as well as women?

b. In an area where the majority of people seek treatment for STIs from pharmacies, are STI clinics a good place to do sentinel surveillance?
Additional Sentinel Populations

Patients at other types of healthcare facilities can potentially be used as sentinel populations. These include:

- Tuberculosis (TB) clinics
- Hospital wards and clinics providing healthcare to refugees or other high-risk groups
- Clinics for factory workers, miners or plantation workers, particularly to measure HIV prevalence among men.

Members of other high-risk populations may not be seen at a particular clinic. In such cases, special community-based sero-surveys may be needed. These populations might include truck drivers, sex workers in brothels or on the streets, or mobile populations.

Criteria for Site Selection

Once you have selected the sentinel population that you are interested in, you need to select the sites where you will carry out the surveillance activities. The selection of sites for HIV sentinel surveillance is a balance between including as much of the selected population as possible and considering logistical necessities. Sentinel surveillance should be implemented in facilities with enough personnel and laboratory capacity to conduct a successful survey. The selection of sentinel sites is guided by the criteria listed in Table 2.6 on the next page.

Use of ANC satellite sites

In some countries, ANCs chosen as sentinel sites have additional, associated satellite ANCs in their vicinity. Data from these satellite sites may or may not be pooled with those from the central site and reported as a single site with the following guidelines:

- The satellite sites’ *catchment populations* should be similar to those of the main site; for example, whether the setting is urban or rural. A catchment population is the population served by a given clinic.

- The satellite sites’ epidemic should be similar to the main site. If the background HIV prevalence differs in these pooled catchment populations, then any change in the main and satellite sites’ proportions of the whole sample can result in a change in the pooled HIV prevalence over time.
Table 2.6. Criteria that guide the selection of sentinel sites for HIV surveillance.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population served</td>
<td>The sites provide services for the selected sentinel populations, such as ANC or STI clinic patients</td>
</tr>
<tr>
<td>Blood samples available</td>
<td>Blood is drawn from patients as part of routine care</td>
</tr>
<tr>
<td>Laboratory access</td>
<td>A reliable laboratory is available on-site or nearby to perform the routine laboratory tests. Alternatively, reliable roads and transport options exist to send specimens to a reference laboratory</td>
</tr>
<tr>
<td>Accessibility</td>
<td>The sites are readily accessible to surveillance staff for data collection or supervision of data collection</td>
</tr>
<tr>
<td>Size of client base</td>
<td>The sites provide services or healthcare to a large enough number of persons so that the target sample size can be obtained within the sampling period</td>
</tr>
<tr>
<td>Geographic diversity</td>
<td>The sites are located in different geographic areas, both in cities or towns and in rural areas</td>
</tr>
<tr>
<td>Resources</td>
<td>Needed resources—human, laboratory, transport—can be mobilised.</td>
</tr>
<tr>
<td>Staff acceptance</td>
<td>On-site staff understand the need for HIV sentinel surveillance, are willing to implement activities, and are open to additional training and supervision.</td>
</tr>
</tbody>
</table>

**Discussing the table**

Looking at Table 2.6, answer the following questions:

a. Why is the size of the client base significant when choosing sites for sentinel surveillance?

b. Why is geographic diversity significant when choosing sites for sentinel surveillance?
India TI example

As of 2004, India has a countrywide sentinel sero-surveillance system with 590 sites. The majority of these sites are among ANC attendees (n=390) or STI clinic attendees (n=171).

Access to high-risk/vulnerable populations like female sex workers, MSM, IDUs, and transgendered people is difficult. Often, such groups are served by NGOs that provide targeted interventions (TIs), such as medical care, condoms, and education in prevention of HIV and AIDS.

The National AIDS Control Organization of India is collaborating with such NGOs to collect HIV sero-surveillance data among high-risk groups. Unlinked anonymous testing is used for surveillance purposes from the participants of the TI sites.

In 2004, there were 59 TI sites: 11 IDU sites in seven states, 11 MSM sites in 11 states, and 37 sex worker sites in 19 states. Figure 2.1 gives the HIV prevalence among sex workers in selected states of India.

Figure 2.1. HIV prevalence among female sex workers at targeted intervention sites, 2003.

While the surveillance data obtained from TI sites should be interpreted with caution, they serve as a useful addition to existing surveillance data. These data are now used in producing the national HIV estimates.
HIV Sero-surveillance

Setting priorities

The number of sentinel sites a country should have, and where these are located, is usually decided at a national level. Ideally, sentinel sites will:

- Represent each district
- Reflect the country-wide epidemic
- Include both urban and rural areas.

There are priorities that should help to determine the placement of a country’s sentinel sites. Table 2.7 lists the first and second priorities for the placement of sentinel sites.

Table 2.7. Priorities for the placement of the sentinel surveillance sites.

<table>
<thead>
<tr>
<th>Priority level</th>
<th>Placement criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>First priority</td>
<td>Include at least one site per district so that all regions or provinces are included in the national system</td>
</tr>
<tr>
<td>Second priority</td>
<td>Include additional sites in particular districts because sexual behaviours and determinants for HIV transmission may not be uniformly distributed</td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 2.7, answer the following questions:

a. According to the priorities listed in Table 2.7, what should you do first in setting up your surveillance system: ensure that you have a sentinel site in each region or establish multiple sites in a single region?

b. Why might it be useful to have multiple sentinel sites in one district or region?

Additionally, population size may vary greatly within or between districts, and HIV transmission rates may differ between urban and rural areas in a single district.

HIV sentinel surveillance requires planning, co-ordination, supervision and logistical support. It is important to select only a few sites in the beginning. You may then increase the number of sites as experience, time, staff availability and financial and logistical resources permit.
When resources are limited, there are a few basic considerations to keep in mind. Table 2.8 summarises these points.

Table 2.8. Guidelines for HIV surveillance when resources are limited.

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim for broad geographic coverage</td>
<td>The eventual goal should be to extend the number of sites to cover a broad distribution of geographic areas.</td>
</tr>
<tr>
<td>Do not over-stretch resources</td>
<td>The number of sites should not be too large. In some countries, several sentinel sites have closed down because the existing meagre resources were over-stretched.</td>
</tr>
<tr>
<td>Quality over quantity</td>
<td>It is better to have good surveys in a few locations than to have poorly conducted surveys in many locations.</td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 2.8, answer the following questions:

a. Explain what is meant by quality over quantity in the table

b. Why is broad geographic coverage referred to as the “eventual” goal?

Recommendations

The most appropriate and practical sentinel population in sub-Saharan Africa is pregnant women attending ANCs.

- Pregnant women are sexually active, or were sexually active and had unprotected sex, and can be easily defined.
- They are an accessible and relatively stable population.
- They are representative of 15- to 49-year-old women in the general population.
HIV Sero-surveillance

**Recommendations, continued**

- Sentinel sites should then be picked according to geographic areas. The areas to consider include urban and border areas and port cities.

STI clinic attendees are the second priority for sentinel surveillance. Other groups, including sex workers, long-distance truck drivers, or other mobile occupational groups, may be useful, but often will require special studies to measure HIV prevalence.

For Asia, sentinel surveillance systems should include a mix of ANC and STI clinics and/or IDU treatment clinics.

- In concentrated epidemics, HIV sentinel surveillance should be conducted where HIV transmission is occurring.
- In areas of lower HIV prevalence, the emphasis should be on setting up surveillance among population groups with high-risk behaviours such as STI clinics, injection drug user treatment clinics, or other venues that are accessed by high-risk groups such as commercial sex workers, MSM, truck drivers, and migrants.
- Sentinel sites should then be picked according to geographic areas. The areas to consider include urban and border areas and port cities.
- In areas with high HIV prevalence in high-risk populations, ANC clinics should be included.

As shown in Table 2.5 below, the local epidemiology should guide the inclusion of special sentinel populations, such as sex workers, MSM, or IDUs out of treatment. Such populations may require collaboration with targeted interventions provided by NGOs or special epidemiological surveys.

Table 2.5. Recommended sentinel populations in sub-Saharan Africa and Asia.

<table>
<thead>
<tr>
<th>Priority level</th>
<th>Population Group Africa</th>
<th>Population Group Asia</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>ANC attendees</td>
<td>ANC attendees/IDU treatment clinics</td>
</tr>
<tr>
<td>Second</td>
<td>STI clinic patients</td>
<td>STI clinic patients</td>
</tr>
<tr>
<td>Third</td>
<td>Other populations, for example, sex workers, long-distance truck drivers, or male occupational groups</td>
<td>Other populations, for example, sex workers, long-distance truck drivers, or male occupational groups</td>
</tr>
</tbody>
</table>
Looking at Table 2.5 on the previous page, answer the following questions:

a. In sub-Saharan Africa, if you already have sentinel surveillance in place in ANC s, and further resources are available, what populations should you focus on next?

b. Which sentinel populations include men?

**Summary**

The primary method of HIV transmission in sub-Saharan Africa is through heterosexual intercourse. To best plan sentinel surveillance, you should take into consideration many factors, including the following:

- The state of the epidemic in your region
- Accessibility of potential sentinel sites
- Available resources.
Unit 2 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. What populations in your district or province are at high risk for HIV infection? Why?

2. For each group, indicate the following:
   - Is the population easily identifiable?
   - Does the population seek care or services in established facilities?
   - Is blood drawn routinely at facilities as part of the service they receive?

3. How many sites are currently involved in HIV sentinel surveillance in your district? Province? Country?

4. Do these sites meet the criteria listed in this unit?

5. Describe any plans to increase the number of HIV sentinel sites in your country. List the improvements that this addition will make to your sentinel surveillance system.
Apply what you’ve learned/case study

Try this case study individually.

You are the surveillance officer for the Inyo district of the Yolo Republic. Your district is large and located on a major highway. It is on the border of a country with a large refugee population. New funding for surveillance has made possible the expansion of activities in your district.

Currently, two of the four ANCs in your district participate in the national HIV sentinel surveillance system. One is located in the main city of your district, Inyo Town, which is also the provincial capital. The other ANC is in a rural area near the provincial capital. Of the remaining two ANCs, one is located far from the capital. It is far from the main highway and near a refugee camp across the border. The other is in a private hospital funded by international charities in Inyo Town.

There is a rapidly growing town, Tehama, on the national border. Truck drivers wait long hours there as they pass customs inspections. Sex workers congregate in the border town, along the highway, and in two distinct areas of Inyo. There is also an STI clinic and outpatient TB programme in the hospital in Inyo Town. You have sufficient funds to add one additional HIV sentinel surveillance population.

a. In what populations might you consider doing the additional sero-survey?

b. What factors would you consider in selecting an appropriate population?

c. Are TB patients a suitable group for the additional sero-survey? Why or why not?

Because there is a generalised epidemic in the Yolo Republic, you have focused sentinel surveillance activities at ANCs. You make the decision to add one additional ANC site.

d. Which site would be the most suitable to add additional sentinel surveillance activities, and why?

e. What are the advantages and disadvantages of different site selections?
Notes
Unit 3
Sample Size, Sampling Methods, Duration
and Frequency of Sampling

Overview

What this unit is about

This unit describes how to get a representative sample of participants in a sero-survey. It also describes how to determine the size of the sample required and the sampling scheme that works best for HIV sero-surveillance.

Warm up questions

1. Which of the following is a reason to have inclusion and exclusion criteria?
   a. Include as few participants as possible in the survey
   b. Avoid inclusion of the same person multiple times
   c. Both of the above

2. True or false? The goal of sampling is to use the data from a sample of the population to estimate the HIV prevalence in the larger population.
   True False

3. Which of the following is a decision that needs to be made at the beginning of a sampling procedure?
   a. The sample size
   b. The sampling scheme
   c. The frequency of sampling
   d. All of the above

4. True or false? As much as possible, the sampling period should be limited, in order to compare HIV prevalence over time.
   True False
Warm up questions, continued

5. Match each sampling scheme with its description:
   
   ___ Consecutive
   a. Randomly selects the initial patient who meets inclusion criteria and then selects every $n^{th}$ eligible patient thereafter

   ___ Systematic
   b. Uses a computer or other method to generate a list of random numbers that is used to identify patients to be included in the sample

   ___ Simple random
   c. Samples every patient that meets the inclusion criteria until the required sample size is achieved

6. Which of the above schemes is the most simple logistically and best reduces the likelihood of selection bias?

7. True or false? All subjects at the sentinel site who meet the inclusion criteria during the sampling period should be included in the survey.
   True       False

8. True or false? When surveys are repeated, they should be carried out in different sites from the initial survey and during a different time of the year. This helps give a clear picture of the epidemic’s scope.
   True       False
HIV Sero-surveillance

**Introduction**

**What you will learn**

By the end of this unit you should be able to:

- Explain the process of sampling
- Determine who is eligible for a sample
- Choose the appropriate sampling scheme for specific situations
- Plan for the duration and frequency of sampling to be conducted.

**The sampling process**

*Sampling* is the process of selecting a representative subset of a larger population, in order to estimate some unknown characteristic of that larger population. Appropriate and consistent sampling methods are important for several reasons:

- They ensure that *sero-surveys* are representative of the populations in which they are conducted. Representative samples resemble the true population.
- They ensure that surveys are consistent from year to year.
- They ensure that surveys are consistent among sites.

When conducting a sentinel survey in *antenatal clinics* (ANCs), the characteristic of interest is the prevalence of HIV infection among women attending these clinics. If conducted correctly, the prevalence in a sample of these women will provide an accurate estimate of HIV prevalence in all women attending the ANC.

**Components of Sampling**

There are several factors to consider when choosing a sample. For each sentinel site, the following factors must be determined:

- The *sample size*, or number of individuals to include in the sample
- The *sampling scheme*, or procedures for choosing individuals to be included in the sample
- The duration and frequency of sampling, or how long to sample and how often to sample.

**Sample size**

The number of subjects included in a sentinel surveillance sample is guided by the need to determine trends in HIV prevalence over time and to identify sub-populations at high risk for infection. This means that the sample size needs to be large enough to be able to detect the difference between two prevalence estimates, such as between two clinic sites or between two years. Statistically, this is referred to as the *margin of error*: ±3%, for example.
Sample size, continued

A related, but somewhat different, statistical concept is confidence interval or confidence limits. In calculations, you specify what margin of error and what confidence interval you would like. These two numbers are then used to calculate sample size. A confidence interval of 95% with a margin of error of ±3% means that if the study were repeated 100 times, 95 times out of 100 the estimate would be within ±3 percentage points of the estimate you got the first time you did the study.

The standard statistical approach for determining the sample size per site requires:

- An estimate of HIV prevalence in the population to be surveyed
- The margin of error considered acceptable (for example, ±3%). This is also called width or interval width.
- The level of confidence desired.

Typically, sample size calculations are done at the level of a country’s national AIDS control programme (NACP) rather than at the district or provincial level. Minimum sample sizes should be calculated for each sentinel site for each survey period.

Practical issues

In practice, sample sizes are balanced against the technical and financial resources available for survey implementation and collection. Very large sample sizes in a sentinel site can provide useful information on the local epidemic. There may not be enough resources to carry out surveys with very large sample sizes, however.

As a rule of thumb, a minimum sample size of 250 to 400 patients per site is recommended. This recommendation is based on the following:

- With the typical prevalence observed in sub-Saharan Africa, a reasonable margin of error of ±3% and 95% statistical confidence can be reached
- This is the maximum sample size that can be obtained in a typical clinic over eight to 12 weeks
- This will produce sufficient statistical power to determine trends in HIV prevalence over a three-year period.
- By taking all eligible patients into the study rather than only a sample of them, you can avoid selection bias. Selection bias involves picking a sample of patients who are not representative of the whole population of patients seen. For instance, they might be younger, older or less likely to have HIV infection.
Determining Sample Size

An exact formula to determine sample size (N) to achieve a certain pre-specified interval (for example, ±3%, which is the same as a width of 6%) with a specified level of confidence (for example, 95%) is shown in Figure 3.1.

![Figure 3.1. Formula to determine sample size needed for a pre-specified interval with specified confidence level.](image)

\[ N = 4 z_{\alpha}^2 \frac{P (1 - P)}{W^2} \]

- \( z_{\alpha} \) is a factor that corresponds to the desired confidence interval (for a 95% confidence level, \( z_{\alpha} = 1.96 \)).
- \( P \) is the expected proportion of patients with the outcome (such as HIV prevalence).
- \( W \) is the width of the interval, for example the width for a margin of error of ±3% is 0.06.

Now answer the questions on the following page.

Discussing the equation

Looking at Figure 3.1 and the bulleted text below it, answer the following questions:

a. What does the equation calculate (that is, what is N)?

b. What does P represent in the equation?

c. What does W represent in the equation?

d. What does \( z_{\alpha} \) represent in the equation?

Practice sample size calculation

Let’s do a practice sample size calculation. You are a surveillance officer and you want to calculate how large your sample must be to measure HIV prevalence. You estimate that the HIV prevalence is 20% in your district, and you want a margin of error of ±5%. Therefore, the calculation will look like this:
Practice sample size calculation, continued

\[ N = \frac{4 \times (1.96)^2 \times 0.20 \times (1 - 0.20)}{(0.10)^2} \]

\[ N = 246 \text{ people} \]

You need 246 people in your sample to achieve the confidence interval that you want.

Using the Statcalc Feature of Epi Info

The Statcalc feature of *Epi Info™* software provides a user-friendly sample size calculator for setting specific target sample sizes. The *Epi Info™* software is distributed by the United States Centers for Disease Control and Prevention (CDC). You may learn more about *Epi Info™* and download the software for free at this site: [http://www.cdc.gov/epiinfo](http://www.cdc.gov/epiinfo).

To use the Statcalc feature in Epi Info, follow these steps:

1. From the main menu, select *Utilities* at the top of the screen.

2. Select Statcalc.

3. Select *Sample size and power* by pressing the “s” key.
Using the Statcalc feature of Epi Info, continued

4. Select *Population serosurvey* by pressing the “p” key.

5. A screen will appear where one is required to enter the following information:
   • Size of population from which the sample will be selected.
   • Expected frequency of the factor under study (err towards 50%) – true rate in the population.
   • Worst acceptable rate (furthest from the rate you would accept in your sample, high or low).
Using the Statcalc feature of Epi Info, continued

6. Press F4 Calculate.

7. The sample size is listed by confidence intervals.
HIV Sero-surveillance

Practice sample size calculation

In a country with a concentrated epidemic, ANC sentinel surveillance is conducted to monitor prevalence in a low-risk population. What sample size would you need in an ANC clinic that has an expected HIV prevalence of 1%? The size of the population is the theoretical universe of people who would access this clinic, for example, 100,000. Use 2.0% as the worst acceptable rate.

In this example, Statcalc calculates the sample size at 379 at a 95% confidence interval.

Sample size rules of thumb

Rules of thumb for sample sizes are:

- The closer the estimated prevalence to 50%, the larger the sample size required to achieve the same confidence interval width. This is because in the formula, the terms p and p-1 are both in the numerator. If p is 50% and p-1 is also 50%, the product of p x p-1 is 0.25. The farther p and p-1 are away from 50%, the smaller the product will be. For example, if p is 10% and p-1 is 90%, then p x p-1 is 0.1 x 0.9 = 0.09.
- The sample size needed gets larger as the desired confidence interval gets smaller; therefore, the margin of error is smaller.
- A sample size must be practical to achieve in the course of a few months.
- In some instances, you may wish to add additional members of a certain subgroup, for example, women 15-24 years old. This is referred to as over-sampling. Its purpose is to have a sufficiently large sample of the particular subgroup to get stable estimates of prevalence.
The following are three possible sampling schemes used to select individuals for the sample at sentinel sites:

- **Consecutive sampling**: Consecutive sampling consists of selecting every patient who meets the inclusion criteria, until you reach the required sample size, or the survey period is over.

- **Systematic sampling**: Systematic sampling consists of making a list of every patient who meets the inclusion criteria, and then selecting every $n^{th}$ (for example, third or fifth) from the list until the required sample size is reached, or the survey period is over.

- **Simple random sampling**: Simple random sampling uses a random number table or other method (for instance, a computer-based method) to generate a list of random numbers. These numbers are then matched with a list of patients who meet the study criteria.

Each sampling scheme has advantages and disadvantages. Table 3.1 on the following page summarises them.
### Table 3.1. Advantages and disadvantages of various sampling schemes.

<table>
<thead>
<tr>
<th>Sampling Scheme</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| **Consecutive sampling:** select every patient that meets the inclusion criteria until you get to the required sample size or the survey period is over. | ▪ Relatively easy to employ  
▪ Less opportunity for intentional or unintentional manipulation by clinic staff or errors due to confusion | ▪ Not based on randomisation  
▪ May be variations in who is seen at ANCs at different times of the year (for example, during the rainy season women may have problems coming from rural areas to the clinic) |
| **Systematic sampling:** make a list of every patient who meets the inclusion criteria and then select every n<sup>th</sup> (for example, third or fifth) from the list until the required sample size is reached or the survey period is over. | ▪ More likely to produce a representative sample if done correctly | ▪ More difficult to do correctly than consecutive sampling  
▪ Requires more attention to procedural details  
▪ Non-random selection of the first patient or failure to sample every n<sup>th</sup> patient will make the sample non-random.  
▪ The method may also take longer to fill the sample size |
| **Simple random sampling:** use a random number table or other method (for instance, computer-based) to generate a list of random numbers and then match the numbers to a list of patients who meet the study criteria until the required sample size is met | ▪ Most likely to produce a true sample of the total population if done correctly | ▪ Complex, prone to errors and confusion, and may take longer to conduct  
▪ Requires a census or a numbered list of potential survey participants |
HIV Sero-surveillance

Discussing the table

Looking at Table 3.1 on the previous page, answer the following questions:

a. Which sampling scheme is most likely to produce a true, random sample if conducted correctly?

b. Which sampling scheme is logistically the simplest?

Of the three methods described above, consecutive sampling is recommended for use in sentinel surveillance. It is recommended because it reduces the likelihood of error or deliberate manipulation by on-site personnel in terms of who is included in the sample. It is also the most simple to implement.

Duration of surveys

HIV prevalence in a given area is likely to change over time. New infections may occur, persons with advanced HIV disease may die, and people may enter or leave the area. Ideally, therefore, HIV prevalence is measured at a single point in time (that is, a point estimate).

- In sentinel surveillance settings, however, such a point prevalence estimate is nearly impossible to obtain because not all eligible patients are in the clinic at a single point in time.
- It is good, however, to limit as much as possible the time-period for sampling.
- Prevalence estimates may be close enough to a point estimate to allow valid comparisons over time.

It is more practical if you give health workers in clinics precise dates when to begin and end the time period for specimen collection. These define the sampling period. How long the sampling period lasts will vary according to clinic volume and the number of patients who meet the inclusion criteria.

Many countries set their sampling period at or below 10 weeks. If volume at the clinic is low, the sampling period may need to be longer; for example, up to 20 weeks. A criterion for site selection is the ability to meet the sample size during the sampling period. If a site does not meet the required sample size within the sampling period, the national surveillance programme may extend the duration of data collection. Extension of the survey period should be done only with the agreement or direction of the national surveillance programme.
**Frequency of surveys**

The sampling period selected should be the same time each year. You may, for example, select the period from 1 August through 30 September. This ensures that data are comparable from year to year and from place to place, if there is seasonal variation in clinic attendance.

- To allow sufficient time for collation, analysis, interpretation and report writing, sero-surveys should be repeated every 1-2 years.
- Conducting surveys more frequently than once per year can exhaust personnel and other resources. Also, more frequent surveys do not usually contribute additional information that is useful for public health decisions.
- Repeat surveys should be conducted in the same sentinel sites, using the same methods, every cycle.
- Among the most important considerations in determining the frequency of surveys is the availability of sufficient financial, technical and human resources to carry out the surveys.

**Eligibility criteria**

The term *inclusion criteria* refers to characteristics required in study participants in order for them to be considered for the sample.

*Exclusion criteria* refer to characteristics of patients who should be excluded from the sample, but who otherwise would be eligible. For ANC surveys the most important exclusion criterion is repeat attendance at the clinic. It is necessary to ensure that no ANC client is sampled more than once during the same surveillance round, and this can be done by linking sampling to specific events that are only scheduled once during pregnancy, such as testing for syphilis.

Table 3.2 gives further examples of possible inclusion and exclusion criteria.

Table 3.2. Examples of possible inclusion and exclusion criteria for women at ANCs.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (only women 15 to 49 years old should be eligible for the sample)</td>
<td>Not attending ANC for the first time</td>
</tr>
<tr>
<td></td>
<td>Attendance at another ANC</td>
</tr>
</tbody>
</table>
Discussing the table

Looking at Table 3.2 on the previous page, answer the following questions:

a. According to the inclusion and exclusion criteria listed above, would a 14-year-old girl attending an ANC for her first prenatal visit be eligible for inclusion in the survey? Why or why not?

b. A 24-year-old woman comes into an ANC and tells you she is 7 months pregnant and has recently moved from a neighbouring district, where she was attending another ANC. Should she be included in the survey? Why or why not?

When you calculate the sample size and decide how long the sampling period should be, you need to note that some subjects at the site will not be eligible for inclusion.

Summary

Sampling is the process of selecting a representative sub-set of a larger population to estimate some unknown characteristic. Consecutive sampling is the recommended sampling scheme. You should set inclusion and exclusion criteria to select patients to produce the most accurate and reliable results. The frequency of sampling should be often enough that you are able to best estimate prevalence, but not so often that you strain available resources.
Unit 3 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. What sample sizes have been used for various HIV sentinel groups in your district or province?

2. How long was the sampling period?

3. Was the required sample size obtained at each site? If not, why not? Was the sampling period extended until the required sample size was met?

4. Describe how you avoided including the same individual twice during the sampling period.
Apply what you’ve learned/case study

Try this case study. We will discuss the answers in class.

Using the formula for sample size estimation based on the precision of a point estimate, calculate the sample size required for the following scenarios.

\[ N = 4 z_\alpha^2 P (1 - P) \div W^2 \]

a. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 10% within ± 5%. Remember that P and W are expressed as decimals (that is, P = 0.10 and W = 0.10)

b. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 10% within ± 2.5%.

c. What happens to the required sample size as the width of the margin of error gets smaller?

d. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 35% within ± 5%.

e. What happens to the required sample size as the estimated prevalence gets closer to 50%?
Notes
Unit 4
Specimen and Data Collection

Overview

What this unit is about

This unit provides the rationale for conducting HIV sentinel sero-surveys using unlinked anonymous blood specimens. It also describes the process of data collection as well as information on selection of HIV tests, testing algorithms and quality assurance (QA) including proper procedures for forms and data entry.

Warm up questions

1. True or false? In unlinked anonymous testing, information about the identity of patients is kept in order to tell them about their results if they test positive.

   True    False

2. Place the following events in the correct order, corresponding to the proper procedure for unlinked anonymous testing:

   a. Blood is collected and labelled with a code
   b. Specimen is tested for HIV
   c. Personal identifying information is removed from specimen
   d. An aliquot is removed into a new tube for HIV testing.

3. True or false? Unlinked anonymous testing without informed consent can sharply reduce participation bias.

   True    False

4. Place the following events in the correct order, corresponding to the preferred data collection method for unlinked anonymous testing:

   a. Send form to laboratory
   b. Add HIV test result to form
   c. Add demographic data to form
   d. Remove demographic section of form and send to data manager.
Warm up questions, continued

5. Which of the following is not a reason for the use of standardised data collection forms?
   a. To ensure that the necessary information is obtained
   b. To ensure that data from different sites can be easily compared
   c. To ensure that a patient’s personal information can be matched with their test result
   d. None of the above

6. True or false? For linked confidential surveys, a separate laboratory form for serologic results should be used so that laboratory personnel do not have access to the patient’s personal identifying information.
   True False

7. For unlinked anonymous testing, as is used in sentinel surveillance, which of the following variables would be inappropriate to collect:
   a. Patient age
   b. Patient marital status
   c. Patient’s number of children
   d. None of the above.
Introduction

What you will learn

By the end of this unit you should be able to:

- Understand the rationale for conducting unlinked anonymous testing (UAT) for HIV sentinel surveillance
- Explain methods for keeping samples anonymous and unlinked
- Explain the importance of standardised forms for data collection
- Describe the protocols for data collection
- Identify the necessary demographic information to be collected for analysis.

Approaches to Sero-surveys

Objectives of HIV testing

HIV sentinel surveillance uses HIV testing to track the prevalence of infection by person, place or time. There are other objectives of HIV testing, which include the following:

- Counselling persons on their infection
- Referring them to care
- Reducing the risk of transmitting or acquiring HIV
- Ensuring the safety of the blood supply
- Performing scientific research
- Determining eligibility for certain types of employment or health insurance

Preventing bias in the survey

To meet the objectives of surveillance, participation in HIV testing must be as complete as possible in the sentinel population. Persons offered HIV testing may have reasons to accept or decline the test.

- Persons at high risk for HIV may accept testing to learn their HIV status and obtain care.
- Persons who already know they are HIV-infected may find testing unnecessary.
- Persons who suspect they are HIV-infected may decline testing to avoid the stigma often associated with HIV infection. Stigma refers to a mark of disgrace or shame.

The degree to which higher- or lower-risk persons choose to be tested is referred to as participation bias. For surveillance data to be as unbiased as possible, participation bias must be minimised.
Considerations in selecting an approach

Table 4.1. Considerations to guide the selection of a testing approach.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation bias</td>
<td>▪ Approaches that allow choice in who gets tested introduce the potential for participation bias.</td>
</tr>
<tr>
<td></td>
<td>▪ Unlinked anonymous testing with no informed consent is recommended for HIV sentinel sero-surveillance to avoid this bias.</td>
</tr>
<tr>
<td>Informed consent</td>
<td>▪ HIV testing generally is done with the explicit consent of the person being tested.</td>
</tr>
<tr>
<td></td>
<td>▪ An exception is often made for HIV sentinel sero-surveillance using the unlinked anonymous approach. The decision not to obtain informed consent is determined by local ethical standards.</td>
</tr>
<tr>
<td></td>
<td>▪ On-site or nearby access to HIV testing, if subjects wish to have it, should be available.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>▪ Persons with HIV infection are subject to stigma, discrimination, and potential harm.</td>
</tr>
<tr>
<td></td>
<td>▪ Therefore, all precautions should be taken so that persons other than the patient do not learn of someone else’s HIV test results.</td>
</tr>
<tr>
<td></td>
<td>▪ In confidential testing, staff members have access to patient-identifying information, but do not release information to anyone but the patient.</td>
</tr>
<tr>
<td></td>
<td>▪ In anonymous testing, no-one knows or records who the patient is, and, therefore, surveillance and clinic staff are not able to identify an individual. Anonymous testing ensures that no one learns the individual’s HIV test results. Results may be returned to patients using a code, but since only the patient knows the code, he or she is the only one to learn the results.</td>
</tr>
<tr>
<td>Linking</td>
<td>▪ <em>Linking</em> refers to whether an individual’s name or identifying information is associated with HIV test results.</td>
</tr>
<tr>
<td></td>
<td>▪ “Unlinked” refers to the deliberate removal of identifying information or means to link HIV test results to individuals.</td>
</tr>
<tr>
<td></td>
<td>▪ Linking also refers to attaching demographic and behavioural information (but not personally identifying) to HIV test results.</td>
</tr>
<tr>
<td></td>
<td>▪ Personal identifiers such as birth date or a name are recorded on the blood drawn for the HIV test, and these identifiers are attached to the HIV test result. The identifier is used to return HIV results to individuals.</td>
</tr>
<tr>
<td>Result disclosure</td>
<td>▪ If test results are returned to individuals, activities should include:</td>
</tr>
<tr>
<td></td>
<td>o Informed consent</td>
</tr>
<tr>
<td></td>
<td>o Pre- and post- test counselling</td>
</tr>
<tr>
<td></td>
<td>o Confirmatory testing</td>
</tr>
<tr>
<td></td>
<td>o Referral to needed healthcare and other services</td>
</tr>
</tbody>
</table>
Discussing the table

Look at Table 4.1, then answer the following questions.

a. What are the five factors that should guide the selection of a testing approach?

b. Choose one of these factors, and explain how it would influence the selection of a testing approach.

Approaches to HIV testing

There are several approaches to testing individuals for HIV for surveillance purposes. The four main considerations that may affect participation bias in HIV testing are these:

- Is testing anonymous or confidential?
- Are specimens linked or not linked to identifying information about a patient?
- Does the patient consent to be tested?
- Are the test results given to the patient?

Additionally, testing can be done as a special study, as a part of routine medical care or compelled by authorities. The six main approaches to HIV testing for surveillance purposes are described below:

**Unlinked anonymous testing without informed consent**

- HIV testing is done on specimens of blood collected for other purposes, such as syphilis testing.
- Individuals do not consent to have HIV testing performed on their blood. They may, however, be aware that HIV testing is periodically done at the site, and that their blood may or may not be included.
- All personal identifying information, such as names or codes that can be linked to individuals’ names, is permanently stripped from specimen tubes and other records prior to testing for HIV. This is done so that no HIV test results can ever be linked to an individual.
- Data are recorded using codes that do not identify individuals.
- Persons do not choose to participate or not participate.
- Persons do not get their HIV test results. They may be referred to HIV testing at the site or a nearby site. They can have blood drawn again for HIV testing. Then, they can receive counselling and their new test results.
Approaches to HIV testing, continued

*Unlinked anonymous testing* with informed consent
- Individuals consent to have HIV testing performed on their blood, and therefore may choose to participate or not participate.
- All personal identifying information, such as names or codes that can be linked to individuals’ names, is permanently stripped from specimen tubes and other records prior to testing for HIV. This is done so that no HIV test results can ever be linked to an individual.
- Data are recorded using codes that do not identify individuals.
- Persons do not get their HIV test results. They may be referred to HIV testing at the site or a nearby site.

*Linked confidential testing* with informed consent
- Persons choose to have their blood tested for HIV and can learn the results of the test.
- HIV testing may be performed on blood drawn for other purposes or explicitly drawn for HIV testing.
- They provide written informed consent, and receive pre-test and post-test counselling.
- Personal identifiers or names are recorded and used to return results to individuals.

*Linked anonymous testing* with informed consent
- Persons choose to have their blood tested for HIV and can learn the results of the test.
- HIV testing may be performed on blood drawn for other purposes, or explicitly drawn for HIV testing.
- Informed consent and pre-test and post-test counselling is required, but the consent may be verbal rather than written.
- No personal identifiers or names are recorded. Instead, each individual is given a unique, non-identifying code.
- Individuals obtain their test results and post-test counselling by presenting the code.

*Mandatory testing*
- Done when HIV testing is a necessary pre-requisite to obtain a certain benefit or service. Persons may choose to seek the benefit or not.
- Most commonly recommended for blood transfusion safety.
- Not recommended for HIV sentinel sero-surveillance, because populations who are tested on a mandatory basis are typically not representative of the general population.

*Compulsory testing*
- Testing is required, and the individual does not have the choice to accept or refuse the HIV test. This is done rarely in police investigations, such as in the
**Approaches to HIV testing**, continued

- criminal investigation of rape or of intentional HIV transmission, or as part of a physical examination at entry into the military of some countries.
- Not typically recommended for HIV sentinel surveillance because the results from the population tested cannot be generalised to a larger population. In countries with universal conscription and mandatory testing of military recruits, however, compulsory testing data can provide a good estimate of HIV prevalence among young men.

**Recommended sentinel surveillance**

Given the high importance of minimising participation bias and preserving confidentiality, unlinked anonymous HIV testing without informed consent is the recommended testing approach for sentinel surveillance.

Unlinked anonymous testing is done only on blood that is left over from specimens that are regularly collected for other purposes, such as syphilis testing. The major disadvantage of UAT is that persons do not get their test results. Because such information may directly impact their health and risk of acquiring or transmitting HIV, UAT should be done in settings where patients can be referred to voluntary counselling and HIV testing programmes.

Linked testing (confidential or anonymous) with informed consent is the preferred approach when the specimens are collected explicitly for the purpose of HIV testing and diagnosis. One example of this HIV sero-surveillance carried out in populations not easily accessed in health settings, such as sex workers and truck drivers. In these cases the preferred method for estimating HIV prevalence may be a *community-based sero-survey*. In this type of survey, members of a high-risk group are sampled, and those included in the sample are counselled and offered HIV testing after giving informed consent in a community setting. They also receive their test results and, if results are positive for HIV, can be counselled and referred to care.

Linked testing with informed consent is also the method used in *population-based surveys*. This type of survey is usually a household survey in which members of a household consent to a behavioural questionnaire and HIV counselling and testing. Survey participants may or may not receive their results from those conducting the survey. If not, they will be referred to nearby counselling and testing centres to learn their status.
Procedures for Unlinked Anonymous Testing without Consent

Guiding principles

The guiding principles of UAT without consent are:

- HIV testing should only be done on leftover blood that was drawn for routine care.
- All information that could link an HIV test result to an individual is permanently destroyed, prior to HIV testing.

Operational procedures for unlinked anonymous HIV sentinel surveillance supported by the CDC Global AIDS program can be found in Annex 4.2.

Determining eligibility

The very first step in UAT is to identify persons who are eligible for the sample. This is done at the time of the visit by clinic personnel knowledgeable about the inclusion and exclusion criteria. This is the most straightforward way of identifying a sample.

Another way to decide eligibility for the sample is to review information from the clinic records, after the visit. This could be done at the end of the day, but before sending the samples to the laboratory. Because clinic records are often not sufficiently detailed, and because patients are no longer at the site to clarify information about eligibility, such as if they had been seen earlier in their pregnancy at another ANC, this method is less preferable.

Obtaining information

A minimum amount of information that is already routinely collected as part of the clinic visit is collected on all individuals for the purpose of determining HIV prevalence by sub-populations (for example, by age group, gender or geographical location). Procedures for getting this information, while preserving patients’ anonymity, must be clear.

For anonymous unlinked surveys, the types of information that should be collected include:

- Basic demographic information such as:
  - Age
  - Sex
  - Geographic area of residence.
- Additional helpful information that can confirm eligibility, such as:
  - Date of visit
  - Reasons for the current visit
  - Date of last visit (if available) to verify eligibility.
To protect anonymity in unlinked anonymous surveys, data collection instruments should record only the month and year of the visit, rather than the day, month and year.

**Additional data**

When other data are available that are routinely collected as part of the clinic visit, it may be desirable to collect them. Table 4.2 outlines some of additional data that may be collected.

Table 4.2. Additional data to be collected.

<table>
<thead>
<tr>
<th>Additional data types</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic data</td>
<td>▪ Socio-economic or educational level</td>
</tr>
<tr>
<td></td>
<td>▪ Occupation</td>
</tr>
<tr>
<td></td>
<td>▪ Marital status</td>
</tr>
<tr>
<td>Behavioural data</td>
<td>▪ Number of sexual partners</td>
</tr>
<tr>
<td></td>
<td>▪ Condom use</td>
</tr>
<tr>
<td>Clinical data</td>
<td>▪ Signs and symptoms of HIV</td>
</tr>
<tr>
<td></td>
<td>▪ Signs and symptoms of other STIs</td>
</tr>
<tr>
<td></td>
<td>▪ Gravity and parity</td>
</tr>
</tbody>
</table>

**Discussing the table**

Looking at Table 4.2 on the previous page, answer the following questions:

a. What data elements listed above tell us about behaviour?

b. Are any additional data elements routinely collected in your district? Which ones?
**Step by step procedure for UAT**

There are nine steps in UAT at an ANC. Table 4.3 summarises the steps. See Annexes 4.1 and 4.2 at the end of this unit for more information.

### Table 4.3. Steps for ANC unlinked anonymous testing.

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>Clinic staff member #1 collects a specimen from a patient, and labels it with a code (for example, clinic name and an identification number).</td>
</tr>
<tr>
<td></td>
<td><img src="image1" alt="Image of a container labeled with a code" /></td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Clinic staff member #1 labels a clinic form with the same code, and collects demographic and routine clinical information, including identifying information, from the patient.</td>
</tr>
</tbody>
</table>
| | **CLINIC FORM**
| | **Code** |
| | o **Identifying information**
| | o **Demographic Information** |
| **3** | Clinic staff member #1 removes an aliquot, or portion, of the blood sample and places it in a second tube or dry blood spot. |
| | ![Image of a container labeled with a code](image2) ![Image of a container labeled with a new code](image3) |
| **4** | The second specimen with the aliquot of blood is labelled with a new code not linked to personally identifying information. |
| | ![Image of a container labeled with a new code](image4) |
The first tube of blood is sent for routine clinical testing (for example, haemoglobin, syphilis).

Staff member #1 records the new code on a surveillance form. He or she then transfers demographic information from the clinic form to the surveillance form. Thus, the surveillance form contains no personal information or code.

Clinic staff member #2 performs HIV test on blood sample labelled with new code.

HIV test results are recorded in a laboratory log-book with the new code and the HIV test result.

Demographic information from surveillance forms is matched with HIV test results using the new codes, and then analysed.
HIV Sero-surveillance

Discussing the table

Looking at Table 4.3, answer the following questions:

a. In UAT, should the staff member who collects the blood specimen from the patient also perform the HIV test on the aliquot of blood that has been labelled with a new code? Why or why not?

b. Should the new code contain identifying information?

c. What information is recorded on the surveillance form?

d. Why is the surveillance form labelled with the new code?

e. Can HIV UAT results be linked with demographic information for analysis?

f. Can HIV UAT results be linked with personally identifying information?
Ensuring patient anonymity

To ensure patient anonymity at the clinic and laboratory, one staff member should collect the blood specimen, and a different staff member should perform HIV testing.

- One staff member (a clinician or laboratory technician) should collect and process the specimen for routine clinical testing.
- Another staff member should perform the unlinked anonymous HIV test, and record the results.

If one staff member is responsible for both collecting the specimen and performing UAT, it is best if another staff member processes the specimen for UAT. Processing the specimen for UAT involves removing an aliquot of blood and placing it in a new tube labelled with a new code that is not linked to any personal identifying information. In addition, if testing is to occur at the clinic site, samples should be stored for batch testing rather than conducted in real-time to avoid linkage back to ANC name-based logs.

An alternative approach to ensure confidentiality of HIV testing results is to move unlinked anonymous HIV testing off-site to provincial or national laboratories. In this case, the laboratory provides only aggregate HIV results back to the site as feedback and no individually listed HIV test results.

Collecting demographic information

There are several important steps in the process of collecting demographic information. It is important that the anonymity of the specimen not be compromised by the collection of too much, or too detailed, demographic information which could result in the possible identification of individuals.

- At the time of specimen collection, a staff member collects demographic information, such as age, sex, marital status or geographic area of residence, and medical history from the patient as part of routine care.
- This information is recorded onto a clinic form along with the code on the specimen, such as name or clinic identification number.
- After the specimen is processed for unlinked anonymous HIV testing and the aliquot is labelled with a new code, the same staff member records the new code onto a surveillance form and abstracts the needed demographic information, such as age, sex or marital status, onto the surveillance data form. This abstracted information is therefore not linked to any personal identifying information.
Collecting demographic information, continued

- The unlinked anonymous HIV test results can then be matched with the demographic information for analysis with the new code.

Labelling specimens

There are several important steps in the process of labelling specimens.

- The specimen collected for HIV testing is placed in a plastic tube, *cryovial* (a vial designed for freezer storage) or on *filter paper* (porous paper) and labelled with the code.
- If labels are used, the label should be placed on the side of the tube, not on the cap.
- Pre-printed *cryolabels*, which are labels designed to adhere during freezer storage, should be used when specimens are stored in cryovials.
- Surveillance co-ordinators should provide the field staff responsible for specimen collection with a series of labels or permanent markers and the codes to be used.

Logging test results

You should keep individual test results completely secure and confidential. There are certain procedures you can follow to ensure this.

- A separate laboratory log-book for surveillance activities should be maintained to record HIV test results by their corresponding codes.
- The log-book should be accessible only to laboratory and surveillance staff. It should be secured in a locked drawer or cabinet when not in use to ensure the confidentiality of the persons’ test results, as well as their participation in surveillance activities.
- These log-books should be only kept as long as they are needed and then destroyed. Usually they are needed to resolve questions when the data are entered into a computer. There should be a clear clinic policy on how long to retain these log-books.
- For UAT, the log-book should contain only the codes and corresponding HIV test results.
- There should be no personal identifying information for the patients whose specimens are tested. HIV test results can be matched by the new code to the demographic information abstracted earlier, on the surveillance form.
Flow of data collection forms:
Approach A

You can use either of the following two options to collate demographic and serologic data. In the first approach (Approach A in Figure 4.1):

- Demographic data are recorded on the top portion of the form, which is removed and sent to the national data manager.

- The lower portion is sent to the laboratory, where the HIV test result is entered. This portion is then forwarded to the person responsible for data management at the clinic.

- The data entry clerk then enters data from both forms separately into the log-book, matching by the identical survey number on each form and merging them into a single record. This is also the way the data are handled if they are directly entered into a computer, rather than into a log-book.

Flow of data collection forms:
Approach B

In the second approach (Approach B in Figure 4.1):

- Demographic and serologic data are recorded on the same form.

- This requires that the form be sent to the laboratory and then back to surveillance staff for entry into the log-book after it has been completed.

This second method is less desirable for use in UAT because an individual’s identity and test result can more easily be disclosed.

- To protect confidentiality in linked confidential surveys, laboratory personnel should not have access to demographic, risk behaviour or identifying information.

- Thus, you should have a separate laboratory form for serologic test results.

- The form should contain the same survey number as on the risk assessment instrument, along with a code number for reporting results to the clinic, and ultimately to the patient.

These data are then either entered into a computer at the site or sent the national data manager for data entry. The data will must be cleaned and checked for duplicates. The size of the individual sample in each ANC should be the same as the number of forms received at the national level.
Flow of data collection forms: Approach B, continued

The CDC guidelines for UAT are located in Annex 4.2. These guidelines should be used as a checklist when developing a sentinel surveillance protocol using UAT that will be submitted to ethical review boards.

Figure 4.1. Approach to HIV surveillance data management.

Looking at Figure 4.1, answer the following questions:

a. Which approach is a greater threat to patient confidentiality?

b. In Approach A, who is responsible for matching the demographic data with the HIV test result?
**Recommendations**

It is encouraged that all countries and programs that are supporting UAT surveillance in ANC clinics collect information on the availability and uptake of PMTCT services that are located in UAT ANC clinic sites and examine the possibility of using PMTCT data for surveillance. This information will support the goal of returning test results to client and will facilitate the transition from UAT ANC data to PMTCT programme for surveillance purposes.

**Summary**

Unlinked anonymous testing for HIV sentinel surveillance helps to produce the least biased results, giving an accurate picture of the epidemic. It is essential that the samples are completely anonymous and unlinked to protect patient confidentiality. Data collection forms should be standardised so that results can be compared across sites. Be sure to collect appropriate demographic information, such as sex and age, so that meaningful conclusions can be drawn from the data.

**Unit 4 Exercises**

**Warm up review**

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

**Small group discussion**

Get into small groups by country, region or province to discuss these questions.

1. Review the sample national form used to collect information on each sampled pregnant woman for HIV sentinel surveillance in ANCs (Annex 4.3). What demographic information is obtained at sentinel sites in your country? How is that information linked to the test results?

2. Discuss all the steps that may be taken to ensure confidentiality in HIV sentinel surveillance. What are the likely negative outcomes of breached confidentiality? To what extent have these been experienced in your district or province?
Try this case study individually.

You identify an STI clinic in your district that serves a population located on the border of a country with high HIV prevalence and a large refugee population. It is located on a major highway. You wish to determine HIV prevalence in the STI clinic population. Funding to establish the clinic as a sentinel surveillance site will be available starting next year.

You visit the hospital laboratory that conducts syphilis testing for the STI clinic. The laboratory director tells you that she has saved blood specimens from the clinic for the last six months. She was about to discard them but asks whether these specimens could be tested for HIV to determine the prevalence in the clinic population.

a. Do you think that testing these specimens would produce an estimate of HIV prevalence that could be compared to the sentinel surveillance estimate planned for the following year?

b. What information do you need to know about the specimens and their source to assess their suitability for estimating HIV prevalence?

c. Describe the steps you would take to ensure that HIV test results could not be linked back to clinic patients.

d. The laboratory director indicates that they also conduct voluntary HIV testing on STI clinic patients when recommended by the physician and consented to by the patient. HIV prevalence among clinic patients voluntarily tested is 50%. Based on this information, what HIV testing strategy would you use to determine HIV prevalence as a surveillance exercise?

e. Would you use the voluntary HIV testing data from the STI clinic as a measure of prevalence? Why or why not?
HIV Sero-surveillance

Notes
Annex 4.1. Unlinked Testing

**Collection**
- Staff member #1* collects specimen from patient and labels tube with a code (such as, name, clinic identification number).
- Staff member #1 places an aliquot of leftover blood into a new tube for HIV test and labels tube with a new code not linked to any personal identifying information.
- Staff member #1* records demographic information not linked to personal identifying information and new code on surveillance form.

**Data**

**CLINIC FORM**
- Original code (name, clinic identification number)
- Demographic information
- Routine clinical information

**SURVEILLANCE FORM**
- New code
- Abstracted demographic information, such as age, marital status

**Testing**
- Routine clinical testing (such as, anaemia, syphilis)
- HIV test result recorded in laboratory logbook or line listing (result cannot be traced back to patient)
- Staff member #2* performs HIV test. New code

* Staff members #1 and #2 should not be the same person. In this way, the patient's anonymity is ensured.
Annex 4.2. Operational Procedures for Unlinked Anonymous HIV Sentinel Surveillance Supported by the CDC Global AIDS Program

Introduction

In most countries where CDC’s Global AIDS Program (GAP) is active, surveillance activities include HIV unlinked anonymous testing (UAT). The purpose of UAT is to:

- Monitor trends
- Develop estimates and projections
- Assist with program planning
- Target interventions.

CDC ethical consultations as well as technical guidelines on UAT have established criteria for the conduct of UAT for surveillance. To assure that CDC-supported UAT HIV surveillance activities follow these guidelines, we are providing you with a list of elements that should be included in protocols for UAT for HIV surveillance.
Definitions of HIV Testing Procedures for Surveillance

HIV testing terms

HIV testing procedures for surveillance.

<table>
<thead>
<tr>
<th>Testing type</th>
<th>Purpose</th>
<th>Requirements</th>
<th>Specimen coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unlinked anonymous testing (without informed consent)</td>
<td>▪ Testing of unlinked specimens and use of data collected for other routine purposes</td>
<td>▪ No personal identifiers obtained, no counseling required</td>
<td>Coded specimen</td>
</tr>
</tbody>
</table>
| Unlinked anonymous testing (with informed consent) | ▪ Testing of unlinked specimens collected solely for surveillance purposes | ▪ Informed consent required  
▪ No personal identifiers or names obtained, no counseling required | Coded specimen                                       |
| Linked confidential testing (with informed consent) | ▪ Testing of samples linked to the person by name, collected primarily for surveillance | ▪ Informed consent and pretest and posttest counseling required  
▪ Personal identifiers or names obtained | Coded specimen; code linked to personal identifying information |
| Linked anonymous testing (with informed consent)  | ▪ Testing of samples linked to the person by code (which they retain to retrieve test results) collected primarily for surveillance | ▪ Informed consent and pretest and posttest counseling required | Coded specimen; specimen linked to person by code |
Unlinked Anonymous Testing without Informed Consent

Unlinked anonymous testing without consent is the most common HIV testing approach for HIV sentinel surveillance because of minimal participation bias and logistical simplicity. This surveillance activity is conducted in clinical settings, particularly in ANCs.

Essential procedures

1. Unlinked anonymous testing without informed consent must only use left-over blood/fluids from routinely collected specimens.

   - Left-over blood/fluid - blood/fluid remaining after completion of a routine test/procedure for which the blood/fluid was collected. An additional tube of blood or extra fluid cannot be collected solely for the purpose of HIV testing for surveillance without consent.

   - Routine blood draw - blood draw for routine health care, not surveillance. Routine blood draws are those that are recommended by the Ministry of Health (MOH) or other health care service provider as part of defined health care programs. Examples of routine blood draws include:
     - Syphilis testing
     - Haemoglobin measurement in ANCs

   Routine health care programs must not be created exclusively to “provide” left-over blood for surveillance. No additional blood specimens can be collected to assure specimen availability for surveillance.

   - Ongoing specimen collection - programs for which the specimens are collected are continuous and ongoing, occurring independently of surveillance activities, and not just during the surveillance sampling period.
Essential procedures, continued

2. Data resulting from surveillance using UAT methods must be irreversibly unlinked and rendered anonymous prior to HIV testing.
   - Anonymous means that the specimen is labeled with a code other than the subject’s name or medical record number.
   - Unlinked means that the bond between personal identifiers (such as name, ANC medical chart number) and specimen is irreversibly removed before HIV testing.
   - When a sample is collected using unlinked and anonymous methods it is impossible for the test result to be traced back to an individual.

3. Rapid HIV testing for UAT surveillance should not be conducted at the point and time of service provision.
   - HIV testing for UAT should guarantee client anonymity. To avoid the possible identification of a specific woman, rapid HIV testing for UAT surveillance should not be conducted at the point and time of service provision (at the ANC site or clinic when the woman is still in the clinic).
   - In situations where rapid HIV testing is conducted at an ANC site, make the following provisions:
     - Use left over blood (see #1 above)
     - Make samples unlinked and anonymous before any HIV testing (see #2 above)
     - Use different staff for:
       - Collecting samples and demographics data
       - Performing HIV rapid testing.
     - Store samples for batch testing rather than conducting in real-time to avoid linkage back to ANC name-based logs.
Essential procedures, continued

4. Data collection for UAT surveillance should be limited to that which is routinely collected as part of clinical services.
   - Administration of a questionnaire to the client who has not provided consent, specifically to collect additional information for surveillance, is not following the ethical principals of UAT. Therefore, all data collected for the sero-survey should be information routinely collected at the site, such as during the registration process. Do not collect information on risk of infection or sexual behaviors if these data are not routinely collected as part of a routine clinic visit (that is, do not ask/add questions to the clinical service process for the singular purpose of enriching surveillance data).
   - In sero-surveys that use UAT, sociodemographic data collected for each pregnant woman, for example, must not be so comprehensive that they facilitate identification of a specific woman. Therefore, it is suggested that a minimum of sociodemographic information be collected during sero-surveys using UAT.

5. Voluntary counseling and testing (VCT) should be available and accessible to patients from sites where UAT surveillance is being conducted.
   - Surveillance and prevention activities have different objectives: surveillance aims to measure the level of an HIV epidemic and to monitor trends, while prevention activities aim to provide services to prevent and to treat HIV. Inadequate prevention, treatment, and support services in many countries are often a result of limited human and financial resources and inadequate infrastructure. These services are important and should be offered, but generally not through surveillance activities given that the objectives of the two programs (VCT and surveillance) are different. However, the programs responsible for surveillance should, in general, work toward making VCT services available.
   - Clients should be informed of all available VCT services.
Essential procedures, continued

- In some countries surveillance activities may be in early stages and VCT services may not already be available when the surveillance site is selected. In fact, data from surveillance activities may be required to indicate the need for and to advocate effectively for establishing this service. The plan to use these data to advocate or plan for VCT services should be mentioned in the protocol.

- Accessibility to VCT should be defined by the country MOH and described in the protocol.

6. Data generated through UAT-based HIV sentinel sero-surveys should be used for program planning and evaluation, and advocacy purposes.

- In addition to plans for creating estimates and projections for HIV, data from UAT sentinel sero-surveys should have been used previously or there should be documentation on how these data have or will be used for program planning, evaluation, and advocacy. Potential uses of these data include:
  
  o Targeting prevention programs
  o Deciding how to distribute resources within countries
  o Evaluating the national collective success of prevention programs
  o Evaluating the coverage of *prevention of mother–to-child transmission* (PMTCT) programs
  o Advocacy to obtain additional resources
  o Determining the type and scope of the epidemic, and monitoring trends.

- Merely conducting surveys year after year but not using UAT surveillance data should be discouraged.
Unlinked Anonymous Testing with Informed Consent

Unlinked anonymous testing with informed consent, also known as voluntary anonymous testing, is the second most common method used to do HIV surveillance in clinical settings. Countries that wish to collect additional data or do not have leftover blood to do UAT without informed consent can use this option. This method can also be used outside clinical settings.

Essential procedures

1. The procedures for conducting UAT with informed consent are the same as those for UAT without informed consent, except:

   - Blood/fluids collected for non-routine purposes may be used (see #1 above)
   - Data collected does not need to be limited to that which is routinely collected as part of clinical services (see #4 above).

2. The consent must explain the purpose of the survey and the fact that HIV test results will not be returned.

   - Seriously consider whether it is feasible to return HIV test results. If this is not deemed feasible, please explain in the protocol.
   - If verbal consent is obtained, a script of the consent should be included in the protocol.

3. The anonymising procedure methods must be irreversibly unlinked and rendered anonymous prior to HIV testing (see #2 above), with additional provisions to assure anonymity despite face-to-face contact between the client and the surveillance staff.

   - Because there will be direct contact with participants, how anonymity will be maintained must be fully explained. Signed consent forms should not be stored with questionnaires and consideration should be given to obtaining verbal consent. Handling of specimens and questionnaires by surveillance staff in the field should be standardized and fully explained.

   - All procedures for assuring anonymity will be reviewed carefully to determine if a request for exemption for HIV test notification is needed. If at any time the patient identifying information possibly could be linked to HIV test results or if the amount and nature of data collected could result in identification of an individual, a request for exemption for HIV test notification will need to be initiated as per US Department of Health and Human Services policy.
Annex 4.3. Unlinked Anonymous HIV Surveillance Data Collection Form

Ministry of Health
HIV Surveillance Data Collection Form for Antenatal Clinics

Site: __________________________  Site Number: ___________________________

PATIENT INFORMATION:

| Patient ID number or code: ______________________ |
| Date of patient visit (dd/mm/yy): ____/____  Age (in years): ________ |
| Residence: □ Less than 5 km from clinic  □ 5 or more km from the clinic |
| Highest Level of school attended:  □ None  □ Primary  □ Secondary  □ Higher |
| Marital Status: □ Married  □ Single, never married  □ Divorced/Separated  □ Widowed |
| Primary Occupation of Client: (optional) |
| □ Business  □ Domestic Help  □ Police/military  □ Laborer |
| □ Security Guard  □ Professional  □ Student  □ Farmer |
| □ Housewife  □ Not employed  □ Commercial Sex Worker  □ Other |
| Total number of pregnancies, including this pregnancy: ______ |
| Total number of live births: ______ |

TEST RESULT INFORMATION

<table>
<thead>
<tr>
<th>HIV Test</th>
<th>Date (dd/mm/yy): <strong><strong>/</strong></strong>/____</th>
<th>□ Positive</th>
<th>□ Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>Date (dd/mm/yy): <strong><strong>/</strong></strong>/____</td>
<td>□ Positive</td>
<td>□ Negative</td>
</tr>
<tr>
<td>TPHA</td>
<td>Date (dd/mm/yy): <strong><strong>/</strong></strong>/____</td>
<td>□ Positive</td>
<td>□ Negative</td>
</tr>
</tbody>
</table>

Name of person filling out form: ______________________________
Unit 5
Choosing an HIV Test

Overview

What this unit is about

This unit describes different options for HIV testing and provides the rationale for each.

Warm up questions

1. Which of the following factors are involved in the decision to select an HIV testing strategy?
   
a. Sensitivity and specificity of test being used
   b. Objectivity of the test
   c. HIV prevalence in the population being tested
   d. All of the above

2. Match each phase of the HIV testing process with the components it includes:

   ____ Pre-analytical   a. Interpreting results, entering data into tracking system, reviewing quality control

   ____ Analytical       b. Training, laboratory safety, selection of test kits

   ____ Post-analytical  c. Specimen processing and storage, analysis of testing performance, reagent preparation

3. The process by which reference specimens are tested externally to ensure accuracy of a technician’s or laboratory’s performance is known as:

   a. Internal quality assurance
   b. External quality assurance
   c. Quality performance
   d. None of the above.
Introduction

What you will learn

By the end of this unit you should be able to:

- Describe the advantages and disadvantages of different HIV testing options
- Describe how to choose a strategy for HIV testing
- Understand the difference between sensitivity and specificity of a laboratory test
- Identify the phases of the testing process, and what quality control and quality assurance programmes should be implemented in each phase.

Selecting an HIV Antibody Test

There has been much development in HIV diagnostic technology since the first HIV antibody tests became commercially available in 1985. Currently, a wide range of different HIV antibody tests is available. Most are enzyme immunoassay (EIA, formerly known as enzyme-linked immunosorbent assay [ELISA]) tests and can be performed either as conventional tests in the laboratory or as rapid tests.

Conventional EIAs

For many years, HIV testing was done using two different types of antibody tests to determine if someone was infected with HIV. The testing algorithm consisted of two separate tests done on the same small sample of blood:

- An initial EIA
- If the EIA was positive, a confirmatory test (a Western Blot assay [WB] or indirect immunofluorescence assay [IFA], which use different technologies to measure the presence of antibodies to HIV).

The World Health Organization (WHO) has subsequently designed three different strategies for HIV testing that use only EIA tests. These strategies are discussed later in this unit (Table 5.4).

Conventional EIAs are quantitative tests. That is, they measure the concentration of HIV antibodies in a specimen. Some EIAs can measure antibodies to both HIV-1 and HIV-2, which is an important consideration in countries where both strains are present. These tests usually require a properly trained laboratory technician and specific laboratory equipment. They use chemicals that combine with HIV antibodies and cause colour changes, as follows (next page):
Conventional EIAs, continued

- The more HIV antibody that is present, the darker the colour will be.
- The colour change is read by a machine that reports the intensity of the colour as *optical density*.
- Test kit manufacturers establish a certain optical density above which specimens are positive and below which specimens are negative.
- Depending on the testing strategy used, either a single positive specimen or a series of positive specimens will be reported as positive to the surveillance system or clinician.

Rapid tests

Rapid tests are a type of EIA that produces results in 10 to 30 minutes. They are simpler to use than conventional EIAs and can be done either in laboratories or in the field. They are qualitative tests that also use EIA methods to determine if a specimen is positive or negative. Unlike conventional EIAs, no optical density readings are reported for rapid tests. Instead, there is a predetermined optical density built into the test kit above which a colour change will occur, indicating a positive result. In countries with limited laboratory infrastructure, the use of HIV rapid testing algorithms has been more feasible and as effective as conventional EIAs done in laboratories.

Advantages of rapid test

The major advantage of rapid tests is that results are available quickly—usually within 10-30 minutes. They also are simpler to perform. Rapid tests require less laboratory equipment and less skilled staff than conventional EIAs. Rapid test kits do not need to be refrigerated. Also, they can be used for testing small quantities of blood, such as from fingersticks.

The characteristics of EIAs and HIV rapid tests are compared in Table 5.1 on the next page.
Advantages of rapid test, continued

Table 5.1. Comparing EIAs and HIV rapid tests

<table>
<thead>
<tr>
<th></th>
<th>EIAs</th>
<th>Rapid Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time to result</strong></td>
<td>&gt;60 minutes</td>
<td>10-30 minutes</td>
</tr>
<tr>
<td><strong>Testing volume</strong></td>
<td>Suitable for large volume and batch testing</td>
<td>Suitable for small and large volumes</td>
</tr>
<tr>
<td><strong>Staff requirements</strong></td>
<td>Skilled technical staff required</td>
<td>Less skill required</td>
</tr>
<tr>
<td><strong>Equipment requirements</strong></td>
<td>Requires complex equipment, maintenance</td>
<td>None to minimal equipment</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>Test kits require refrigeration</td>
<td>Most test kits stored at room temperature</td>
</tr>
</tbody>
</table>


Discussing the table

Look at Table 5.1, then answer the following questions:

a. Which test requires less laboratory equipment and is easier to perform?

b. Where refrigeration is not available, which test would be more appropriate?

Oral and urine tests

More recently developed EIAs look for antibodies in oral fluid or urine. In general, oral tests are more sensitive than urine tests, and urine tests are rarely used. Oral tests are not suitable for UAT because they cannot be performed on specimens left over from other testing or stored.

Whichever test is chosen, it is essential that the results given to individuals be reliable. Additionally, in HIV surveillance, it is important to carefully consider the step-by-step procedure, the laboratory-testing algorithm, which will most accurately detect HIV infections in a population.
Selecting an HIV Testing Algorithm

The selection of the HIV antibody tests and testing algorithms to be used is a responsibility of national governments and is generally performed by health ministries and national AIDS control programmes.

UNAIDS and WHO recommend three criteria for choosing an HIV testing algorithm or strategy (that is, selecting the appropriate HIV testing technologies and combination of tests):

- Objectivity of the test (surveillance, blood screening or diagnosis)
- Sensitivity and specificity of the test(s) being used
- HIV prevalence in the population being tested.

After these three criteria are defined, an HIV testing strategy can be selected to maximise sensitivity and specificity while minimising cost.

Reliability and accuracy of tests

Different algorithms have certain limitations on how well they can detect all persons who have a disease and, conversely, how well they can detect all persons who do not have a disease. These are described below, and shown in Table 5.2 on the next page.

- Test results can be true positives if they are positive and a patient truly has the disease the test is testing for.
- They can be false positives if a person who does not have the disease tests positive for it.
- They can be true negatives if a person who does not have the disease tests negative.
- Finally they can be false negatives if a person who truly has the disease tests negative.
Reliability and accuracy of tests, continued

Table 5.2. True positives, false positives, true negatives, false negatives.

<table>
<thead>
<tr>
<th></th>
<th>Patient has the disease</th>
<th>Patient does not have the disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive test result</strong></td>
<td>True positive</td>
<td>False positive</td>
</tr>
<tr>
<td><strong>Negative test result</strong></td>
<td>False negative</td>
<td>True negative</td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 5.2, answer the following questions:

a. If a patient has a disease, but the test result for the disease is negative, what is this result known as?

b. Can you think of some problems that might be associated with a false negative? A false positive?

Sensitivity and specificity

Two terms, sensitivity and specificity, are used to quantify how well a test performs.

- Sensitivity refers to the ability of a test to detect all persons with a disease. It is the proportion of those who are positive by the test, divided by all persons who truly have the disease. See Table 5.3 on the next page. In the table it is $a/(a+c)$.

- Specificity refers to a test’s ability to detect all persons who do not have a disease. It is the proportion of persons who test negative, divided by all persons who truly do not have the disease. See Table 5.3. In the table it is $d/(b+d)$. 
Positive and negative predictive values

There are two other ways to convey how well a test performs. These are **positive predictive value** (sometimes called predictive value positive) and **negative predictive value** (sometimes called predictive value negative). They are expressed in terms of what proportion of positive (or negative) tests identify people who truly have (or do not have) a disease. In Table 5.3, positive predictive value is \( \frac{a}{a+b} \) and negative predictive value is \( \frac{d}{c+d} \).

In general, the more frequent a disease is in a population, the higher the positive predictive value of a test will be. Thus, positive predictive value of an HIV test will be higher in higher prevalence areas. It will also be higher in populations more likely to be infected, such as patients with AIDS.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Present</th>
<th>Absent</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>A</td>
<td>b</td>
<td>a+b</td>
</tr>
<tr>
<td>Negative</td>
<td>c</td>
<td>d</td>
<td>c+d</td>
</tr>
<tr>
<td>Total</td>
<td>a+c</td>
<td>b+d</td>
<td>a+b+c+d</td>
</tr>
</tbody>
</table>

**Table 5.3. A guide for calculating sensitivity and specificity.**

**Discussing the table**

Looking at Table 5.3, answer the following questions:

a. Label each cell (a, b, c and d) as true or false positive or negative.

b. Describe test sensitivity both in words and in mathematical symbols.

c. Describe test specificity both in words and in mathematical symbols.

d. Describe positive predictive value both in words and mathematical symbols.

An ideal test will have high sensitivity, specificity, positive predictive value and negative predictive value.
HIV Sero-surveillance

How HIV prevalence affects test selection

The determinants of predictive values are the specificity and sensitivity of the test and the prevalence of HIV in the population concerned. Even with a very accurate test (high sensitivity and high specificity), the positive predictive value of a test may not be sufficiently high in settings with a low HIV prevalence.

In general, the higher the prevalence of HIV infection in the population, the greater is the probability that a person testing positive is truly infected. Conversely, the probability that a person with a negative test result is uninfected declines slightly as HIV prevalence increases. It is necessary to conduct a second or supplemental test if the first test is reactive, as this markedly increases the positive predictive value.

In settings with a low-level HIV epidemic, tests with a sensitivity or specificity greater than 99% should be used to achieve satisfactory positive predictive values.

Studies have shown that the sensitivity and specificity of rapid tests are similar to those of the conventional EIAs.

HIV testing algorithm for surveillance

The WHO/UNAIDS HIV surveillance working group has recommended that the testing strategy of serial testing with two tests, as depicted in Figure 5.1 on the following page, be used irrespective of HIV prevalence. This replaces the previous options of strategies according to prevalence.

The strategy states:

- A two-test strategy is recommended **irrespective of HIV prevalence**.
- Rapid tests, automated EIAs and combinations are appropriate for the two-test strategy.
- The Western blot assay is not recommended for surveillance testing.
- Test 1 should be more sensitive and test 2 should be more specific.
HIV Sero-surveillance

**HIV testing algorithm for surveillance, continued**

Figure 5.1. Strategy for HIV testing for surveillance.

FIRST TEST (A1)

A1+  A1-

SECOND TEST (A2)

A1+A2+  A1+A2-
Positive  Negative

Testing for HIV-1 versus HIV-2

We can assume that *HIV-2* (one of the sub-types of HIV that is primarily located in West Africa) can be found in all sub-Saharan African countries. Therefore, the HIV test performed must be able to detect the presence of both *HIV-1* and *HIV-2*. Most rapid tests and EIAs detect both *HIV-1* and *HIV-2* but do not differentiate between them.

It is sometimes important for surveillance efforts to differentiate between *HIV-1* and *HIV-2* infections to determine how the infection is spreading in the country. For instance, if a country has a new introduction of *HIV-2* from a neighbouring country, surveillance officers can follow its distribution in the population over the next few years. A laboratory test is available that differentiates between *HIV-1* and *HIV-2*. This test should be performed in referral laboratories.

**Ensuring Quality in the Laboratory**

To ensure the reliability of test results, a laboratory needs to have quality control and quality assurance systems in place and carefully follow its procedures.
Quality control

*Quality control* (QC) assesses a laboratory’s machinery to check that the HIV test results obtained from a specimen are correct. For QC of the laboratory equipment, positive and negative controls must be run on the machines from time to time to verify that the test device is accurately detecting HIV antibodies. The test kit manufacturer or a reference laboratory can provide these controls.

- **Positive controls** are specimens known to be positive.
- **Negative controls** are specimens known to be negative.

By running these specimens, laboratories can test their procedures and reagents to see if there are any problems. They should get the correct results 100% of the time.

Quality assurance

*Quality assurance* (QA) assesses a laboratory’s processes for obtaining tests results comparing the results for a specific specimen with other tests conducted on the same specimen. This can be done by one of the two following entities, described in more detail later in this unit:

- Laboratory itself (internal quality assurance)
- Outside reference laboratory (external quality assurance).

To conduct quality assurance of the entire HIV testing process, laboratories should routinely be monitored during the pre-analytical, analytical and post-analytical phases of the testing process.

- The pre-analytical phase includes activities that occur before a specimen is actually tested.
- The analytical phase occurs during the actual testing of the specimen.
- The post-analytical phase refers to activities done after a specimen has been tested.

QA and the phases of the testing process

There are a variety of components in each phase of the testing process that should be monitored by quality assurance programmes. These components are listed in Table 5.5 on the next page.
QA and the phases of the testing process, continued

Table 5.5. Components for review by quality assurance programmes in the pre-analytical, analytical and post-analytical phases of the testing process.

<table>
<thead>
<tr>
<th>Pre-Analytical Phase</th>
<th>Analytical Phase</th>
<th>Post-Analytical Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Training</td>
<td>▪ Specimen processing and storage</td>
<td>▪ Interpreting results</td>
</tr>
<tr>
<td>▪ Laboratory safety</td>
<td>▪ Written procedure manual</td>
<td>▪ Transcribing results, such as recording results on the correct identifier code</td>
</tr>
<tr>
<td>▪ Number of trained personnel available and capable of performing HIV testing</td>
<td>▪ Reagent preparation</td>
<td>▪ Entering data into the tracking system (computer or hard copy)</td>
</tr>
<tr>
<td>▪ Specimen collection, labelling and transport conditions</td>
<td>▪ Testing performance</td>
<td>▪ Maintaining records</td>
</tr>
<tr>
<td>▪ Deciding on handling of specimens before testing</td>
<td>▪ Performance and maintenance of equipment, such as spectrophotometers and washers</td>
<td>▪ Reviewing quality control</td>
</tr>
<tr>
<td>▪ Deciding on the sources and types of specimens to be tested</td>
<td>▪ Correct use of reagents</td>
<td></td>
</tr>
<tr>
<td>▪ Deciding on the number of specimens tested</td>
<td>▪ Inclusion of internal quality controls in the test kits</td>
<td></td>
</tr>
<tr>
<td>▪ Selection of test kits</td>
<td>▪ Quality control monitoring procedure.</td>
<td></td>
</tr>
<tr>
<td>▪ Expiration dates of test kits. Kits need to be used before expiration dates. Older kits should be used before newer kits.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ HIV test kit reagents. Reagents must be stored at the appropriate temperature as specified by the manufacturer. Certain reagents, such as conjugates for EIAs, may require refrigeration.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Discussing the table

Looking at Table 5.5 on the previous page, answer the following questions:

a. In which phase are results analysed and interpreted?

b. In which phase are specimens tested?

Internal quality assurance

Internal quality assurance is meant to allow laboratory technicians to check their performance for themselves. Below is an example of a procedure for internally testing quality, although it may not be appropriate for all sites:

- Set aside an aliquot of every twentieth negative and every fifth positive specimen and mark it with an identification number. The specimens are stored in a “deep” or non-frost-free freezer (-70°C).
- Once there are sufficient stored aliquots, the stored specimens are tested a second time.
- The laboratory technicians can then compare the initial results and the results of re-testing, to monitor the reliability of their techniques.

External quality assurance

Countries should require that all laboratories at all levels, including the national reference laboratory, HIV laboratories in hospitals, blood transfusion services and private HIV laboratories, participate in an external quality assurance programme to monitor and evaluate each laboratory’s performance.

External quality assurance programmes may be instituted either by a national or international reference laboratory. Reference laboratories function as a recognised centre of expertise and standardisation of diagnostic techniques. The steps to implementing an external quality assurance programme, such as a proficiency testing programme, are listed on the following page. Proficiency testing should be done once or twice each year.
External quality assurance, continued

1. The national reference laboratory sends all participating laboratories a *proficiency panel* of approximately six specimens to identify as HIV-positive or HIV-negative. Proficiency panels are a set of samples for which the test results are known by the reference laboratory. This panel should contain HIV-negative and HIV-positive samples (both weak and strong specimens) representative of the HIV strains circulating in a country, and from different stages of disease; for instance, from early HIV infection to late-stage AIDS.

2. The panels are tested at the local laboratories in much the same way as they routinely test their specimens for HIV.

3. The local laboratories report their findings to the reference laboratory.

4. The reference laboratory collates the results and provides feedback to each participating laboratory.

External quality assurance must be carried out for the national reference laboratory as well. This should be provided by an independent laboratory, such as the laboratory at a large university, or by one of WHO’s regional quality assurance programmes.

**QA with limited laboratory infrastructure**

In geographic areas with limited laboratory infrastructure, laboratories can prepare a dried blood spot on filter paper and send it to the national reference laboratory to be tested for quality assurance purposes.

**Summary**

HIV antibody tests can be performed using conventional EIAs in a laboratory or using rapid tests. You should take into consideration several factors when selecting a test for your region, including the epidemic state and the available resources. To ensure the accuracy and reliability of testing equipment, quality control and quality assurance programmes should be in place for each of the main testing phases.
Unit 5 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

Describe the quality assurance procedures that are put in place for HIV sentinel surveillance in your country and list some ways to improve quality assurance at the local and national levels.

Apply what you’ve learned/case study

Try this case study. We will discuss the answers in class.

You are the newly hired district surveillance officer for Inyo district in the Yolo Republic, and are charged with co-ordinating HIV sero-prevalence studies. You have been asked to help set up a new laboratory at an ANC in Tehama, a town near the border. Prevalence at other ANC sentinel surveillance sites in the district have run approximately 8% for the last three years. You choose a test that has a sensitivity of 0.9995 and a specificity of 0.995.

a. What is the positive predictive value of the test?

b. What testing algorithm would seem most appropriate for testing for HIV as part of the next HIV sentinel surveillance round at this new laboratory?

c. What are five steps that you would do to ensure quality of the laboratory before the first test was run?
HIV Sero-surveillance

Notes
Unit 6
Training and Supervision

Overview
What this unit is about

This unit outlines the responsibilities, training and supervision of personnel involved in HIV sentinel surveillance.

Warm up questions

1. Which staff members should be trained prior to conducting sero-surveys?
   a. Supervisors and managerial staff
   b. Laboratory staff
   c. Clinic staff
   d. All of the above

2. True or false? When planning for the supervision of testing facilities, the national surveillance organisers should hire an outside supervisor to staff each of the facilities where HIV testing occurs.
   True False

3. List three types of personnel necessary to conduct an HIV sero-survey.

4. The national surveillance supervisor should be responsible for supervision of:
   a. Specimen collection
   b. Data management
   c. Laboratory equipment
   d. Sampling
   e. All of the above.
**HIV Sero-surveillance**

**Introduction**

What you will learn

By the end of this unit you should be able to:

- Describe requirements for staffing, training and supervising of HIV sentinel surveillance programmes
- Identify potential sources of conflict when adding supervisory staff to existing programmes.

**Training**

Sentinel surveillance staffing

A variety of people are needed to conduct a *sero-survey*. These include clinic staff, laboratory technicians, supervisory staff, data managers or statisticians and survey co-ordinators. Responsibilities for each surveillance staff member, regardless of his or her position in the programme, should be clearly defined in the sero-survey protocol. Tables 6.1 through 6.3 outline appropriate responsibilities for sero-survey personnel at different levels.

Table 6.1. Responsibilities of sero-survey personnel at local (clinic) level.

<table>
<thead>
<tr>
<th>Level and Title</th>
<th>Appropriate Responsibilities</th>
</tr>
</thead>
</table>
| Clinic staff (nurse or laboratory technician) | ▪ Ensure that eligible individuals are included in the sero-survey  
▪ Draw blood specimens  
▪ Split specimens for standard syphilis testing and for HIV testing  
▪ Label and properly store specimens in preparation for transport to the testing laboratory  
▪ Fill in data collection forms  
▪ Transmit data collection forms to regional level  
▪ Train for other staff members’ duties in the case of absence |
| Supervisory staff (nursing supervisor or senior laboratory technician) | ▪ Ensure efficient operation of sero-survey  
▪ Supervise other surveillance staff  
▪ Provide adequate oversight, ensure confidentiality |
| Courier (as needed)                          | ▪ In some cases, someone from the Ministry of Health will be available to transport specimens to the testing laboratory. If not, the clinic laboratory technician may be required to do so, especially if specimens will be tested in the same town or city. |
Sentinel surveillance staffing, continued

<table>
<thead>
<tr>
<th>Level and Title</th>
<th>Appropriate Responsibilities</th>
</tr>
</thead>
</table>
| Laboratory technician   | • Order equipment, supplies, and test kits  
                          • Conduct HIV testing  
                          • Report results to data entry clerk  
                          • Participate in quality control and quality assurance programmes |
| Data entry clerk        | • Examine data for missing values and try to resolve these by communicating with clinic  
                          • Combine data from data collection forms and Laboratory results into single data set |
| Survey co-ordinator     | • Ensure provision of equipment, supplies, and test kits  
                          • Ensure adequate oversight and confidentiality at the regional level  
                          • Provide training for local level and regional staff  
                          • Disseminate survey findings |

*This table describes a system where laboratory testing and data entry occur at the regional level. These activities can also occur at the local level.*

Table 6.3. Responsibilities of sero-survey personnel at national level.

<table>
<thead>
<tr>
<th>Level and Title</th>
<th>Appropriate Responsibilities</th>
</tr>
</thead>
</table>
| Laboratory technician   | • Ensure provision of equipment, supplies, and test kits to regional laboratories  
                          • Conduct HIV tests as needed, for example, for difficult or borderline specimens  
                          • Oversee quality assurance of testing procedures at regional and local levels |
| Data manager/statistician| • Enter data in the program’s computerised database if this is not done at the regional level  
                          • Examine data for missing values  
                          • Manage data  
                          • Analyse data |
| Surveillance co-ordinator| • Develop sero-survey protocol with help from programme staff  
                          • Ensure adequate funding  
                          • Provide adequate oversight and training at the regional and national levels  
                          • Ensure confidentiality  
                          • Interpret findings in conjunction with regional level survey co-ordinators and prepare survey reports and national reports |
Discussing the tables

Looking at Tables 6.1, 6.2 and 6.3, answer the following questions:

a. At which level(s) should testing procedures be subject to confidentiality measures?

b. At which level(s) are the HIV tests conducted in this system? Could they be conducted at another level? If so, where?

Writing a survey protocol

A key to a successful sero-survey is a clear, comprehensive survey protocol. The survey co-ordinator is responsible for preparing the survey protocol with help from programme staff.

- The protocol should describe all the steps and tasks involved in a sero-survey.
- The protocol should be detailed enough that it can be read and used at the local, regional and national levels, if questions arise about each person’s responsibilities.
- It can also serve as a guide to training needs, and can be used for training survey personnel.

Identifying training needs

Skilled and knowledgeable personnel are essential for a successful surveillance system. It is necessary to assess training needs while planning surveillance activities. The survey co-ordinator should identify the training needs of staff in the survey protocol. The survey protocol should be explicit about training needs.

- It should specify what types of personnel will need to be trained.
- It should specify where training will occur.
- It should specify who will be responsible for doing the training.

Assessing training needs should start with a comprehensive job description of all the activities to be carried out, the skills required to perform each task and the risks associated with improper performance of the tasks. The survey co-ordinator should then compare the job description with the staff assigned to each duty and identify the gaps in knowledge where trainings are needed.
Conducting training

All personnel involved in a sero-survey must be trained. After appropriate individuals are identified and selected at the local, regional and national levels to conduct the sero-survey, the national surveillance staff should conduct training before every sero-survey. It is important to identify all participants who should attend the training. These will include supervisors, laboratory staff and clinic staff. Vigorous attempts should be made to enable them to attend the training.

The following should be included in all trainings:

- A review of the survey protocol, operational procedures and the field protocol
- Results from previous sero-surveys conducted at the site or in the region
- An opportunity for participants to discuss their concerns and ask for any clarification of sero-survey operations.

Training sessions may be conducted either at the clinic site or in a central location at the regional or national level. Sessions that involve staff from multiple sites offer the opportunity to share experiences and can bring down the costs of conducting the training.

Maintaining motivation

It is important for personnel to understand the necessity and importance of conducting these surveys. Maintaining motivation among sero-survey personnel will make it easier to conduct high-quality, timely sero-surveillance activities. Examples of ways to maintain staff motivation include:

- Developing a sense of sero-survey “ownership.” This might include:
  - Discussing the importance of these surveys
  - Showing results from previous surveys and how they can be used.
- Defining clearly responsibilities and roles for all staff involved – at all levels
- Emphasising the importance of each person’s contribution to the sero-survey’s success
- Providing adequate staff training
- Ensuring that the needed equipment and forms are available before the survey starts
- Assigning data management and analysis responsibilities to regional co-ordinators
- Providing adequate monetary compensation.
Supervision

Supervision is an important part of quality assurance for sero-surveys. At the national level, there must always be a person responsible for ensuring that all the required activities take place and that surveillance is conducted uniformly in all sites. Annex 6.1 includes a checklist for quality assurance of surveillance activities.

The supervisor should monitor all aspects of sentinel surveillance, including:

- Sampling
- Data and specimen collection and management
- Laboratory equipment.

As it is impossible for this person to be present to supervise at all facilities, he or she may delegate to other supervisors, who may then delegate to a supervisor at the facility level. The levels of supervision should be kept to a minimum. At all levels, supervisors should be sensitive about their role in HIV surveillance.

When supervisory activities are planned, it is helpful to make use of the existing management structure at the facility level. As part of this, it is prudent to give the supervisory role to the regular facility supervisors. This will minimise conflicts with the facility administrators, offer more ownership in the process and encourage effective management of the surveillance activities.

A checklist for quality assurance of surveillance activities can be found in Annex 6.1.

Summary

To ensure that the surveillance process is smooth and effective, be sure that all staff undergo the necessary training. Also, use existing management structures when you assign supervisory roles, to avoid conflict and inefficiencies.
Unit 6 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. Your health facility has been selected as a sentinel site for HIV surveillance and needs to recruit a surveillance staff person. Discuss the activities, skills and duties that should be included in a comprehensive job description for the surveillance activities that will be taking place. What type of training will be necessary?

2. In a national HIV surveillance programme, where the chosen sentinel sites are at the health-centre level, a national co-ordinator often supervises regional or provincial co-ordinators, who in turn supervise district surveillance officers. This chain of supervision goes down to the health-centre level. What are the advantages of following this existing national structure, and what would be the advantages of decreasing the number of supervisory levels?
Try this case study individually.

As part of your duties as the Inyo District HIV surveillance officer, you are charged with assisting central Ministry of Health staff in training personnel for a new ANC sentinel surveillance site. You have been asked to invite appropriate people to the training.

a. Identify the types of participants you plan to invite.

b. What elements of sentinel surveillance do you think need to be covered in this training?

c. A staff member asks a question about the difference between linked and unlinked testing and why unlinked testing is being done at the clinic. How do you respond?

d. You receive a report that an individual patient’s results were released inadvertently to clinic staff. You view this as a serious breach in study procedures. How would you investigate this, and what would you do?

e. At the end of the surveillance cycle, you discover that the clinic did not report any data for the last month of the survey period. How do you address this problem?
Notes
### Appendix 6.1. Checklist for Quality Assurance of Surveillance Activities

Supervisory surveillance staff may use the following checklist as they monitor the quality of operational activities conducted at the sentinel site during supervisory visits.

| Site name: _____________________ | Site number: _____________________ |
| Supervisor name: _____________________ | Date (dd/mm/yy): _____________________ |

#### SAMPLING

| Total no. women visiting ANC since surveillance start: _____________________ |
| Total no. women sampled since surveillance start: _____________________ |
| No. of women sampled on last ANC day: _____________________ |
| Sampling consecutive? ( )Yes ( )No: _____________________ |
| ANC staff ( )Yes ( )No: ___ | Lab tech ( )Yes ( )No: ____________ |
| No. data forms: ________ | No. blood samples: ________ |
| No. data forms without ID#: ________ | No. blood samples without ID#: ________ |

**Comments:**

#### EQUIPMENT

| Cryovials stored in fridge: ( )Yes ( )No: _____________________ |
| Fridge temperature: ________ |
| Fridge working uninterrupted since last visit? ( )Yes ( )No: ____________ |
| Centrifuge working? ( )Yes ( )No: ____________ |

**Comments:**

#### SAMPLE and DATA FORM TRANSPORT: ( )Yes ________________

| No. data forms taken: ________ | ID# range taken: ____________ |
| No. samples taken: ________ | ID# range taken: ____________ |

**Site staff name: _____________________ | Signature: _____________________**

**COMMENTS:**
Unit 7
Data Management, Analysis and Interpretation

Overview

What this unit is about

This unit describes the process of data collection, including proper procedures for forms and data entry. It also explains the overall idea of data analysis and interpretation.

Warm up questions

1. ________________ is the process of entering paper records into a computerised database.

2. True or false? The best way to summarise sentinel surveillance data is by calculating a single prevalence figure for the whole survey.

   True       False

3. True or false? Data dictionaries (electronic files that describe the basic organization of a project or database) should be developed at the local clinic level.

   True       False
Introduction

What you will learn

By the end of this unit you should be able to:

- Describe the process for sero-survey data entry
- List the variables for analysing sentinel surveillance data.

Data Entry and Management

Following demographic data collection and laboratory testing for HIV, results are brought to a site for data entry. This site can be at the clinic level, at the regional level or at the national level. At the clinic and regional levels, merging the results from HIV tests and the demographic and medical history data on the data collection forms is most often done by hand. Ideally, computers would be used to merge these results, but often computers are available only at the national level.

This unit starts with a brief discussion of steps to take when entering serosurveillance data into a computer, and then continues on to discuss analysis and interpretation of the data.

Databases

Data entry is the process of entering paper records, which in this case are the merged demographic data collection forms and HIV test results, into a computer database.

- Databases store the variables, such as age group, clinic site and district, for each patient in the survey sample.
- Data can be stored either as numbers or as text. Most variables will be converted into numbers. For instance, an HIV test result can be coded as “1” for positive, ”2” for negative or ”9” for missing value.
- Databases and data entry screens are set up centrally by information technology staff at the national level. Data entry screens are the forms on the computer screen into which a data entry clerk enters the data. They are the primary mechanism for inputting data from paper forms into the computer. An example of one for ANC sero-surveys is shown below.
**Databases, continued**

Figure 7.1. Sample data entry screen.

<table>
<thead>
<tr>
<th>Record Identifiers</th>
<th>Demographic History</th>
<th>Laboratory Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Name*</td>
<td>Residence</td>
<td>HIV Test Result</td>
</tr>
<tr>
<td>District</td>
<td>Highest School Level</td>
<td>HIV Test Date</td>
</tr>
<tr>
<td>Region</td>
<td>Marital Status</td>
<td>RPR Test Date</td>
</tr>
<tr>
<td>Survey ID*</td>
<td>Occupation</td>
<td>TPMA Test Date</td>
</tr>
<tr>
<td></td>
<td>Total Pregnancies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Live Births</td>
<td></td>
</tr>
</tbody>
</table>

### Discussing the table

Looking at Figure 7.1, answer the following questions:

a. Does the data entry screen above include spaces for all of the demographic variables that are collected during HIV surveillance in your district?

b. In the data entry screen above, which are the required fields (that is, what information must be entered)?

### Data dictionary

A *data dictionary* should also be developed centrally. Data dictionaries are electronic files that describe the basic organization of a project or database. They contain all of the rules that guide data entry.
The steps for data entry are as follows:

1. Enter data either as numbers or text, depending on the variable, for each patient on a data entry screen. Data entry screens are designed so that you can enter all the variables for one patient at one time. See the example in Figure 7.1, above. When you finish entering the data for one patient, the computer saves the data in a database. The next person’s record then appears on the screen. Data entry should be a continuous process, to avoid backlogs of forms to be entered, and the consequent increase in errors. Only persons trained in computer data entry should carry out this function.

2. Re-enter the data. Ideally, all data are double-entered, meaning they are entered two times in order to catch mistakes that may have been made.

3. Check data for errors either automatically or manually. Table 7.1 below describes each of these two options.

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic</td>
<td>The computer programme that runs the data entry screen and the database also contains rules on what values can be entered for each variable. This involves built-in check programmes (the “Check Code” function in <em>Epi Info</em>™, freely distributed epidemiological software) that checks for impossible values as the data are entered. For instance, if “1” is the code for a positive HIV test, “2” for a negative test and “9” for a missing value, the computer will recognise a value of “7” as impossible, and will not allow it to be entered.</td>
</tr>
<tr>
<td>Manual</td>
<td>This method involves checking for errors after data entry. A data entry clerk will display the values for a single variable for all patients, and see if there are patterns that suggest problems with data recording or entry. Also, data can be displayed for each clinic site. For instance, one clinic may not have reported any results for one month. Another clinic may have reported everyone as being HIV-positive.</td>
</tr>
</tbody>
</table>
Discussing the table

Looking at Table 7.1 on the previous page, answer the following questions:

a. In an automatic data checking portion of a computer program, what is an ‘impossible value’?

b. Can you think of some data entry problems that you might look for during manual data checking?

Analysis and interpretation

According to the principles of second-generation HIV surveillance, data on HIV prevalence are only one component of a complete system. Data from sentinel surveillance should be analysed and interpreted in conjunction with other data. These data may include, for example, sexually transmitted infection (STI) prevalence (which may be available from sentinel sites themselves), behavioural data, and case surveillance data.

The process of analysing and interpreting sentinel surveillance data is guided by the following questions:

- Is the prevalence of HIV increasing, decreasing or remaining essentially stable?
- What is the trend in HIV prevalence among 15- to 24-year-olds?
- Which sentinel sites have the highest HIV prevalence? Which groups have the highest HIV prevalence? In which groups is HIV prevalence rising? Falling?
- What are the differences between sites where the prevalence of HIV infection is low (for example, <1%) and those where it is relatively high (for example, >5%)?
- What are the differences between sites where the prevalence of HIV infection is increasing and those where there is a decrease or no change?
Examine trends

Analysis of HIV sentinel surveillance data should focus on the prevalence of HIV by person, place and time. Changes in HIV prevalence by time are of greatest importance. Due to selection biases, sentinel surveillance data may over- or under-estimate the true prevalence of HIV in a population. If methods for conducting sentinel surveillance are consistent from year to year, changes over time may reflect real changes in prevalence.

Trends in time indicate whether the prevalence is rising, falling or remaining stable. A focus on the trend, rather than absolute prevalence, is a principle of second-generation HIV surveillance.

Trends in HIV prevalence among young persons aged 15 to 24 years merit special attention. Because young women have likely not been sexually active for many years, their HIV infections were probably acquired recently. Therefore trends in HIV prevalence in this age group are most likely to reflect trends in HIV incidence.

Analysis by variables

In addition to analysis by age group, sentinel surveillance data should be analysed by each of the variables collected. Such analysis may indicate where HIV transmission is highest. Analyses should therefore include HIV prevalence by:

- Year of survey
- Sentinel site, district, province and region
- Age group
- Female and male, if other than ANC
- Residence, such as rural versus urban
- Marital status
- Other demographic variables if collected, such as education or occupation
- Risk behaviour if collected, such as number of partners or condom use
- Presence of STIs.
Analysis by variables, continued

Ideally, data should be analysed separately for each site according to the following guidelines:

- Results should be summarised for the entire survey sample at each site, and for each sub-group for which information on age and sex has been collected.
- It is not a good practice to summarise sentinel surveillance data by calculating a single prevalence figure for the whole survey.
- Because the sample represents only the clinics in the survey, the overall prevalence does not reflect the true prevalence among all women in the country or region.
- Summary information that can, at best, be presented is the median and range for each type of sentinel site, on a regional and national basis.

Summary

Data entry is the process of entering paper records from surveillance into a computer database. Be sure to have procedures in place that prevent errors in the data entry process. You can then analyse and interpret that data, using variables such as the following:

- Sentinel site, district, province and region
- Age
- Sex
- Marital status.
Unit 7 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. What variables are used in the analysis of HIV sentinel data in your country, region or province?

2. Answer the following questions about your district or province
   a. What were the highest and lowest prevalence levels during the last HIV sentinel surveillance period in your district or province?
   b. What are the sites with these rates?
   c. Are the rates increasing or decreasing at these sites?

3. Do you analyse the data by age group? Why?
Try this case study individually.

You are the newly hired district surveillance officer for Inyo district in the Yolo Republic and are charged with co-ordinating HIV sero-prevalence studies. Unlinked, anonymous annual HIV sero-prevalence studies have been conducted in all five ANCs in this district for the past seven years. You decide to examine the trends in HIV prevalence at the ANCs to assess the status of the HIV epidemic in your district. Since you have included all the ANCs in the district in your survey, it is appropriate to calculate single prevalence values for the district.

<table>
<thead>
<tr>
<th>Number of HIV tests done</th>
<th>1997</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of HIV tests done</td>
<td>400</td>
<td>450</td>
<td>500</td>
<td>475</td>
<td>425</td>
<td>486</td>
<td>499</td>
</tr>
<tr>
<td>Number of HIV+ tests</td>
<td>76</td>
<td>81</td>
<td>90</td>
<td>71</td>
<td>60</td>
<td>54</td>
<td>55</td>
</tr>
</tbody>
</table>

Use these data to calculate the annual HIV prevalence, and develop a figure or graph that you think would explain the trends.

a. What do you observe in sero-prevalence trends, and what might these trends mean?

b. What additional information would be helpful in understanding these trends?

c. Are there additional ways to examine these data to assess the epidemic?
Notes
Unit 8
Uses and Dissemination of HIV Sentinel Sero-surveillance Data

Overview

What this unit is about
This unit describes the uses of HIV sentinel sero-surveillance data for public health action, and how to disseminate them most effectively.

Warm up questions

1. True or false? Reading or hearing about HIV in the media strengthens basic information and prevention messages.

   True   False

2. List two potential audiences for surveillance data.

3. List three potential uses of HIV surveillance data.

4. True or false? When disseminating HIV surveillance results, a single message that can be used for all target audiences is the best way to transmit the information.

   True   False
HIV Sero-surveillance

Introduction

What you will learn

By the end of this unit you should be able to:

- Discuss various uses for HIV sentinel sero-surveillance data
- Discuss how to develop a clear and understandable message about surveillance data
- Understand the tools for disseminating data to target groups.

Uses of HIV Surveillance Data

A goal of second-generation HIV surveillance is to enhance the use of surveillance data for public health action. The impact of data can be enhanced when several sources of information are used. Data from HIV sentinel sero-surveillance are therefore only one of several sources that can be used for public health action. Data can be used for a variety of purposes, such as:

- Targeting prevention and care programmes
- Monitoring and evaluation
- Resource allocation and programme planning
- Informing and educating the public
- Guiding scientific research
- Monitoring indicators
- Triangulation
- Mobilising political commitment
- Advocacy.

Each of these uses is described in detail below.

Targeting prevention and care programmes

A principal use of HIV prevalence data is to identify groups of persons at highest risk for HIV infection. These groups may be persons in certain age groups or who attend certain clinics. They may be from certain geographical areas. By identifying these groups or areas with the highest HIV prevalence, public health workers can direct information, education, healthcare and other programmes to keep the uninfected members of the group uninfected and to assist those already infected.

Table 8.1 on the next page illustrates the advantages and disadvantages of using sentinel surveillance data in guiding prevention and care programmes.
Targeting prevention and care programmes, continued

Table 8.1. Advantages and disadvantages of using sentinel sero-surveillance data in guiding prevention and care programmes.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Presenting HIV sentinel surveillance data by person and place, using variables that are routinely collected, is helpful in determining where the burden of disease is greatest in a country.</td>
<td>▪ HIV sentinel surveillance data have not been very useful in identifying specific high-risk behaviours since only limited behavioural data are collected.</td>
</tr>
<tr>
<td>▪ It can also show which particular demographic groups are most severely affected.</td>
<td>▪ If sentinel surveillance is only conducted in antenatal clinics (ANCs), trends in HIV prevalence among men will be missed, prevalence among young women may be over-estimated and prevalence in older women may be under-estimated.</td>
</tr>
<tr>
<td>▪ Most countries have used sentinel surveillance data to direct increased attention to high-prevalence areas. This positive trend needs to continue.</td>
<td></td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 8.1, answer the following questions:

a. What is a drawback of only conducting sentinel surveillance in ANCs?

b. What is an effective way of determining where the disease burden is greatest in a country?

Monitoring and evaluation

HIV sero-surveillance data can be used to evaluate the long-term health impact of an HIV prevention programme, by detecting changes in the prevalence of HIV infection over time. Evaluation refers to determining how well a programme is functioning (process evaluation) and what its impact is (impact evaluation). Monitoring refers to looking at a programme’s performance over time. There are two limitations, however, in using prevalence for monitoring and evaluating prevention programmes.
Monitoring and evaluation, continued

- First, prevalence surveys measure prevalence, not incidence. Prevention programmes are designed to decrease the incidence of HIV, and then eventually its prevalence. Because there is no readily available non-experimental method to measure incidence directly in a sentinel survey, changes in incidence can only be approximated by changes in prevalence. Changes in prevalence among 15- to 24-year-olds best approximate changes in incidence, since these infections are likely to be recently acquired.

- The second limitation is that populations targeted for prevention are usually exposed to more than one prevention message, through mass media, schools, clinics and word-of-mouth. As such, changes in HIV sero-surveillance data do not typically reflect the impact of a single prevention programme. They must be interpreted along with behavioural and other sources of data to identify the plausible causes for changes in prevalence levels.

HIV sentinel sero-surveillance data add power to the plausibility of the prevention programme’s results. It may take time for prevention efforts to translate into changes in HIV prevalence. Additionally, HIV sero-surveillance data alone cannot give a complete picture of whether the epidemic is growing, decreasing or staying the same. HIV sero-surveillance data are part of a package of information used to form the whole picture of the status and direction of the HIV epidemic in a country.

A specific sub-set of HIV sero-surveillance data deserves special mention. Data from ANC sites can be used to estimate the number of newborns who will be exposed to HIV. Decreases in prevalence in pregnant women means that fewer babies will be exposed to HIV, and less mother-to-child transmission will occur.

Resource allocation and programme planning

You can use data from HIV sentinel surveillance to estimate current and future HIV prevalence in your country. Prevalence data and other variables are fed into computer models such as Spectrum and EPP (Estimation and Projection Package). These estimates can be used to allocate resources for prevention, care, and treatment.
Resource allocation and programme planning, continued

This enables you to make short-term projections on HIV incidence and prevalence, and on the annual incidence of AIDS cases. These estimates of AIDS cases are more reliable than the total number of AIDS cases that can be obtained from AIDS surveillance systems, and can be used as a cross-check. More importantly, this information can be used to allocate resources for AIDS care. It can also help you make plans for future prevention, care and treatment services.

You can use ANC sentinel surveillance data to predict the future number of children who will be born with HIV infection. These projections use similar models, which also include data on risk of transmission from mother to child, infant mortality rates and fertility rates of HIV-infected women.

Public education

Disseminating information on HIV prevalence data through the mass media or individual counselling can help to give people a realistic perception of the risk for HIV infection in their community. This is extremely important for those in high prevalence areas who continue to engage in high-risk behaviours. Reading or hearing about HIV in the media is likely to reinforce basic information and specific prevention messages. It also may help in removing stigma surrounding HIV infection.

Guiding scientific research

Epidemiologic and prevention research is most efficiently done where rates of HIV transmission are highest. HIV sentinel surveillance can also be an important part of scientific research. In epidemiologic research, which examines the distribution and determinants for disease, higher prevalence in certain populations will suggest where disease transmission is highest. This will be where HIV epidemiology and the impact of prevention programs are most easily studied. An example of a successful case is described below:

- A sentinel surveillance study of factory workers in Zimbabwe who donated blood found rapidly rising HIV prevalence.
- This result led to a detailed examination of risk factors for getting infected at or near the factory.
- Study data showed that the factory workers met sex workers at beer halls and were subsequently infected.
- This information led to an intervention trial at the beer halls.
HIV sentinel surveillance data are used as indicators for performing monitoring and evaluation of the impact of prevention programmes. Indicators are specific data that are gathered to measure how well a prevention or treatment programme is doing. UNAIDS have developed the concept of Impact Indicators to communicate these outcomes most effectively. Examples of Impact Indicators are listed below, with details for measuring the Indicators.

Impact Indicator 1 is HIV prevalence among pregnant women. Following the principles of second-generation HIV surveillance:

- This indicator is based on HIV prevalence in ANCs using unlinked anonymous testing in women aged 15 to 24 years.
- The indicator is measured by dividing the number of HIV-positive blood samples by the total number of blood samples taken from women aged 15 to 24 years at ANCs.
- It is used as a proxy measure of incidence in this youngest age group, because 15- to 24-year-old women with HIV probably were infected within the preceding few years.
- It is strongly recommended that two separate figures be reported: one for women aged 15 to 24 and one for women across the entire reproductive age range of 15 to 49.
- Using the prevalence in women aged 15 to 24 in the indicator gives a more accurate picture of recent infection.

Impact Indicator 3 from UNAIDS is HIV prevalence in sub-populations with high-risk behaviours. In countries with low-level or concentrated epidemics, surveillance activities are more effective if resources are concentrated on tracking behaviours and HIV prevalence in sub-populations, where risk for HIV infection is concentrated. Examples of sub-populations at high risk for HIV infection include:

- Sexually transmitted infection (STI) clinic patients
- Sex workers
- Long-distance truck drivers
- Frequent clients of sex workers.

Sentinel sites for these populations typically include STI clinics and other general-medicine clinics located near areas where sex work occurs.
Monitoring indicators, continued

Table 8.2. Summary of Impact Indicators 1 and 3.

<table>
<thead>
<tr>
<th>Population(s) it reflects</th>
<th>Impact Indicator 1</th>
<th>Impact Indicator 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant women</td>
<td>Generalised</td>
<td>Low-level or concentrated</td>
</tr>
<tr>
<td>Sub-populations with high-risk behaviour</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussing the table

Looking at Table 8.2, answer the following questions:

a. What epidemic state(s) is impact indicator 1 used in?

b. What populations(s) does impact indicator 3 represent?

Triangulation

An important way that you can use sentinel sero-surveillance data is in combination with other data. The process of examining several different sets of data, which are measuring different things to come up with a better understanding of how and where the epidemic is spreading, is called triangulation or data synthesis. Second-generation surveillance stresses comparing of HIV sero-surveillance data and HIV behavioural surveillance data, to enhance the explanatory power of the surveillance data. Integrating these data with other sources of data can give a more complete picture of the HIV epidemic. Some other sources of data may include:

- STI and tuberculosis (TB) surveillance data
- Blood donor data
- HIV case reporting
- Death registration information.

STIs can indicate recent risk behaviour, such as unprotected sex, because many STIs and STI syndromes are of short duration and have been acquired recently. As TB is an opportunistic infection associated with HIV, trends in TB surveillance data can indicate trends in HIV infection from some years earlier. Also, TB trends can reflect the effectiveness of HIV treatment programmes in the future, because as HIV is treated with antiretroviral drugs, TB rates should come down.
Mobilising political commitment

HIV prevalence data have been extremely useful in obtaining, reinforcing, and increasing the commitment of various governmental and non-governmental organizations (NGOs) to prevention and control programmes.

- HIV prevalence data are also extremely helpful for gaining political commitment.
- However, it is challenging to maintain political commitment, and efforts must be made to sustain it.

For continued political and financial commitment, you must effectively analyse and present HIV surveillance data to policy-makers and decision-makers. Selected kinds of people who need to be informed include politicians, potential donors or funders, public health planners, health personnel at national and local levels, health promotion and prevention staff and the media, as well as individuals, groups and communities. You should make efforts to release surveillance reports with the shortest possible delay, and to mould and target communications to the variety of audiences.

Advocacy

An important use of HIV surveillance data is advocating or lobbying for the health and social needs of populations impacted by HIV/AIDS. Foremost, public and governmental recognition of the very existence of an HIV epidemic in a country or province depends upon demonstrating that HIV is present. HIV sentinel surveillance can fulfil this role as follows:

- In countries with low-level or concentrated epidemics, sentinel surveillance can confirm the presence of HIV in a population or region. This is most effectively done through selecting sentinel sites where infection is most likely to first appear, such as STI clinics.
- In generalised epidemics, the appearance and persistence of HIV in pregnant women makes a compelling argument for the spread of the infection beyond groups at highest risk.
- Governmental and NGOs are less able to ignore the reality of HIV when its existence and impact are documented thoroughly, through sentinel surveillance.
Disseminating HIV Surveillance Data

There are several distinct steps to disseminating HIV surveillance data. They include:

- Establishing the message you want to communicate
- Selecting the audience to which you want to deliver the message
- Selecting the channel through which the message will be delivered
- Selecting the tool for delivering the message
- Evaluating the impact of the message.

Each of these will be discussed below.

Establish the message

The first step in effectively disseminating the results of a particular round of HIV sentinel surveys is establishing a message. Working with senior public health officers, the surveillance team needs to decide its objective. What is the most important information that the team wants to convey? Is the epidemic increasing or decreasing? Is there evidence that what is being done is working?

Messages will differ from audience to audience as well. That is to say, changes in HIV prevalence may have several explanations, and different audiences may be interested in different explanations.

- A foreign donor may be most interested in how well a new antiretroviral treatment programme is working. A falling HIV prevalence may, for instance, be the result of poorer survival of persons with HIV, and suggest that antiretroviral drugs are not getting to the sickest patients.
- The media may want to know how one country compares with another or how effective the overall prevention effort. A falling HIV prevalence in this case might be interpreted as a result of an effective prevention programme.

In both cases the most likely reason for the declining prevalence needs to be worked out by a thorough review of all data. Next, the content of the message needs to be decided upon, crafted in a clear and concise way and expressed at an appropriate level for the target audience.
Once the message has been established, the target audience should be defined. Today, especially with the multiple sectors of civil society and government involved in the response to HIV, the audience for up-to-date information on the HIV epidemic is much broader than just health professionals.

Important potential target audiences include:

- Health professionals
- General public
- Policy-makers and other decision-makers
- Media
- Other sectors
- Non-governmental organizations (NGOs)
- Other national and international organisations
- Surveillance staff members at national and local levels who help conduct sero-surveys.

The content of the message and the target audience should be linked. The message sent to the recipient will differ if the country’s national AIDS control programme (NACP) wants to mobilise the population for World AIDS Day, for example, or if the NACP wants to secure a greater commitment from the Ministry of Education for school-based prevention programmes.

Perhaps the most important audience for prevalence data is the people who generated them. HIV prevalence data should be communicated to the surveillance staff members, at the national and local levels, who conducted the sero-surveys. They need to receive feedback about how well the sero-survey was conducted and what it found. Feedback enhances and helps maintain the system.

The selection of an appropriate channel of communication increases the probability that the message will reach the target audience and achieve the objective. Examples of communication channels for disseminating HIV surveillance results are listed on the following page:
Select the communication channel(s), continued

- Television
- Radio
- Newspapers
- Scientific journals
- Conferences
- Newsletters
- Press releases
- The internet, including government websites
- Epidemiologic bulletins and technical reports.

Using the most widely read newspapers may be the most efficient and effective channel to make the results of an HIV sentinel surveillance round known to the general public. On the other hand, if the NACP wants to highlight results for decision-makers, a face-to-face briefing may be the best way to get the message across.

Select the tool(s)

It is essential to use the appropriate tools to transmit the message once the audience and channel of communication are defined (Table 8.3). For example, if decision-makers are the target audience and the channel is a face-to-face briefing, visual tools and graphs, with a short text explaining the major conclusions, will be much more efficient than technical reports, since this audience is pressed for time and may be less technically oriented.

Table 8.3. Examples of essential tools and audiences for communicating information about HIV prevalence.

<table>
<thead>
<tr>
<th>Audiences</th>
<th>Channels</th>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical professionals involved in NACP and</td>
<td>Dissemination or evaluation</td>
<td>Full technical report on HIV, STI and behavioural surveillance</td>
</tr>
<tr>
<td>monitoring and evaluation</td>
<td>workshops</td>
<td></td>
</tr>
<tr>
<td>Non-governmental organisations, other sectors</td>
<td>Conferences</td>
<td>A non-technical review of data from different sources</td>
</tr>
<tr>
<td>and partners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media, journalists, general population</td>
<td>Press conferences</td>
<td>A press release highlighting the main findings</td>
</tr>
<tr>
<td>Policy-makers, decision-makers</td>
<td>Face-to-face briefings and planning meetings</td>
<td>Brief summaries of main findings with some graphics</td>
</tr>
</tbody>
</table>
HIV Sero-surveillance

Discussing the table

a. Are the same tools used to disseminate the results of surveillance to each of the different audiences?

b. Why might it not be appropriate to distribute a full technical report to decision-makers or the media?

The tools used to transmit information should convey the information clearly. Whether a full technical report or a brief summary is used, visual tools such as graphs may help communicate the message. When you present the message in an easy to understand way, the audience is more likely to use the data.

Evaluate impact

An important final step is an informal evaluation of how well the surveillance message was delivered. While formal evaluation may be difficult and unnecessary, programmes should be able to have a sense of how influential their communications efforts have been in shaping policy.

- Informal conversations with the press may give ideas about what to include in press releases in future.
- Conversations with aides to senior policy-makers may similarly help to shape the scope and depth of future briefing materials.
- Finally, in behavioural surveys that are conducted as part of second-generation surveillance, you have the opportunity to ask people about the most effective ways to communicate messages about the HIV epidemic to them.

Surveillance staff should try to learn as much as they can about how they can improve messages, make more effective use of channels and tools, and better define the audiences for these important data.

Summary

HIV sentinel surveillance data can be used in many ways, including monitoring and evaluation, guiding scientific research, triangulation and public education. Several methods are available to disseminate this data, such as television, radio, newspaper or scientific reports. You should tailor the message itself, based on the target audience, so that it is most effective.
Unit 8 Exercises

Warm up review

Take a few minutes to review your answers to this unit’s Warm up questions and make any necessary changes.

Small group discussion

Get into small groups by country, region or province to discuss these questions.

1. How have HIV sentinel surveillance data been used in your province or district? How have they been disseminated to you? Have you disseminated them to others in your district?

2. How can HIV surveillance data be presented to different target audiences? What methods can be used to disseminate the results of the survey to the sentinel sites? What do you think would be most useful in your country?

Apply what you’ve learned/case study

Try this case study. We will discuss the answers in class.

You are the HIV sero-prevalence co-ordinator for a province in the Yolo Republic. Annual sero-surveys have been conducted at five ANCs in three districts of the province for the past 4 years. You are in the process of analysing your province’s local data and preparing the information for dissemination. The following table summarises your analysis so far:

Number of women (total and HIV+) at ANC sites.

<table>
<thead>
<tr>
<th>Women</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women, all sites</td>
<td>2 009</td>
<td>1 993</td>
<td>2 003</td>
<td>1 999</td>
</tr>
<tr>
<td>All HIV+ women, all sites</td>
<td>299</td>
<td>277</td>
<td>305</td>
<td>290</td>
</tr>
<tr>
<td>Women age 15-24 years old, all sites</td>
<td>491</td>
<td>507</td>
<td>497</td>
<td>501</td>
</tr>
<tr>
<td>HIV+ women, age 15-24 years old, all sites</td>
<td>39</td>
<td>31</td>
<td>25</td>
<td>19</td>
</tr>
</tbody>
</table>

Now answer the questions on the following page.
HIV Sero-surveillance

Apply what you’ve learned/case study, continued

a. At a local meeting of NGO directors, you are asked whether or not there is any indication that the money and effort spent on HIV prevention in the province has been successful. They request a brief summary of the antenatal sentinel surveillance data for their next meeting. What data would you include in this summary?

How would you present the data?

What data other than HIV prevalence would be useful to include?

What conclusion do you present to NGO directors?

b. The Ministry of Health and the NACP inform you that the budgets for HIV prevention and care for your province are going to be reduced to US$300 000 for the coming year. Their policy is that money should be concentrated in the health districts in greatest need and that half should be spent on prevention and half on care programmes. They ask you to plan how you will allocate the $300 000 in the three districts within your province. You start by examining the ANC data by district and site and find the following (next page):
Apply what you’ve learned/case study, continued

Number of women, by district, site, age group, and sero-status.

<table>
<thead>
<tr>
<th>Women</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women</td>
<td>2 009</td>
<td>1 993</td>
<td>2 003</td>
<td>1 999</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>398</td>
<td>401</td>
<td>400</td>
<td>402</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>402</td>
<td>401</td>
<td>398</td>
<td>396</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>404</td>
<td>389</td>
<td>401</td>
<td>403</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>397</td>
<td>399</td>
<td>391</td>
<td>399</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>408</td>
<td>403</td>
<td>413</td>
<td>399</td>
</tr>
<tr>
<td>All HIV+ women</td>
<td>299</td>
<td>277</td>
<td>305</td>
<td>290</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>99</td>
<td>91</td>
<td>97</td>
<td>93</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>31</td>
<td>42</td>
<td>60</td>
<td>67</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>36</td>
<td>33</td>
<td>30</td>
<td>23</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>97</td>
<td>88</td>
<td>97</td>
<td>88</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>36</td>
<td>23</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Women age 15-24 years old</td>
<td>491</td>
<td>507</td>
<td>497</td>
<td>501</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>98</td>
<td>99</td>
<td>101</td>
<td>102</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>99</td>
<td>97</td>
<td>102</td>
<td>97</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>101</td>
<td>104</td>
<td>93</td>
<td>99</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>100</td>
<td>103</td>
<td>99</td>
<td>103</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>93</td>
<td>104</td>
<td>102</td>
<td>100</td>
</tr>
<tr>
<td>HIV+ women, age 15-24 years old</td>
<td>39</td>
<td>31</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>10</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>3</td>
<td>4</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>9</td>
<td>6</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>9</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

Using the HIV sentinel surveillance data above, what are your recommendations on where the $150 000 for HIV prevention should be spent?

Using the HIV sentinel surveillance data above, what are your recommendations on where the $150 000 for HIV care should be spent?

What other factors would you consider before making your recommendations?
Apply what you’ve learned/case study, continued

c. You receive a call from a reporter working for your national newspaper. She says that she heard a rumour that HIV has gone down in your province and would like your comments. You tell her that you are on your way to a meeting right now, but promise to call her back as soon as possible and also prepare a written press release.

Using the data presented above, what would you include in the press release? What further explanation would you provide? Whom would you contact before returning the call?
HIV Sero-surveillance

Final Case Study

1. You are the HIV surveillance officer for Inyo Province in the Yolo Republic. Inyo Province currently conducts HIV sentinel surveillance at antenatal and STI clinics serving female sex workers. You are considering adding more sites to the province’s sentinel surveillance system.

a. What must you consider when selecting sites for sentinel surveillance?

b. In Inyo Province, the estimated prevalence of HIV is 35% among female sex workers. What would be an adequate sample size to measure HIV prevalence within a margin or error of ± 5%?

c. What method of HIV testing would be most appropriate in conducting sentinel surveillance of female sex workers attending STI clinics?

d. Inyo Province conducts HIV surveillance at 20 sentinel sites. As the HIV surveillance officer for Inyo Province, you are charged with supervising the staff at all sentinel sites. How would you ensure that sentinel site staff are adequately trained and that surveillance is conducted in the same manner at all sentinel sites?
Final Case Study, continued

2. HIV surveillance at various sentinel sites between 1999 and 2005 found the following data:

HIV Prevalence at select sentinel site in Inyo Province, 1999-2005.

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of sites</th>
<th>Area</th>
<th>1999</th>
<th>2001</th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant women</td>
<td>6</td>
<td>urban</td>
<td>32%</td>
<td>30%</td>
<td>23%</td>
<td>21%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>2</td>
<td>rural</td>
<td>17%</td>
<td>19%</td>
<td>20%</td>
<td>22%</td>
</tr>
<tr>
<td>STI patients</td>
<td>2</td>
<td>urban</td>
<td>52%</td>
<td>57%</td>
<td>54%</td>
<td>51%</td>
</tr>
<tr>
<td>Sex workers</td>
<td>5</td>
<td>urban</td>
<td>63%</td>
<td>66%</td>
<td>61%</td>
<td>55%</td>
</tr>
<tr>
<td>Tuberculosis patients</td>
<td>1</td>
<td>urban</td>
<td>-</td>
<td>-</td>
<td>73%</td>
<td>82%</td>
</tr>
<tr>
<td>Tuberculosis patients</td>
<td>1</td>
<td>rural</td>
<td>-</td>
<td>-</td>
<td>32%</td>
<td>36%</td>
</tr>
</tbody>
</table>

a. What trends do you see? At which sites would you expect HIV prevalence to be the highest in 2006?

b. What are the limitations of the above data? What are the limitations of sentinel surveillance?
Summary

- The objectives of the surveillance activity must be well defined. The best design option for HIV surveillance is the sentinel surveillance system.

- The key considerations in selecting sentinel populations for HIV sentinel surveillance are the local epidemiology of HIV and the major risk behaviours for HIV transmission. The most useful and accessible sentinel populations in the generalised epidemics of sub-Saharan Africa are pregnant women attending antenatal clinics. In concentrated epidemics, such as in Asia, sentinel populations should include sex workers, intravenous drug users, men who have sex with men, and STI clinic patients in addition to pregnant women at antenatal clinics.

- It is prudent to begin HIV sentinel surveillance by selecting only a few sites and gradually increase them to cover a broad distribution of geographic areas, taking into consideration the availability of staff and financial and logistical resources.

- A sample size of between 250 and 400 is usually adequate for surveillance among pregnant women attending an ANC. Higher sample sizes lead to more precise estimates. Consecutive sampling of patients is recommended. To examine prevalence trends, a survey frequency of once per year is sufficient.

- Participation bias is a critical issue for HIV sentinel surveillance. Consequently, the most common method for testing blood specimens for surveillance is the unlinked anonymous method without informed consent. However, it is recommended to transition to the use of PMTCT programme data.

- Data collected at each site and for each sentinel population at that site should be analysed separately. Results should be summarised for the entire survey sample at each site and for each sub-group for whom information on age and sex has been collected.

- To monitor HIV infection trends over time, measure the HIV incidence rate. The most available proxy for incidence is prevalence among youth ages 15 to 24 years.

- Ensure that the data generated are utilised. Some of the purposes for which HIV surveillance data may be utilised include mobilisation for political commitment, increasing financial allocation, monitoring/evaluating HIV control programmes and educating and counselling individuals.
Appendix A, References and Further Reading


HIV Sero-surveillance


HIV Sero-surveillance
Appendix B, Glossary and Acronyms

**ACASI**: Acronym for ‘audio computerised assisted survey instruments.’

**Accuracy**: Refers to how well the sample reflects (nearest to the truth) the study population.

**Acquired immunodeficiency syndrome (AIDS)**: See Advanced HIV infection.

**Active infection**: An infection that is currently producing symptoms (disease) or in which the organism that causes disease is reproducing.

**Active surveillance**: A system in which the organisation conducting surveillance initiates procedures to obtain reports. Example: making telephone calls or visits to health facilities to obtain information.

**Adherence**: The extent to which a patient takes his/her medication according to the prescribed schedule (also referred to as ‘compliance’).

**Advanced HIV disease reporting**: The systematic and standardized ongoing reporting of persons diagnosed with advanced HIV disease (clinical stage 3 or 4 and/or CD4 counts ≤350).

**Advanced HIV infection**: (also Advanced HIV disease) The late stage of HIV infection that includes development of one or more opportunistic illnesses (illnesses that occur because of low levels of CD4 lymphocytes, or immunodeficiency). Advanced HIV infection (disease) is the term now used for AIDS in updated WHO Guidelines.

**Aetiological case reporting**: A surveillance system in which a laboratory test has confirmed the presence of the pathogen.

**Aetiologic**: Refers to the causes of disease. Also known as ‘aetiologic.’

**Agent**: A factor, such as a micro-organism, chemical substance, or form of radiation, whose presence is essential for the occurrence of a disease.

**Aggregate case reporting**: A single form summarises all of the patients who were diagnosed with the condition at certain sites in a given time period.

**AIDS**: Acronym for ‘Acquired Immunodeficiency Syndrome.’

**AIDS case reporting**: The identification and reporting of persons meeting the AIDS case definition to permit public health authorities to track the disease over time. Also known as ‘AIDS case surveillance.’
**AIDS case surveillance**: The identification and reporting of persons meeting the AIDS case definition to permit public health authorities to track the disease over time. Also known as ‘AIDS case reporting.’

**AIDS-defining illness**: Any of a series of health conditions that are considered, in isolation, or in combination with others, to be indicative of the development of AIDS. These conditions result from low levels of CD4 lymphocytes which are destroyed by HIV.

**AIDS Indicator Survey (AIS)**: A standardized tool to obtain indicators for effective monitoring of national HIV/AIDS programs. The protocols will help us provide, in a timely fashion and at a reasonable cost, the information required for meeting HIV/AIDS program reporting requirements.

**Algorithm**: Step-by-step procedure for decision-making; a recipe for achieving a specific goal.

**Aliquot**: A portion of a sample; for example, an aliquot of a 100 millilitre sample of blood might be a 5 millilitre portion of that sample.

**Alliances**: Partnerships created to assist with formative assessment. These partnerships differ based on the type of most-at-risk group being sampled, but usually include gatekeepers, governmental or non-governmental organisations, influential members of the target group, advocates, and physicians and others who provide health care to the target group.

**Anonymous**: Having no known name or identity. Removing all personally identifying information from a sample that will be tested for HIV, for example, in order to protect the patient’s identity.

**Anti-microbial resistance**: The ability of an organism to avoid destruction or deactivation typically caused by drugs or chemicals designed to do so.

**Antibiotic medicines**: Drugs that kill or inhibit the growth of bacteria.

**Antibodies**: Molecules in the blood or secretory fluids that tag, destroy, or neutralise bacteria, viruses, or other harmful toxins.

**Antimicrobial agents**: An agent that kills or inhibits microbial growth. ‘See Antibiotic medicines.’

**Antiretroviral drugs**: Drugs used to fight infections caused by retroviruses, such as Advanced HIV Disease.
**Antiretroviral drug resistance:** Resistance to one or more antiretroviral drugs. Antiretroviral drug resistance is one of the more common reasons for therapeutic failure in the treatment of HIV.

**Antiretroviral therapy (ART):** Treatment with drugs that inhibit the ability of HIV to multiply in the body.

**Area map:** A map used as a graph showing variables by geographic location.

**Artefact:** An inaccurate observation, effect or result caused by experimental error.

**Asymptomatic:** Without symptoms.

**At-risk groups:** Groups of people that are at increased risk for passing HIV on to others or for being infected by others.

**B-lymphocytes:** Also known as ‘B-cells.’ Blood cells of the immune system involved in the production of antibodies. In persons living with AIDS, the functional ability of both the B and the T lymphocytes is damaged, with the T lymphocytes being the principal site of infection by HIV.

**Bacterial vaginosis:** A chronic inflammation of the vagina caused by the bacterium *Gardnerella vaginalis*.

**Bangui:** The initial WHO AIDS surveillance case definition, developed to provide case definition of AIDS for use in countries where testing for HIV antibodies was not available.

**Bar chart:** A visual display of the size of the different categories of a variable. Each category or value of the variable is represented by a bar (or column). The Y-axis represents frequency. The X-axis represents different classes.

**BED assay:** A simple enzyme immunoassay (EIA) that can be used for detecting recent HIV-1 infection (within the last 160 days). It uses a branched peptide that includes sequences from HIV sub-types B, E and D, and allows detection of HIV-specific antibodies among various sub-types.

**BED capture-EIA test:** This test detects an antibody to a small HIV protein, gp41. It was first tested in HIV types B, E and D, hence its name BED.

**Behavioural surveillance:** Surveys of HIV-related behaviour that involve asking a sample of people about their risk behaviours, such as their sexual and drug-injecting behaviour.

**Beneficence:** To promote the interest of the patient or participant. To balance the benefits and risks to people involved in surveys. These risks include physical harm, such as violence and psychological harm, such as social stigmatisation.
HIV Sero-surveillance

Bias: A systematic error in the sample selection and the collection or interpretation of data.

Biological surveillance: Surveillance that involves regular and repeated cross-sectional surveys, but collects biological samples that are tested for HIV and other related illnesses, such as sexually transmitted diseases and tuberculosis.

Bivariate analysis: One of the main types of behavioural surveillance analysis that is performed to determine whether one variable is related to the distribution of another. For example, there might be an association between a respondent's age (the explanatory variable) and their use of condoms (the outcome variable). Variables are associated if the value of one tells you something about the value of another. Statistical tests in bivariate analysis determine whether any observed difference reflects a true difference, or may be due to chance.

Body fluids: Any fluid produced by the human body, such as blood, urine, saliva, sputum, tears, semen, mother's milk, or vaginal secretions. Fluids that commonly transmit HIV are blood, semen, pre-ejaculate, vaginal fluids, and breast milk.

Bridging populations: Persons in high-risk sub-populations who interact with people of lower risk in the general population, making it more likely that the HIV epidemic shifts from concentrated to generalised.

BSS: Acronym for ‘behavioural surveillance survey.’

Candida albicans: The fungal causative agent of vulvovaginitis in women and inflammation of the penis and foreskin in men.

CAPI: Acronym for ‘computer-assisted personal interview.’

Capture-recapture: A technique used to estimate numbers of persons in a target population. Two or more lists containing individuals in common can establish the number of individuals missing from both, thereby estimating the total population of interest.

Carrier: A person or animal without apparent disease who harbours a specific infectious agent and is capable of transmitting the agent to others.

Case: An individual in the population or sample with a particular disease of interest.

Case-based reporting: each person diagnosed with the disease is reported separately, as opposed to aggregate case reporting in which data from patients with the disease are combined.

Case-control study: A type of observational analytic study. Enrolment into the study is based on presence (‘case’) or absence (‘control’) of disease. Characteristics such as previous exposure are then compared between cases and controls. The purpose of case control studies is to identify factors that are associated with, or explain the occurrence of the specific disease or condition being studied.
**Case definition:** A set of standard criteria for deciding whether a person has a particular disease or health-related condition, by specifying clinical criteria and limitations on time, place and person.

**Case fatality rate:** The proportion of patients who become infected or develop a disease that dies as a result of that infection or disease.

**Case reporting:** A surveillance system in which persons who are identified as meeting the case definition are reported to public health authorities.

**CASI:** Acronym for ‘computerised assisted survey instruments.’

**Catchment population:** A geographic area that is to be examined or surveyed. Can refer to the population served by a given clinic.

**Categorical surveillance system:** System that deals with reporting a single disease.

**Categorical variable:** Items that can be grouped into categories, such as marital status or occupation.

**Cause of disease:** A factor (characteristic, behaviour, etc.) that directly influences the occurrence of disease. A reduction of the factor in the population should lead to a reduction in the occurrence of disease.

**CD4 count:** A measure of the number of CD4 cells in a millilitre (mL) of blood. The CD4 count is one of the most useful indicators of the health of the immune system and a marker for the progression of HIV/AIDS.

**CD4 receptors:** Markers found on the surface of some body cells, including T-cells. These receptors are targets of HIV, and thus CD4+ cells are attacked by the virus.

**Census sampling:** Every unit, or case, is measured for the entire population. A de facto census allocates persons according to their location at the time of enumeration. A de jure census assigns persons according to their usual place of residence at the time of enumeration (Last).

**Centers for Disease Control and Prevention (CDC):** The US Department for Health and Human Services agency with the mission to promote health and quality of life by preventing and controlling disease, injury, and disability.

**Chain referral sample:** Any sampling method wherein participants refer other potential participants for inclusion in the sample. There are several types of chain referral sampling methods, most of which are non-probability samples. Examples of chain referrals include RDS, network sampling, random walk and snowball sampling.
**Chancroid**: An acute, sexually transmitted, infectious disease of the genitalia caused by the bacteria *Haemophilus ducreyi*. The infection produces a genital ulcer that may facilitate the transmission of HIV.

**Characteristic**: A definable or measurable feature of a process, product, or variable.

**Chlamydia trachomatis**: The most common sexually transmitted bacterial species of the genus Chlamydia that infects the reproductive system. Chlamydia infection causes infection of the cervix of women and the urethra of men and is frequently asymptomatic. If left untreated, it can cause sterility in women.

**Clinic-based surveys**: Surveys that use samples that have been selected in clinical facilities, such as STI or drug treatment clinics. The most common type of the clinic-based surveys that are done using biological markers, such as HIV infection, is clinic-based sentinel sero-surveillance.

**Cluster**: Any aggregate of the population of interest (for example, departments, villages, health facilities).

**Cluster sampling**: The population of interest is broken into groups or clusters and a sample of clusters is randomly selected (Levy & Lemeshow).

**Clustered bar chart**: A bar chart in which the columns are presented as clusters of subgroups. Also known as ‘stacked bar chart.’

**Code**: A unique identification for a specimen. It may or may not be linked to any personal identifying information.

**Cohort analysis**: Analysis that involves following groups of subjects over time.

**Cohort studies**: Cohort studies follow a group of initially uninfected people over time, and test them repeatedly. Cohort studies follow a well-defined group of people who have had a common experience or exposure, who are then followed up for the incidence of new diseases or events, as in a cohort or prospective study tested repeatedly over a long period of time.

**Community advisory board**: Members of the community who offer input into study design and local procedures. CAB members include community activists and/or professionals associated with HIV/AIDS prevention and services delivery. Some CAB members are trial participants.

**Community-based surveys**: Surveys that use samples that have been selected from non-clinical settings. They often include most-at-risk populations, such as sex workers or truck drivers, who are not included in clinic-based surveys. As with clinic-based surveys, the most common type of community-based survey is called 'repeated cross-sectional community-based sentinel sero-surveillance.'
**Community sites:** Locations in the community, such as households or brothels.

**Completeness of data elements:** The extent to which the information requested in the case report form is provided.

**Completeness of reporting:** One of several attributes of a surveillance system. The term refers to the proportion of cases that were reported. Completeness of reporting is also referred to as the sensitivity of the surveillance system and is determined by using an alternative (and thorough) method of identifying cases of the disease and then dividing the number of cases reported by the total number of cases identified. Completeness is often reported as a percentage.

**Compulsory testing:** Testing that is required of all individuals in a population to be surveyed. For example, requiring HIV tests to be done on all members of a prison population.

**Concentrated HIV epidemic:** The epidemic state in which HIV has spread to a high level in a defined subpopulation but is not well established in the general population. HIV prevalence is consistently >5% in at least one defined subpopulation and is <1% in pregnant women in urban areas.

**Confidence interval:** The compound interval with a given probability, for example, 95% that the true value of a variable such as mean, proportion, or rate is contained within the limits. Also known as ‘confidence limits.’

**Confidence limits:** See ‘confidence interval.’

**Confidentiality:** Protecting information that concerns a study participant or patient from release to those who do not need to have the information.

**Consecutive sampling:** This sampling method consists of sampling every patient who meets the inclusion criteria until the required sample size is obtained or the survey period is over. While this method is not strictly a probability sample, it is easier to use and offers less occasion for sampling bias.

**Contact:** Exposure to a source of an infection, or a person so exposed.

**Contagious:** The characteristic of an organism or person that renders it capable of being transmitted from one person to another by contact or close proximity.

**Continuous variable:** Items that occur in a numerical order, such as height or age.

**Convenience sampling:** The selection of entities from a population based on accessibility and availability. Available participants may be people on the street, patients in a hospital or employees in an agency. This type of sampling does not generally represent the population of interest and is best used in the exploratory stage of research.
**Core data elements:** Information about a patient that must be collected during a survey.

**Cotrimoxazole preventative therapy (CPT):** Administering cotrimoxazole prophylaxis to prevent opportunistic infections among HIV-infected patients.

**Cotrimoxazole prophylaxis:** A combination of two anti-infection drugs, sulfamethoxazole and trimethoprim, used to prevent opportunistic infections in patients with HIV.

**Coupon:** Used in RDS studies to provide incentives to participants. Coupons in RDS can be used both to track participation for reimbursements and to link the recruiters to the recruits. Other methods may use coupons to encourage participation, much like the advertisements placed in popular clubs or bars. Some coupons may have two parts that can be easily separated. One part of the coupon serves as the referral coupon, which the recruiter uses to recruit a peer into the study. The other part of the coupon serves as the payment coupon. It is kept by the recruiter and he or she will use it to claim an incentive for having recruited a peer into the study. Both parts of the coupon have the unique identification number of the recruit printed on them. The dual system eliminates the need to collect names for incentive collection.

**Coupon rejecters:** People who are offered a coupon by a recruiter, but decline to take it.

**Cross-sectional survey:** A survey that is conducted over a given period of time, such as during a single year, rather than over an extended period of time.

**Cruising area:** Cruising areas are public space, such as parks, public restrooms, bath houses, dance clubs and railway stations where MSM meet, congregate and arrange and/or engage in sexual activity.

**Cryolabel:** Labels designed to adhere during freezer storage.

**Cryovial:** A vial that is designed to be stored in a freezer.

**CSW:** Acronym for ‘commercial sex worker.’

**DALYs:** See ‘disability-adjusted life years.’

**Database:** A computer programme that stores the variables for each patient in the survey sample or surveillance system.

**Data dictionary:** Electronic files that describe the basic organisation of a project or database. They contain all of the rules that guide data entry.

**Data entry:** The process of entering paper records into a computer database.
Data entry screens: The forms on the computer screen into which a data entry clerk enters the data.

Data synthesis: See ‘triangulation.’

Definitive diagnosis: A diagnosis based on laboratory or other tests specifically designed for diagnosis and considered authoritative.

Demographic Health Survey: National household surveys that provide data for a wide range of monitoring and impact evaluation on topics including HIV prevalence and attitudes and beliefs about HIV/AIDS.

Demographic information: The ‘person’ characteristics of epidemiology (usually collected with “place” and “time”) – age, sex, race and occupation – used to characterise the populations at risk.

Denominator: The population (or population experience, as in person-years, etc.) at risk in the calculation of a proportion or rate. The denominator is the lower portion of a fraction used to calculate a rate or ratio.

Dependent variable: In a statistical analysis, the outcome variable(s) or the variable(s) whose values are a function of other variable(s).

Descriptive statistics: Used to describe the basic features of the data, they provide simple summaries about the sample and the measures.

DHS: Acronym for ‘demographic and health surveys.’

Dichotomous variable: A special type of nominal variable that has only two categories, such as male/female.

Differential recruitment: Recruiters successfully bring recruits in at different rates.

Direct transmission: The immediate transfer of an agent from a reservoir to a susceptible host by direct contact or droplet spread.

Disaggregated data: Data which is divided up according to different variables, to provide a more detailed analysis.

Disability-adjusted life years (DALYs): A measure of burden of disease in a population obtained by combining ‘years of life lost’ and ‘years lived with disability.’

Disease burden: The size of a health problem in an area, as measured by cost, mortality, morbidity or other indicators.

Disease registry: The file of data that contains reported diseases.
**Disease reporting:** The process by which notifiable diseases are reported to the health authority.

**Disinhibition:** Poor decision-making when considering risk-taking behaviours.

**Distribution:** The frequency and pattern of health-related characteristics and events in a population. In statistics, the observed or theoretical frequency of values of a variable.

**Double-entered:** Entered twice, to avoid mistakes by identifying and correcting discrepancies.

**Double Y-scale:** On a graph, two Y-axes, one on the vertical left for data with large values and one on the vertical right for data with smaller values.

**Dysuria:** Painful, frequent or difficult urination.

**EIA:** See ‘enzyme-linked immunoassay.’

**ELISA:** See ‘enzyme-linked immunosorbent assay.’

**Emic:** Refers to accounts, descriptions, and analyses expressed in terms of the concepts and categories regarded as meaningful and appropriate by the members of the population of interest.

**Endemic disease:** The constant presence of a disease or infectious agent within a given geographic area or population group; may also refer to the usual prevalence of a given disease within such area or group.

**Enumeration units:** The sampling units from the final stage of a multistage sampling design. See ‘Listing units.’

**Enzyme immunoassay (EIA):** A type of test that identifies antibodies to an organism such as HIV. EIAs rely on a primary antigen-antibody interaction and can use whole viral lysate of HIV or one or more antigens from the virus.

**Enzyme-linked immunosorbent assay (ELISA):** A type of enzyme immunoassay (EIA) to determine the presence of antibodies to an infectious agent such as HIV in the blood or oral fluids.

**Epidemic:** The occurrence of a disease (or other health-related event) at a greater than expected level of increase to a baseline. For example, the high prevalence of HIV found in many parts of the world today, including sub-Saharan Africa, Latin America and South and Southeast Asia.
Epidemic state: The prevalence the epidemic has reached in a country or region. Can be low-level, concentrated, or generalized within a sub-population or within the general population.

Epidemiology: The study of the distribution and determinants of the frequency of health-related states or events in specified populations, and the application of this study to the control of health problems.

Epi Info™: Freely distributed epidemiological software available on the CDC website (www.cdc.gov/epiinfo).

Equilibrium: In RDS, the point in the recruitment process where a variable is not expected to change by more than 2% with each successive wave.

Ethnographic assessments: Ethnographic assessments are written analyses of the cultural practices, beliefs and behaviours of a particular culture, network or sub-group.

Ethnographic mapping: Collecting information on the geographic location, temporal movement of and interactions among members of the study population.

Etic: Refers to accounts, descriptions and analyses expressed in terms of the concepts and categories regarded as meaningful and appropriate by the community of scientific observers.

Exclusion criteria: Characteristics of patients who should be excluded from the sample, but who would otherwise be eligible.

Experimental study: A study in which the investigator specifies the exposure category for each individual (clinical trial) or community (community trial), then follows the individuals or community to detect the effects of the exposure.

External validity: The ability to make inferences from the study sample to the population of interest.

Factor: An intrinsic factor (age, race, sex, behaviours, etc.) which influences an individual's exposure, susceptibility, or response to a causative agent.

False negatives: Test results that are negative when the patient actually has the disease that is being tested for.

False positives: Test results that are positive when the patient does not actually have the disease that is being tested for.

Female sex workers: Females who engage in sex work, or the exchange of sex for money, which includes many practises and occurs in a variety of settings. These may include ‘direct’ or ‘formal’ sex workers, who are sometimes included in registries and
often found in brothels, and ‘indirect’ or ‘casual’ sex workers, who do not engage in sex work full time and are unlikely to be included in registries.

**Filter paper**: Porous paper on which samples can be placed.

**Focus groups**: A group setting in which people are asked by a facilitator about their views about a topic. Participants are free to talk with other group members as well as the facilitator. Focus groups allow interviewers to study people in a more natural setting than they can in a one-to-one interview.

**Formative assessment (or research)**: Research conducted before the study begins. Researchers use qualitative methods, such as focus groups, in-depth interviews, mapping or observations of the target population and the individuals who work with them to ensure that the research team sufficiently understands the community.

**GAP**: Acronym for the CDC’s ‘Global AIDS Program.’

**Gatekeepers**: Persons who can provide access to a high-risk population. Examples are a brothel owner who can provide access to female sex workers, or a prison warden who can provide access to prisoners.

**General population surveillance**: Surveillance that measures HIV risk behaviours in a sample of people selected to represent the people living in a region or nation. The surveillance can be restricted to certain ages (for example, young people aged 15-24) or genders.

**Generalisability**: The results from the sample are the same as the results we would have obtained had we tested every person in the study population (that is, the results from the sample are generalisable to the study population).

**Generalised HIV epidemic**: The epidemic state in which HIV is firmly established in the general population. HIV prevalence is consistently >1% in pregnant women.

**Genital discharge syndrome**: This syndrome includes infections due to *N. gonorrhoea*, and *C. trachomatis*.

**Genital ulcer syndrome**: Genital lesions due to *T. pallidum, H. ducreyi*, HSV, *C. trachomatis* or *C. granulomatis*.

**Geographical Information System (GIS)**: System of hardware, software. **Gigolo**: Male sex workers who identify as straight. They tend to have foreign clients and engage in male-male sexual activity.

**Glycoprotein (HIV)**: Proteins on the surface of the HIV virus that bind to CD4 receptors on target cells and procedures designed for integrated storing, management,
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manipulation, analysing, modelling and display of spatially referenced data for solving planning and management problems.

**Gonorrhoea**: An infection caused by *Neisseria gonorrhoeae* bacteria. Although gonorrhoea is considered primarily a sexually transmitted infection, it can also be transmitted to newborns during the birth process.

**Gram-negative**: Bacteria that do not absorb the stain during the process of Gram staining.

**Gram-positive**: Bacteria that do absorb the stain during the process of Gram staining.

**Gram stain**: A laboratory method of staining microscopic slides of organisms in order to identify and classify the various types of bacteria. Bacteria are classified as either Gram-negative (does not absorb the stain) or Gram-positive (absorbs the stain).

**Graph**: A diagram that shows a series of one or more points, lines, line segments, curves or areas, representing variations of a variable in comparison with variations of one or more other variables.

**Grey literature**: Material that is not published in easily accessible journals or databases. Besides programme evaluations, government surveillance reports and programme planning documents mentioned earlier, it includes the abstracts of research presented at conferences, and unpublished theses and dissertations.

**Haemophilus ducreyi**: The causative agent of chancroid. See ‘chancroid.’

**Health indicator**: A measure that reflects, or indicates, the state of health of persons in a defined population; for example, the infant mortality rate.

**Health information system**: A combination of health statistics from various sources, used to derive information about health status, healthcare, provision and use of services, and impact on health.

**Health-seeking behaviour**: The actions individuals or populations take to care for their health, for example, attending a clinic or district hospital when they feel ill.

**Hard-to-reach populations (HTRP)**: Groups of people linked by behaviours, socioeconomic situations or societal structures, who for various reasons (e.g. law, stigma) refrain from involvement in the legal economy and other aspects of the majority social institutions. Includes but is not limited to: IDUs, MSM, CSW and undocumented migrants.

**Hepatitis B virus (HBV)**: The causative agent of hepatitis B. The virus is transmitted by sexual contact, the use of contaminated needles and instruments and by contaminated
serum in blood transfusion. The infection may be severe and result in prolonged illness, destruction of liver cells, cirrhosis or death.

**Hepatitis C virus (HCV):** The causative agent of hepatitis C. This virus is transmitted largely by the use of contaminated needles and instruments and by blood transfusions. The disease progresses to chronic hepatitis in up to 50% of the patients acutely infected.

**Herpes simplex virus 1 (HSV-1):** A virus that causes cold sores or fever blisters on the mouth or around the eyes, and can be transmitted to the genital region.

**Herpes simplex virus 2 (HSV-2):** A virus causing painful sores of the anus or genitals. While this is a sexually transmitted infection, it may be transmitted to a newborn child during birth from an infected mother.

**Herpes viruses:** A group of viruses that includes herpes simplex type 1 (HSV-1), herpes simplex type 2 (HSV-2), cytomegalovirus (CMV), Epstein-Barr virus (EBV), varicella zoster virus (VZV), human herpes virus type 6 (HHV-6), and HHV-8, a herpes virus associated with Kaposi's sarcoma.

**Highly active antiretroviral therapy (HAART):** The use of at least three ARV drugs in combination to suppress viral replication and progression of HIV disease by reducing the viral load to undetectable levels.

**High-risk behaviours:** Behaviours that increase the risk that a person will contract a disease.

**High-risk group:** A group in the community with an elevated risk of disease, often because group members engage in some form of risky behaviour.

**High-risk group surveillance:** Surveillance that measures HIV risk behaviours in groups whose behaviours, occupations or lifestyles could expose them to higher risk of acquiring and transmitting HIV than the rest of the population. These groups are often important in establishing, accelerating or sustaining the HIV epidemic.

**High-risk heterosexuals (HRH):** Includes but is not limited to: mobile populations, uniformed personnel and sex partners of other MARPs.

**Histogram:** A graph that represents a frequency distribution by means of rectangles whose widths represent class intervals and whose areas represent corresponding frequencies.

**HIV:** See 'Human Immunodeficiency Virus.'

**HIV-1:** A type of HIV with slight genetic variations from HIV-2. More easily transmitted than HIV-2.
**HIV-2**: A type of HIV with slight genetic variations from HIV-1. Less easily transmitted than HIV-1.

**HIV case reporting**: the systematic, standardized, ongoing collection of reports of persons diagnosed with HIV infection (clinical stages 1-4) and/or advanced HIV disease (clinical stages 3 and 4).

**HIV clinical stages**: In these modules, a classification by WHO of HIV disease on the basis of clinical manifestations that can be recognized and treated by clinicians in diverse settings, including resource-constrained settings. In order of severity, starting with the lowest, the stages are:
- **Stage 1**: Often asymptomatic or with swollen glands
- **Stage 2**: Symptoms, including moderate weight loss and respiratory infections
- **Stage 3**: More severe symptoms, including extreme weight loss and severe bacterial infections. Called advanced HIV disease.
- **Stage 4**: End-stage HIV infection (AIDS), with manifestations such as wasting syndrome, tuberculosis, lymphoma. Called advanced HIV disease.

**HIV-negative**: Showing no evidence of infection with HIV (for example, absence of antibodies against HIV) in a blood or tissue test.

**HIV-positive**: Showing indications of infection with HIV (for example, presence of antibodies against HIV) based on a test of blood or tissue.

**HIV sub-types**: Distinct lineages of HIV that contain genetic differences.

**HIV viral suppression**: Lowering the level of HIV RNA in plasma, below the threshold of detection.

**Homophily**: In RDS, a measure of the tendency of people to connect to other people like themselves.

**HSV-2**: see herpes simplex virus 2.

**Human immunodeficiency virus (HIV)**: A retrovirus that causes AIDS by infecting T-cells of the immune system.

**Human papilloma virus (HPV)**: A causative agent of genital warts.

**IDSR**: See ‘Integrated disease surveillance and response.’

**IDU**: Acronym for ‘injection (injecting or intravenous) drug user.’

**Immune response**: The activity of the immune system against foreign substances such as infectious agents including bacteria and viruses.
**Immune system:** The body's complicated natural defence against disruption caused by invading foreign agents (for example, microbes or viruses).

**Immunodeficient:** A situation in which a patient’s health is compromised because his/her immune system is insufficient to ward off infections, thus making the person susceptible to certain diseases that they would not ordinarily develop.

**Immunology:** The science of the system of the body that fights infections.

**Impact evaluation:** An evaluation of a programme that determines what the impact of the programme is, as opposed to ‘process evaluation.’

**Impact indicators:** A standardised set of indicators developed by UNAIDS to help monitor HIV prevalence in particular populations.

**Incentive:** A reward or reimbursement given to participants in a study. In RDS surveys, there are typically two levels of incentive: primary incentive and secondary incentive. A participant receives the primary incentive for enrolling in the study and completing an interview. The same participant receives secondary incentive(s) for recruiting his or her peers into the study. Incentives are not absolutely necessary in every situation and should be determined during formative research.

**Incidence:** A measure of the frequency with which an event, such as a new case of illness, occurs in a population over a period of time. The denominator is the population at risk; the numerator is the number of new cases occurring during a given time period.

**Inclusion criteria:** Characteristics required in study participants, in order to be considered for the sample.

**Incubation period:** A period of sub-clinical or unapparent pathologic changes following exposure, ending with the development of the infection.

**Independent variable:** An exposure, risk factor, or other characteristic being observed or measured that is hypothesised to influence the outcome (that is, the dependent variable).

**Indicators:** Specific data that are gathered to measure how well a prevention or treatment programme is doing as well as define an aspect of behaviour that is key to the spread of HIV. Indicators provide a way to track changes in behaviours over time and provide a way to compare levels of risk behaviours between different population groups.

**Indicator mutations:** Genotypic mutations that best predict resistance to a specific antiretroviral agent.

**Indirect transmission:** The transmission of an agent carried from a reservoir to a susceptible host by suspended air particles or by animate (vector) or inanimate (vehicle) intermediaries.
**Infectiousness**: The ability of an organism to cause infection.

**Infectivity**: The proportion of persons exposed to a causative agent who become infected by an infectious disease.

**Information bias**: Error that results from people who have a disease being misclassified as not having the disease.

**Informed consent**: The permission granted by a patient or a participant in a research study after he or she has received comprehensive information about a research study or medical procedure. Informed consent protects the person’s freedom of choice and respects his or her autonomy with regard to decisions affecting his or her body and health.

**In-group affiliation**: In RDS, what homophily measures (group similarity based on ethnicity, age, socio-economic status and so forth).

**Injection drug users (IDUs)**: Also called ‘intravenous drug users,’ they are persons who use or have used needles or syringes to inject drugs. Injection drug use is considered a high-risk behaviour.

**Institutional review board (IRB)**: The committee designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim of protecting the rights and welfare of research participants. Also known as ethics committee.

**Institutional sampling**: Individuals in an institution, such as prison, are sampled.

**Integrated disease surveillance (IDS)**: An approach to surveillance in which communicable diseases are prioritised. Surveillance for all of the high-priority diseases is conducted in an integrated manner and is initiated at the district level. These diseases have a high potential for epidemic spread and can be controlled through public health measures.

**Internal validity**: The absence of substantial differences between groups at baseline; the absence of substantial difference of attrition rates between groups at follow-up.

**Internally displaced persons (IDPs)**: IDPs are persons who have left their homes due to civil unrest or natural disasters, but have stayed in their homeland and have not sought sanctuary in another country.

**Interval width**: The range of certainty as to the true value of the calculated outcome value. For example, in the case of a 95% confidence interval, there is 95% certainty that the true outcome lies between the upper and lower bound of the interval. Statistically, this interval is equal to two standard deviations on either side of the calculated outcome value.
**Interviewer error:** Problems stemming from the actions and behaviours of the person doing the interview.

**Intradermally:** Injected into the layers of the skin.

**Intramuscularly:** Injected into a muscle.

**Intravenously:** Injected into a vein.

**Involuntary migrants:** Involuntary migrants include persons who have migrated away or have been displaced from their home countries due to an established or well-founded fear of persecution, or have been moved as a result of deception or coercion.

**Isolates:** A population of bacteria or other cells that has been isolated and cultured.

**Isoniazid prophylaxis:** Giving isoniazid to individuals with latent Mycobacterium tuberculosis infection, in order to prevent the progression to active disease. Prophylaxis with isoniazid significantly reduces the incidence of tuberculosis in adults with HIV and a positive tuberculin skin test result.

**Key informants:** Members of the target group, who can often become informal assistants.

**Kick-off meeting:** A meeting you host for community members who may in turn become seeds for the RDS survey. The purpose of the meeting is to educate seeds on study goals and process, inform seeds of their importance to the success of the study and encourage the seeds to be enthusiastic.

**Klebsiella granulomatis:** The bacterial causative agent of granuloma inguinale or donovanosis.

**Laboratory-initiated reporting:** A surveillance system in which the reports of cases come from clinical laboratories.

**Laryngeal TB:** Tuberculosis involving the larynx, producing ulceration of the vocal cords and elsewhere on the mucosa, and commonly attended by hoarseness, cough, pain on swallowing, and hemoptysis.

**Latent period:** A period of unapparent infection following exposure to a pathogen, ending with the onset of symptoms of chronic disease.

**Lessons learned:** Information from actual studies that will help you make decisions when planning your study.

**Linked anonymous HIV testing:** In linked anonymous testing, a person agrees to have an HIV test, but the specimen is labelled with a code without a name or identifiers that could reveal the person’s identity. This method is voluntary and requires obtaining
inform consent and making the test results available (with appropriate counselling) to the person tested.

**Linked confidential HIV testing:** In linked confidential testing, a person agrees to have an HIV test with the assurance that the test result will be kept confidential and only selected health-care providers may be informed. This method is voluntary and requires obtaining informed consent and discussing the test results with the person. Linked confidential testing also allows for the collection of more detailed demographic and risk-behaviour information.

**Linking:** Refers to whether a tested individual’s names or identifying information is associated with his or her HIV test results.

**Listing units:** The sampling units from the final stage of a multistage sampling design. See enumeration units.

**Log scale:** In a graph, when the data covers a large range of values, they are presented on a logarithmic scale. This type of scale reduces data to a smaller range so that it is easier to work with.

**Longitudinal surveillance:** Surveillance over time during which patients’ status can be updated. *Longitudinal databases* allow the update of patients records over time with, for example, start dates for care, disease progression, new information.

**Low-level HIV epidemic:** The epidemic state in which HIV has never spread to significant levels in any sub-population, although HIV infection may have existed for many years. HIV prevalence has not consistently exceeded 5% in any defined sub-population. This state suggests that networks of risk are rather diffuse or that the virus has only been recently introduced.

**Lymphocytes:** A type of white blood cell that is involved with fighting infections in the body. The T lymphocyte is the cell that HIV infects and destroys.

**Macrophage cells:** Tissue cell derived from monocytes that protect the body against infections.

**Male sex workers:** Males who engage in sex work, or the exchange of sex for money, which includes many practices and occurs in a variety of settings.

**Mandatory testing:** Testing that is required of a patient if he or she is to obtain certain services; for example, mandatory HIV testing of individuals who request marriage certificates.

**Margin of error:** An estimation of the extent to which a survey’s reported percentages would vary if the same survey were taken multiple times.
**Markov process**: A mathematical theory that provides a probabilistic description of the state of a system at any future time. The Markov process is especially relevant to RDS because of the nature of the recruitment process, whereby a chain of peers recruiting peers is monitored through a coupon mechanism.

**Marriage pressure**: Family pressure on sons to marry to provide stability for parents and the continuation of the family name as well as to avoid the stigma of a person being MSM.

**MARP**: Acronym for most-at-risk population, a group within the community with an elevated risk of disease, often because group members engage in some form of high-risk behaviour.

**Masking**: Describes the behaviour of reclusive respondents, people who do not want to be found.

**Mean**: The measure of central location commonly called the average. It is calculated by adding together all the individual values in a group of measurements and dividing by the number of values in the group.

**Men who have sex with men (MSM)**: Men who have sex with men (MSM) are one of the highest risk groups in the Americas, Asia, Europe and Oceania. For the purposes of this manual, we also consider male sex workers, transvestites and transgendered persons (*hijra*) in the MSM category.

**Microbe**: A micro-organism, such as a bacteria or virus.

**Microbicide**: A chemical or other agent that destroys microbes.

**MICS**: See ‘Multiple Indicator Cluster Survey.’

**Migrants**: see ‘mobile populations’

**Mobile populations**: Refers collectively to groups of people who move from one place to another (migrants). They may move temporarily, seasonally, or permanently and for either voluntary or involuntary reasons.

**Monitoring**: Evaluating a programme’s performance over time.

**Monitoring and Evaluation (M&E)**: Collecting and analysing accurate and reliable information that can be used to improve programme performance and planning.

**Monocyte**: A type of white blood cell.

**Morbidity**: Any departure, subjective or objective, from a state of physiological or psychological well-being.
**Mortality rate**: A measure of the frequency of occurrence of death in a defined population during a specified interval of time.

**Mortality rate, infant**: A ratio expressing the number of deaths among children under one year of age reported during a given time period divided by the number of births reported during the same time period.

**MSC**: See ‘multi-stage cluster sampling.’

**MSM**: Acronym for ‘men who have sex with men.’

**MSW**: Acronym for ‘male sex worker.’

**MTCT**: Acronym for ‘mother-to-child transmission.’ See ‘perinatal transmission.’

**Multi-stage cluster sampling (MSC)**: Two- or more- stage sampling. Final units from selected clusters may be randomly selected.
- Simple two-stage cluster sampling
- Probability proportional to size sampling (PPS) is used when all clusters do not have the equal probability of being selected in the sample. PPS is a class of unequal probability sampling in which the probability of a unit being sampled is proportional to the level of some known variable (Levy & Lemeshow).

**Multivariate analysis**: One of the main types of analysis conducted in behavioural surveillance that is performed to look at the influence of at least two variables on another variable. Since relationships between variables are often complex and interwoven, multivariate techniques can pinpoint the individual effects of several explanatory variables on an outcome variable, which may be related to each other.

**Natural history of disease**: The temporal course of disease.

**Needs assessment**: A systematic examination of the type, depth and scope of a problem.

**Negative controls**: Specimens known to be negative and used to ensure that a laboratory reagent is working properly prior to testing specimens from patients.

**Negative predictive value**: In HIV testing, the probability that a person with a negative test result is not infected. Also known as ‘predictive value negative.’

**Neisseria gonorrhoeae**: The causative agent of gonorrhoea.

**Network**: This sampling method may be used for groups whose members are socially linked. Ego-centred network sampling is based on random, representative or any other form of quota sampling (Schensul). Full relational network sampling begins with identification of individuals (see ‘seeds’) who act as entry points to the network.

**NGO**: Acronym for ‘non-governmental organisation.’
**Nominal variable**: Variables that represent discrete categories without a natural order, such as marital status.

**Non-probability sampling**: The sampling units are selected through a non-randomised process; therefore, the probability of selecting any sampling unit is not known.

**Non-random mixing**: The tendency of people to associate preferentially with others who are like themselves.

**Non-vesicular genital ulcer disease**: An STI syndrome characterised by ulcers and the absence of vesicles.

**Notifiable disease**: A disease for which law or regulation requires reporting to the health authority.

**Numerator**: The upper portion of a fraction. In a rate, the numerator is usually the number of people infected.

**Operational definitions of target populations**: Definitions that are operationally useful for sampling and fieldwork purposes. For example, a definition that clearly identifies what constitutes a sex worker, in terms of duration of selling sex, form of payment, type of venue where they work, etc.

**Operations manual**: A document that describes every step to be taken during the implementation of a survey or study. Ideally, it provides standard operational procedures for every foreseeable occurrence.

**Opportunistic infections**: Illnesses caused by various organisms infecting immunodepressed persons that usually do not cause disease in persons with healthy immune systems. Persons with advanced HIV infection (that is, AIDS) suffer opportunistic illnesses of the lungs, brain, eyes, and other organs. These illnesses are referred to as AIDS-defining illnesses or conditions.

**Opt-in**: A patient or participant agrees to be tested.

**Opt-out**: A patient or participant refuses to be tested.

**Optical density**: The intensity of colour as measured by a machine in an EIA HIV antibody test, indicating whether the patient’s sample is HIV-positive.

**Ordinal variable**: Variables that have a natural order, such as level of education.

**Over-sampling**: A sample may obtain more members of a particular sub-group than their representation in the target population warrants. In some cases, over-sampling is carried on purpose to learn more about a small sub-group, such as female injection drug users in communities that are predominantly male.
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**p24 antigen**: A protein that appears in the serum of infected individuals approximately one week before HIV antibodies appear, or about 14 days after actual infection. In very large sero-surveys, persons who tested negative for HIV antibody can be retested for p24 antigen.

**Pandemic**: An epidemic occurring over a very wide geographic area (several countries or continents) and usually affecting a large proportion of the population. HIV is an example of a pandemic.

**Parameter**: The summary numerical description of variables about the target population.

**Parenteral transmission**: Transmission of an infectious agent through blood. Parenteral transmission of HIV can occur from the sharing of injection drug equipment, from transfusions with infected blood or blood products, or from needle stick injuries.

**Participant observation**: A qualitative research method in which direct observation is carried out over a period of time, and which is understood and accepted by the group being observed.

**Participation bias**: Error in results from a study that is due to differences in characteristics between those who participate in a survey and those who do not. For example, persons who already know they are HIV-infected may find testing unnecessary; those who suspect they are HIV-infected may decline testing in order to avoid stigma.

**Partner concurrency**: Having extensive sexual network connections to many persons at the same time, which increases the spread of HIV and STIs.

**Passive surveillance**: A system in which a health-care provider or worker notifies the health authority of any cases of these diseases, as opposed to ‘active surveillance.’

**Pathogen**: A biological agent that causes disease or illness to its host (for example, bacteria or virus).

**Payment coupon**: Kept by the recruiter. He/she will use it to claim an incentive for having recruited a peer into the study.

**Perinatal transmission**: Transmission of an infectious agent, such as HIV, from mother to baby before, during, or after the birth process. Also known as ‘vertical transmission’ or ‘mother-to-child transmission.’

**Period prevalence**: The amount a particular disease that is present in a population over a specified period of time.

**Pie chart**: A circular chart in which the size of each ‘slice’ is proportional to the frequency of each category of a variable. A pie chart compares subclasses or categories to the whole class or category using different coloured slices.
PLACE: See ‘Priorities for local AIDS control efforts.’

PLWHA: Acronym for ‘Persons living with HIV/AIDS.’

PMTCT: Acronym for ‘prevention of mother-to-child transmission.’

Point estimate: The amount of a particular disease present in a population.

Point prevalence: Refers to prevalence at a single point in time. Also known as ‘point incidence.’

Population: The total number of inhabitants of a given area or country. In sampling, the population may refer to the unit from which the sample is drawn, not necessarily the total population of people.

Population-based sero-survey: A type of sero-survey that uses a probability sample of a population defined by geographic boundaries, such as villages or provinces, in order to obtain a direct measure of HIV prevalence in a general population.

Population sub-group: A group within a population that share certain characteristics or behaviours.

Positive controls: Specimens known to be positive, as used in proficiency testing.

Positive predictive value: The probability that a person with a positive test result is infected; in surveillance this refers to the proportion of cases reported by a surveillance system or classified by a case definition which are true cases. Also known as ‘predictive value positive.’

PPS: See ‘Probability proportional to size sampling.’

Precision: Refers to how well the results can be reproduced each time the survey is conducted.

Presumptive clinical diagnosis: Diagnosis made solely on the basis of symptoms, without the use of specific diagnostic tests.

Pre-surveillance assessment: Describes a set of activities that occur prior to beginning formal HIV and behavioural surveillance in high-risk groups. These activities include developing detailed plans and reviewing and collecting information that will help in planning and designing surveillance activities.

Prevalence: The proportion of persons in a given population with a disease or condition at a given point in time; a specific group infected. Prevalence is a direct measurement of the burden of disease in a population.
Prevalence assessment: Surveys that determine prevalence of a disease in a population.

Prevalence monitoring: Monitoring prevalence repeatedly over time to track trends.

Primary incentive: The incentive a participant gets for enrolling in the study and completing an interview.

Primary units: A sampling frame of larger unit. When it is difficult or impossible to make a list/sampling frame of each individual in the target population, we can develop a sampling frame of some larger unit; that is, clusters or primary sampling units. We then sample in stages by first sampling clusters and then sampling people within the clusters.

Priorities for Local AIDS Control Efforts (PLACE): A new, rapid assessment tool used to identify high transmission areas, which formalises the collection of information on high transmission areas. PLACE uses key informants to identify sites where people meet new sex partners, then interviews people at the site in order to characterise the site in each area and map sites, and, finally, interviews individuals socialising at the site to describe the characteristics of the people at the site.

Priority communicable disease: These are diseases that have the potential for epidemic spread and can be controlled through public health action. They are the diseases included in the Integrated Disease Surveillance form.

Prisoner: Any person involuntarily confined or detained in a penal institution, including persons detained pending arraignment, trial, or sentencing.

Probability proportional to size sampling: A class of unequal probability sampling in which the probability of a unit being sampled is proportional to the level of some known variable (Levy & Lemeshow).

Probability sampling: A sampling scheme that ensures that each entity in a population has a known, non-zero chance of being selected.

Process evaluation: An evaluation of a programme that determines how well the programme is functioning, as opposed to 'impact evaluation.'

Proficiency panel: A set of samples designed to judge the accuracy and precision of a laboratory. A necessary component of laboratory quality assurance. In the context of HIV testing this may be a group that contains approximately six HIV-negative and HIV-positive (weak to strong) specimens representative of the HIV strains circulating in a country and of the different stages of HIV infection. The panel should be sent to participating laboratories once or twice each year for quality assurance testing.

Proficiency testing: The act of sending a proficiency panel to a laboratory, designed to test the accuracy and precision of that laboratory.
**Prophylaxis:** Treatment to prevent or suppress infection, often given before a person’s exposure to the pathogen. For example, the treatment given to mother’s during childbirth in order to prevent infection of the newborn child.

**Proportion:** The relationship of a part to the whole, in which the numerator is included in the denominator; often depicted as a percent by multiplying by 100.

**Prospective case reporting:** To watch a group of cases for outcomes, such as the development and progress of HIV disease, over time and to relate this to other factors such as suspected risk or protection factors.

**Prostitués homosexuels:** Homosexual prostitutes. Male sex workers who identify as homosexual or gay.

**Protocol:** The detailed plan for conducting a research study or other activities in which specific steps are required, including surveillance activities.

**Purposive sampling:** A non-random sampling method that involves choosing respondents with certain characteristics.

**Qualitative research:** Research that focuses on the characteristics or quality of things, rather than the quantity. The sample included qualitative research is usually much less used than that included in quantitative research.

**Quality assurance:** The dynamic and ongoing process of monitoring a system for reproducibility and reliability of results that permits corrective action when established criteria are not met.

**Quality control:** A laboratory’s internal processes for running specimens to ensure that the test equipment and reagents function properly.

**Quantitative research:** Research that focuses on quantity of things, rather than the quality. Quantitative research has powerful tools for the analysis of numbers, but researchers know that the things counted are often qualitative categories or definitions.

**Questionnaire faults:** Problems with the way questions are phrased, set out and ordered, which lead to misunderstandings of the questions.

**Random error:** Also called non-systematic error. This is the type of error that results from chance and leads to imprecise results.

**Random sample:** A sample derived by selecting individuals such that each individual has the same probability of selection.

**Random walk:** A variation of link-tracing sampling procedure in which the respondent is asked to give the names of other members of a hidden population. From that list, one is
selected randomly, located and added to the sample. The process is repeated for a desired number of waves. (S.K. Thompson et al.)

**Range:** The difference between the largest and smallest values in a distribution.

**Rapid assessment and response (RAR):** A method that is used to assess the nature and extent of a public health problem and to suggest ways to address the problem. RAR is not designed as a surveillance tool, but as a way to assess a situation quickly, and bring in resources to address it.

**Rapid HIV test:** An HIV antibody test that is simple, does not require any reagents or equipment other than what is contained in the kit and provides results in less than 20 minutes.

**Rapid plasma reagin test (RPR):** A common serologic test for syphilis. Specifically, a non-treponemal test for anticardiolipin antibodies.

**Rate:** An expression of the frequency with which an event occurs in a defined population.

**Ratio:** The quantitative relationship between two or more things; the value obtained by dividing one quantity by another.

**RDS:** See ‘Respondent driven sampling.’

**RDSAT:** Acronym for respondent driven sampling analysis tool (a freeware software package for analysing RDS data).

**Reference laboratory:** A laboratory that functions as a recognised centre of expertise and standardisation of diagnostic techniques.

**Referral coupon:** Used by the recruiter to recruit a peer into the study.

**Refugees:** By legal definition, refugees are persons who are outside their country of nationality and who are unable or unwilling to return to that country. They cannot return due to a well-founded fear of persecution because of race, religion, political opinion or membership in an ethnic or social group.

**Relative risk:** A comparison of the risk of some health-related event such as disease or death in two groups. For example, an HIV-uninfected individual who has sexual intercourse with an HIV-infected person once a year may have a 5% chance of infection. But if the uninfected individual uses a condom every time, the relative risk when compared to condom non-use is 15%.
**Reliability**: Refers to how reproducible a result is from repeated applications of a measure to the same subject.

**Representative sample**: A sample whose characteristics correspond to those of the original population or reference population.

**Representativeness**: The degree to which the sample truly reflects the study population (that is, whether it is representative of the study population).

**Resistance**: The ability of an organism, such as HIV, to overcome the inhibitory effect of a drug.

**Resource assessment**: A component of RAR, a systematic examination of the response (funds, people, buildings, knowledge) that is either available or required to solve the problem.

**Respondent driven sampling (RDS)**: A sampling technique that does not require a sampling frame. It is an adaptation of a non-probability sampling method (snowball sampling) and is based on the assumption that members of the sub-population themselves can most efficiently identify and encourage the participation in surveillance of other sub-group members. RDS starts with initial contacts or 'seeds' who are surveyed and then become recruiters. Each of these recruiters is given coupons to use to invite up to three eligible people that he/she knows in the high-risk group to be interviewed. The new recruits bring their coupon to a central place where they are interviewed. The recruits then become recruiters. This occurs for five to six waves. Both the recruits and the recruiters are given incentives to encourage participation.

**Retrospective case reporting**: To look backwards and examine exposures to disease, for example, HIV infection, and suspected risk or protection factors in relation to an outcome (infection) that is established at the start of the reporting.

**Retrovirus**: A type of RNA virus that produces reverse transcriptase which converts RNA into DNA. HIV is an example of a retrovirus.

**Reverse-transcription**: The process by which HIV’s genetic material (RNA) is transformed into DNA, which allows it to fuse with the host’s genetic material (DNA).

**RIBA**: Acronym for recombinant immunoblot assay, also known as Western blot. Immunoblot assays confirm anti-HCV reactivity. Serum is incubated on nitrocellulose strips on which four recombinant viral proteins are blotted. Color changes indicate that antibodies are adhering to the proteins. A positive result is if two or more proteins react and form bands. An indeterminate result is if only one positive band is detected.

**Risk**: The probability that an event will occur; for example, that an individual will become ill within a stated period of time.
Risk factor: An aspect of personal behaviour or lifestyle; an environmental exposure; an inborn, inherited, or demographic characteristic. Associated with an increased occurrence of disease or other health-related event or condition. For example, injection drug use is a risk factor for acquiring HIV.

RPR: See ‘Rapid Plasma Reagin test.’

Safety protocol: A study document that describes how to deal with field incidents or adverse events.

Sample: A selected subset of a population. There are specific types of samples used in surveillance and epidemiology such as convenience, systematic, population-based and random.

Sample size: The number of subjects to be used in a given study.

Sample frame: A list of units from which a sample may be selected. A sample frame is a fundamental part of probability sampling.

Sampling bias: Also called selection bias. This refers to errors in sampling that decrease accuracy and lead to incorrect estimates. We also use the term ‘biased samples’ to mean that errors were made in choosing the people in the sample.

Sampling element: Individual member of the population whose characteristics are to be measured. See ‘Sampling unit.’

Sampling error: The part of the total estimation error of a parameter caused by the random nature of sampling.

Sampling interval: The standard distance between elements selected in the sample population.

Sampling scheme: Procedure for choosing individuals to be included in a sample.

Sampling units: Refers to individual members of the population whose characteristics are to be measured. See ‘Sampling element.’

Sampling variation: Difference between the estimate you measure in a sample and the true value of the variable in the study population.

Scale line graph: A graph that represents frequency distributions over time where the Y-axis represents frequency and the X-axis represents time

Second-generation surveillance: Built upon a country's existing data collection system, second-generation HIV surveillance systems are designed to be adapted and modified to meet the specific needs of differing epidemics. This form of surveillance aims to improve...
the quality and diversity of information sources by developing and implementing standard and rigorous study protocols, using appropriate methods and tools. Second generation surveillance refers to activities outside of those activities generally considered to be a part of routine case surveillance such as case reporting and sentinel sero-surveys and uses additional sources of data to gain additional understanding of the epidemic. It includes biological surveillance of HIV and other STIs, as well as systematic surveillance of the behaviours that spreads them.

**Secondary incentive**: The incentive a participant gets for recruiting his or her peers into the study.

**Seeds**: Non-randomly selected (by the investigators) members of the target population who will initiate the RDS recruitment process by recruiting members of his or her peer group. From each seed, a recruitment chain is expected to grow.

**Selection bias**: A systematic error in the process respondent selection for a study or survey.

**Sensitivity**: The proportion of persons with disease who are correctly identified by a screening test or case definition as having disease.

**Sentinel case reporting**: Reporting cases of a disease from sentinel sites.

**Sentinel populations**: Populations that are subject to sentinel surveillance activities. They may not necessarily be representative of the general population, but rather they might be the first affected by HIV. Examples include sexually transmitted infection patients or truck drivers.

**Sentinel sites**: Sites at which sentinel surveillance activities take place, including clinics attended by individuals who may or may not be representative of the general population but are likely to represent groups initially infected or at higher risk for infection than the general population.

**Sentinel surveillance**: A surveillance system in which a pre-arranged sample of reporting sources at ‘watch post’ or ‘sentinel’ sites agrees to report all cases of one or more notifiable conditions. Often designed to provide an early indication of changes in the level of disease. Depending on the nature of the population surveyed, these data may be representative of the general population, or they may simply give more detailed information about the populations tested.

**Sero-conversion**: The development of antibodies to a particular microbe. When people develop antibodies to HIV, they ‘sero-convert’ from HIV-negative to HIV-positive.

**Sero-incidence surveillance**: Collecting blood samples for measuring newly acquired HIV infection for the purposes of surveillance.
Serologic test: A blood test that determines the presence of antibodies to particles such as viruses. For example, a blood test that detects the presence of antibodies to HIV.

Sero-prevalence: The proportion of a population that is infected, as determined by testing blood for the appropriate antibody. For example, the proportion of a population that is infected with HIV, as determined by testing for HIV antibodies in blood samples.

Sero-prevalence surveillance: Collecting blood samples for the purpose of surveillance. Latent, sub-clinical infections and carrier states can thus be detected, in addition to clinically overt cases. This is especially important in the case of HIV and other STIs, which often have a long latent period before symptoms are apparent.

Sero-status: Refers to the presence/absence of antibodies in the blood. For example, the presence or absence of HIV.

Sero-surveillance: Collecting blood samples for the purpose of surveillance. Latent, sub-clinical infections and carrier states can thus be detected, in addition to clinically overt cases. This is especially important in the case of HIV and other STIs, which often have a long latent period before symptoms are apparent.

Sexual transmission: Transmission of an infectious agent, such as HIV, that occurs predominately through unprotected vaginal or anal intercourse, and less frequently through oral intercourse.

Sexually transmitted diseases: Symptomatic. Caused by organisms that are spread by sexual contact from person to person.

Sexually transmitted infection (STI): Asymptomatic. Diseases that are spread by the transfer of organisms from person to person during sexual contact.

Sex workers (SWs): Persons who engage in sex work, or the exchange of sex for money, which includes many practises and occurs in a variety of settings. These may include ‘direct’ or ‘formal’ sex workers, who are sometimes included in registries and often found in brothels, and ‘indirect’ or ‘casual’ sex workers, who do not engage in sex work full time and are unlikely to be included in registries. The term ‘sex worker’ can be used to refer to female, male and transgendered sex workers.

Simple random sampling (SRS): Sampling where everyone has an equal chance of being randomly selected (a non-zero probability) and we know what that chance is.

Skewed: A distribution that is asymmetrical and does not follow a normal (bell-shaped) distribution.

Snowball sampling: Relies on informants to identify other relevant study participants in a chain referral pattern. Informants (seeds) who meet inclusion criteria are identified.
This sampling design is based on chain referral and relies on the seed(s) to identify other relevant subjects for study inclusion. Those other subjects may identify other relevant subjects for inclusion. Snowball sampling is useful for studying populations that are difficult to identify or access. Representativeness is limited.

**Social influence:** Mild peer pressure from the recruiter who will receive a secondary incentive for recruiting his/her peers.

**Social network:** Members of a peer group who know each other.

**Socio-metric stars:** Seeds who are not only willing to recruit their peers, but are well-regarded by their peers and have a lot of them. Such seeds are more likely to influence others to be recruited into the study.

**Specificity:** The proportion of persons without disease who are correctly identified by a screening test or case definition as not having disease.

**SRS:** See simple random sampling.

**Stacked bar chart:** See ‘clustered bar chart.’

**Stakeholders (or stakeholder’s group):** Those with an interest in the results of surveillance activities. Includes public health practitioners, healthcare providers, data providers and users, representatives of affected communities; governments at the district, province and national levels; members of professional and private non-profit and donor organisations.

**Standard error:** Estimate of precision in probability sampling that can be used to construct a range of values within which the true population measure is likely to fall. We usually want to be 95% sure that the true population measure lies in our range.

**Standardised Testing Algorithm for Recent HIV Sero-conversion (STARHS):** A calculation for measuring new infection that uses a single blood test. STARHS uses the results of two EIA tests, one highly sensitive and another modified to be less sensitive. The less sensitive EIA test is called the ‘detuned’ assay.

**Statistics:** A branch of applied mathematics concerned with the collection and interpretation of quantitative data and the use of probability theory to estimate population parameters.

**Steering method:** In RDS, using additional methods to recruit a special sub-population of interest; for example, providing an extra coupon to be used only to recruit female IDUs.

**STI:** See ‘sexually transmitted infection.’
Stigma: A mark of disgrace or shame. For example, in some societies, being infected with HIV causes a person to be stigmatised.

Strata: A sub-group in stratified sampling.

Strategic information (SI): Refers to any data collected by surveillance or monitoring and evaluation of a programme or system. Includes, but is not limited to, process indicators, output indicators and surveillance data.

Stratification: The classification of a survey population into sub-groups or strata on the basis of selected characteristics.

Stratified and constant incentives: In a study of SWs, a constant incentive level was considered too low to attract the more hidden SWs who earned a higher income. The research team considered using a stratified incentive process. The SWs received an incentive based on the type of sex work they did. For instance, a street-based SW received a $5.00 incentive, while a call-girl-type SW received a $10.00 incentive.

Stratified sampling: Stratified sampling is generally used to obtain a representative sample when the population is heterogeneous, or dissimilar, where certain homogeneous, or similar, sub-populations can be isolated (strata). A stratified sample is obtained by taking samples from each stratum or sub-group of a population.

Street children: Children who live and/or work on the streets, including orphaned, homeless, runaway, or neglected children who live chiefly in the streets without adequate protection, supervision, or direction from responsible adults.

Subcutaneously: Below the skin, as in an injection.

Sub-population: See ‘population sub-group.’

Sufficient cause: A causal factor or collection of factors whose presence is always followed by the occurrence of the effect (of disease).

Surveillance: The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community, in order to control and prevent disease in the community.

Surveillance sites: The places from which case reports are obtained. This includes sites at which universal reporting and sentinel reporting are done. These may be healthcare facilities or other locations at which sero-surveys are conducted.

Survey population: The target population modified to take into account practical considerations (for example, all commercial sex workers in a city over the age of 15, excluding those who are based at home, as they cannot be accessed).
**Survey protocol:** A manual that describes all the steps and tasks involved in a sero-survey.

**Survival sex:** To barter sex for the necessities of living, such as food, shelter, goods, money. Engaged in by vulnerable populations, for example, by displaced women, street children, and transgendered people who are marginalised and discriminated against.

**Susceptible:** Vulnerable or predisposed to a disease.

**Symptomatic:** Exhibiting symptoms.

**Symptoms:** Any perceptible, subjective change in the body or its functions that indicates disease or phases of disease, as reported by the patient.

**Syndrome:** A group of symptoms as reported by the patient and signs as detected in an examination that together are characteristic of a specific condition.

**Syndromic case reporting:** A surveillance system in which a diagnosis of the infection is made through the presence of symptoms using a standard case definition. Frequently used for surveillance of sexually transmitted infections in countries in which access to laboratory testing may be limited.

**Syndromic prevalence:** The prevalence of a particular syndrome, or set of symptoms, in a given population. Usually calculated when testing equipment is not available to verify the presence of particular pathogen in a laboratory.

**Syphilis:** A sexually transmitted disease resulting from infection with the bacterium *Treponema pallidum*. Syphilis can also be acquired by newborns from their mothers during pregnancy.

**Systematic sampling:** A sampling method that consists of randomly selecting the initial patient who meets the inclusion criteria and then selecting every ‘nth’ (for example, third or fifth) eligible patient thereafter until the predetermined sample size is reached or the survey period is over.

**Systemic:** Concerning or affecting the body as a whole.

**Table:** A set of data arranged in rows and columns.

**Target population:** The group that meets a survey’s measurement objective (for example, all commercial sex workers in a city).

**Targeted sampling:** Targeted sampling uses pre-existing indicator data (qualitative and quantitative) to construct a sampling frame from which recruitment sites are then randomly selected. Qualitative indicator data includes ethnographic data and key informant interviews. Types of quantitative indicator data include cases of HIV/AIDS.
and STIs, admissions to drug treatment and population characteristics from census data. There are several limitations: 1) indicator data may not be useful in characterising the target population; 2) sampling may be biased and difficult to replicate; 3) geographic areas may not be sampled in proportion to the number of members in the population of interest; 4) the population of interest may not be sampled in proportion to the intensity of risk behaviour and 5) the probability of selecting a member of the population of interest may not be known.

**TB:** Acronym for tuberculosis.

**Testing (HIV) strategy:** The use of an appropriate HIV test or combination of HIV tests. The choice of testing strategy used is based on the objective of the test, the sensitivity and specificity of the test, and HIV prevalence in the population being tested.

**T-helper lymphocyte:** Also known as ‘T-cell.’ Immune cells that seek and attack invading organisms. HIV enters T-cells through their CD4 receptor proteins, making T-cells virtual HIV-factories.

**Time-location sampling (TLS):** Similar to conventional cluster sampling, but gets around the problem of clusters that are not stable (that is, clusters where the number and type of people vary by, for example, time of day). Time-location sampling allows the same site to be included in the sample frame more than once (for example, at different times of the day or different days of the week).

**Timeliness of reporting:** One of several attributes of a surveillance system. Timeliness may be defined as the time period between the diagnosis of the disease and the receipt of a case report form at the health district.

**Transactional sex:** Distinct from other forms of commercial sex. Includes the receipt of gifts or services in exchange for sex.

**Transgendered persons:** Persons who identify with or express a gender and/or sex different from their biologic sex.

**Transition probability:** The likelihood that a person will change from one state to another, for example becoming HIV positive.

**Transmission:** Any mode or mechanism by which an infectious agent is spread through the environment or to another person.

**Trend:** A long-term movement or change in frequency, usually upwards or downwards.

**Treponema pallidum:** The bacterial causative agent of syphilis.
**Triangulation:** The process of examining several different sets of data, which are measuring different things to come up with a better understanding of how and where an epidemic is spreading. For example, the use of antenatal clinic data, census data, and registered deaths in order to create a more complete picture of the AIDS burden in a country.

**Trichomonas vaginalis:** A sexually transmitted protozoan parasite that causes the vaginal infection, *trichomoniasis*, characterised by itching, burning and vaginal discharge. Reinfection is common if sexual partners are not treated simultaneously.

**True negatives:** Test results that are negative when the patient actually does not have the disease that is being tested for.

**True positives:** Test results that are positive when the patient actually has the disease that is being tested for.

**Tuberculosis:** An airborne, often fatal bacterial infection caused by *Mycobacterium tuberculosis*. It causes damage to the lungs and other parts of the body. Infection is more likely in people with weak immune systems.

**UAT:** See ‘unlinked anonymous testing.’

**UNAIDS:** Acronym for The Joint United Nations Programme on HIV/AIDS.

**UNGASS:** Acronym for United Nations General Assembly Special Session on HIV/AIDS.

**Univariate analysis:** The most basic, yet often the most important, type of behavioural surveillance analysis, because it shows the distribution of each variable. Most of the indicators defined for behavioural surveillance purposes are calculated through univariate analysis. They would include variables like the proportion of young men who have had sex with more than one partner during a given time period. When trends are analysed, statistical techniques are used to calculate how likely it is that changes in the proportions could have occurred by chance, or whether observed changes are likely to reflect real changes.

**Universal case reporting:** A surveillance system in which all persons who are identified as meeting the case definition for a particular disease are reported. For example, all persons with AIDS who receive care at any healthcare facility are reported. This is in contrast to sentinel reporting in which only selected sentinel sites report all persons who meet the case definition.

**Universal conscription:** Military conscription in which all physically able men between certain ages (for example 17–28) must perform military service.
**Universal precautions:** Recommendations issued by CDC to minimise the risk of transmission of bloodborne pathogens, particularly HIV and HBV, by healthcare and public safety workers. Barrier precautions are to be used to prevent exposure to blood and certain body fluids of all patients.

**Unlinked anonymous testing (UAT):** Testing that occurs when a sample of blood originally collected for other purposes is tested for HIV after being anonymised. The person whose blood is taken does not know that his/her blood will be tested for HIV. All information that could identify the person is removed from the sample so that the results of the test cannot be linked back to them.

**Unprotected sex:** Having sex without using a condom as protection against HIV and other sexually transmitted infections.

**Urethritis:** Inflammation of the urethra.

**Vaccine:** When injected into an individual, a vaccine protects against subsequent infection by a particular organism or results in a less severe illness should infection occur. Currently there is no vaccine for HIV.

**Validity:** The validity of a measure is the extent to which it actually measures what it is suppose to measure: the truth.

**Values:** Magnitude of measurements (statistics).

**Variable:** Any characteristic or attribute that can be measured.

**VCT:** See ‘voluntary counselling and testing.’

**VDRL:** See ‘Venereal Disease Research Laboratory test.’

**Venue-based:** Locations in the community, such as bars, tea houses, and street corners.

**Venue-based sampling:** Recruit respondents in places and at times where they would reasonably be expected to gather. The venues act as screeners in identifying potential respondents. Venue-based sampling requires comprehensive formative research.

**Venereal Disease Research Laboratory test (VDRL):** A common serologic test for syphilis. Specifically, a non-treponemal test for anticardiolipin antibodies.

**Vertical surveillance system:** See ‘categorical surveillance system.’

**Vertical transmission:** See ‘perinatal transmission.’

**Vesicular:** Pertaining to vesicles or blisters.
**Viral load**: The amount of HIV in the circulating blood. Also known as ‘viral burden’ or ‘viral dose.’

**Viral load test**: Test that measures the quantity of HIV in the blood.

**Virulence**: The relative capacity of an organism to overcome the body’s immune defences.

**Virus**: Micro-organisms that typically contain a protein coat surrounding nucleic acid (RNA or DNA) that are capable of growth only within living cells.

**Vital records**: Certificates of birth, death, marriage and divorce that are required by law.

**Voluntary counselling and testing (VCT)**: A programme that provides both counselling and testing services to communities, allowing persons who are tested to obtain emotional and medical support before and after their HIV tests.

**Voluntary migrants**: People who temporarily work or travel away from their homes.

**Volunteerism**: A term used to describe overly cooperative subjects, leading to a potential bias if such cooperative people differ from the rest of the population of interest.

**Vulnerable population**: A group whose members are discriminated against and who face stigma, making them vulnerable to negative consequences of surveillance, including social and physical harm.

**Western blot**: A type of HIV test, Western blot uses an electroblotting method in which proteins are transferred from a gel to a thin, rigid support and detected by binding of labeled antibody to HIV.

**WHO**: Acronym for the ‘World Health Organization.’

**Width**: See ‘interval width.’

**X-axis**: The horizontal line of a graph, usually found at the bottom.

**Y-axis**: The vertical line of a graph, usually found at the left but sometimes also at the right.

**Years of potential life lost**: A measure of the impact of premature mortality on a population, calculated as the sum of the differences between some predetermined minimum or desired life span and the age of death for individuals who died earlier than that predetermined age.

**YLL**: See ‘years of potential life lost.’
Notes
Appendix C, Links

Organisational Sites

The Global Fund to Fight AIDS, Tuberculosis and Malaria
The Global Fund was created to finance a dramatic turn around in the fight against AIDS, tuberculosis, and malaria. These three diseases kill more than six million people a year. This massive scaling-up of resources is already supporting aggressive interventions against all three.
www.theglobalfund.org

World Bank, The Global HIV/AIDS Program
The Global HIV/AIDS Program was created in 2002 to support the World Bank’s efforts to address the HIV/AIDS pandemic from a cross-sectoral perspective. The program offers global learning and knowledge sharing on approaches and best practices to addressing HIV/AIDS.
http://www1.worldbank.org/hiv_aids/globalprogram.asp

World Health Organization (WHO)
The World Health Organization is the United Nations specialised agency for health. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. WHO is governed by 192 Member States through the World Health Assembly. The Health Assembly is composed of representatives from WHO's Member States.
www.who.int

WHO: Department of HIV/AIDS
The HIV/AIDS Department co-ordinates a strategic, organisation-wide response to the HIV/AIDS epidemic and enables WHO to provide enhanced technical support in HIV/AIDS to countries and regional offices.
www.who.int/hiv/en

WHO: Regional Office for Africa (AFRO)
Co-ordinates public health activities for the African region.
www.afro.who.int

WHO-AFRO Office of Surveillance, Response and Monitoring
Its mission is to contribute to the prevention and control of HIV/AIDS and STIs by strengthening HIV/AIDS and STI surveillance in the WHO African Region.
www.afro.who.int/aids/surveillance
HIV Sero-surveillance

WHO-AFRO Integrated Disease Surveillance (IDS)
The mission of the IDS is to contribute to the improvement of epidemic preparedness and response and to the control of communicable diseases in the African region.
www.afro.who.int/csr/ids

UNAIDS (Joint United Nations Programme on HIV/AIDS)
As the main advocate for global action on HIV/AIDS, UNAIDS leads, strengthens and supports an expanded response aimed at preventing the transmission of HIV, providing care and support, reducing the vulnerability of individuals and communities to HIV/AIDS and alleviating the impact of the epidemic.
www.unaids.org

Epidemiological information on HIV/AIDS from UNAIDS
The UNAIDS reference group on estimates, models, and projections provides the relevant technical basis for the UNAIDS/WHO global estimates and projections of HIV prevalence. Issues covered include estimation of HIV incidence and prevalence, AIDS mortality, orphanhood, and the role of epidemiology in planning prevention programmes.

United Nations Children's Fund (UNICEF)
UNICEF is one of the United Nations’ key agencies in the fight against HIV/AIDS, mobilizing financial resources and helping persuade governments to put HIV/AIDS at the top of their agendas and to treat the epidemic as a national emergency. UNICEF is working in 160 countries around the world to combat the epidemic.
www.unicef.org/aids

Family Health International (FHI)
Family Health International has pioneered ways to curtail the spread of HIV/AIDS. Many of the HIV prevention "best practices" in use today have emerged from FHI’s work in more than 60 countries.
www.fhi.org/en/HIVAIDS

The Body
An AIDS and HIV Information Resource based in New York City, NY, USA. Provides Information on various questions related to HIV/AIDS
www.thebody.com

HIV InSite
HIV InSite is developed by the Center for HIV Information (CHI) at the University of California, San Francisco (UCSF). HIV InSite's mission is to be a source for comprehensive, in-depth HIV/AIDS information and knowledge.
hivinsite.ucsf.edu
PlusNews
PlusNews is an e-mail and Internet-based HIV/AIDS information service for Sub-Saharan Africa, run by the Integrated Regional Information Network (IRIN), a news service that forms part of the UN Office for the Coordination of Humanitarian Affairs (OCHA).
www.plusnews.org

Cochrane HIV/AIDS Group
An affiliate of the International AIDS Society and the UCSF AIDS Research Institute, the Cochrane Collaborative Review Group on HIV Infection and AIDS is an international network of health-care professionals, researchers and consumers working to prepare, maintain and disseminate systematic reviews on the prevention and treatment of HIV infection and AIDS.
http://www.igh.org/Cochrane/

US Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) Sites

Centers for Disease Control and Prevention (CDC)
CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States.
www.cdc.gov

Global AIDS Program (CDC)
The Global AIDS Program (GAP) exists to help prevent HIV infection, improve care and support and build capacity to address the global HIV/AIDS pandemic.
www.cdc.gov/nchstp/od/gap

Division of HIV/AIDS Prevention (CDC)
The mission of the Division of HIV/AIDS Prevention is to prevent HIV infection and reduce the incidence of HIV-related illness and death, in collaboration with community, state, national and international partners.
www.cdc.gov/hiv/dhap.htm

National Center for HIV, STD, and TB Prevention (CDC)
Umbrella organisation at the CDC for the divisions listed above.
www.cdc.gov/nchstp/od/nchstp.html

National Institutes of Health (NIH)
National Institutes of Health is the Federal focal point for medical research in the United States. The NIH, comprising 27 separate institutes and centres, is one of eight health agencies of the Public Health Service, which, in turn, is part of the U.S. Department of Health and Human Services. Simply described, the goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose and treat disease and disability.
www.nih.gov
HIV Sero-surveillance

National Library of Medicine (NLM)
NLM provides a wide variety of resources related to the biomedical and health sciences. The Web site has information on how to access the various NLM databases, including how to establish an account for free access to its HIV/AIDS databases.
www.nlm.nih.gov

National Institute of Allergy and Infectious Diseases (NIAID)
News releases from the NIH's primary AIDS research institute, plus AIDS reagent programme catalogue and other information.
www.niaid.nih.gov

National Institute on Drug Abuse (NIDA)
NIDA's mission is to lead the nation in bringing the power of science to bear on drug abuse and addiction. This charge has two critical components: The first is the strategic support and conduct of research across a broad range of disciplines. The second is ensuring the rapid and effective dissemination and use of the results of that research to significantly improve drug abuse and addiction prevention, treatment, and policy.
www.nida.nih.gov

Division of AIDS and Health and Behavior Research of the National Institute of Mental Health
The Division of AIDS and Health and Behavior Research (DAHBR) supports research and research training to: develop and disseminate behavioral interventions that prevent HIV/AIDS transmission, clarify the pathophysiology and alleviate the neuropsychiatric consequences of HIV/AIDS infection and use a public health model to reduce the burden of mental illness.
www.nimh.nih.gov/dahbr/dahbr.cfm

National Institute for Child Health & Human Development (NICHD)
NICHD is part of the National Institutes of Health, the biomedical research arm of the US Department of Health and Human Services. The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from the reproductive process, and that all children have the chance to fulfil their potential for a healthy and productive life, free of disease or disability.
www.nichd.nih.gov

Fogarty International Center
The Fogarty International Center promotes and supports scientific research and training internationally to reduce disparities in global health.
www.fic.nih.gov
NIH Office of AIDS Research (OAR)
NIH’s OAR is located within the Office of the Director of NIH and is responsible for the scientific, budgetary, legislative and policy elements of the NIH AIDS research program.
http://www.oar.nih.gov/

Other U.S. Government Sites

United States Agency for International Development
USAID is an independent federal government agency that receives overall foreign policy guidance from the Secretary of State. The agency works to support long-term and equitable economic growth and to advance U.S. foreign policy objectives by supporting: economic growth, agricultural and trade, global health, democracy, conflict prevention and humanitarian assistance.
www.usaid.gov

Development Experience Clearinghouse
The Development Experience Clearinghouse (DEC) is the largest online resource for USAID-funded, international development documentation, including fact sheets on HIV/AIDS in Africa.
www.dec.org

United States Department of Commerce, U.S. Census Bureau’s International Programs Center
The International Programs Center, part of the Population Division of the U.S. Bureau of the Census, conducts demographic and socio-economic studies and strengthens statistical development around the world through technical assistance, training, and software products. The IPS maintains an HIV/AIDS Surveillance database, the Monitoring the AIDS Pandemic (MAP) Network, and a series of HIV/AIDS country profiles.
http://www.census.gov/ipc/www

Veterans Health Administration: Public Health Strategic Health Care Group, AIDS Information Center
Provides a variety of educational links related to HIV/AIDS care, treatment, policy and research. Detailed information is also provided on blood exposure and needle stick safety in healthcare settings as well as treatment guidelines and recommendations.
http://www.publichealth.va.gov/
Appendix D, Answers to Warm Up Questions and Case Studies

Answers are provided in italics for each unit’s warm up questions and case study.

Answers to the questions within the unit are not included. Unit questions are designed to stimulate small group discussion among participants in the workshop or class.

Unit 1 Answers

Warm up questions

1. HIV sero-surveillance refers to the component of second-generation HIV surveillance that measures HIV prevalence. *HIV sero-surveillance measures HIV prevalence in specific populations on a regular basis using sero-surveys.*

2. Which of the following is one of the epidemiologic principles that guides HIV surveillance?
   - HIV infections are not uniformly distributed in a population.
   - There are a limited number of ways that HIV can be transmitted.
   - HIV infection enters different areas and populations at different times, and spreads at different rates.
   - All of the above.
   *HIV surveillance assumes that behavioural and biological risk factors result in a non-uniform distribution of infection in the population. Similarly, this will result in different populations being affected at different rates. Also, HIV can only be transmitted through sexual, parenteral, and mother-to-child pathways.*

3. Blood donation is ideally voluntary and entails selecting donors at lowest risk of infection. HIV prevalence data from blood banks are likely to ________ true prevalence in a population.
   - a) Over-estimate
   - b) Under-estimate

   *Because HIV-uninfected people are more likely to be recruited to donate blood, the prevalence in this group will be lower than that of the general population.*

4. True or false? In low-level epidemics, HIV surveillance should primarily focus on measuring HIV prevalence in antenatal clinics. *False. Surveys should target high-risk groups where HIV infection will probably appear first and spread fastest.*
Warm up questions, continued

5. True or false? Second-generation HIV surveillance is the only way to conduct HIV surveillance. *False. Second-generation surveillance consists of an integrated group of goals and principles for tracking the epidemic.*

6. Which type of surveillance better shows the clinical disease burden of the HIV epidemic?
   a. *HIV case reporting*
   b. *HIV sero-surveillance*

   *While HIV sero-surveillance measures HIV infection in the blood, HIV case reporting deals with the presence of clinical symptoms.*

7. Which of these is a goal of HIV surveillance?
   a. Identifying sub-groups at greater or lesser risk for infection
   b. Monitoring trends in the prevalence of infection over time
   c. Assessing risk factors of HIV transmission
   d. *All of the above*

   *All of the above are required in order to meet the over-all goal of HIV surveillance, which is to detect, describe, and track cases of HIV infection for the purposes of public health action.*

8. True or false? Sentinel surveys are harder to do than population-based surveys and give a more accurate picture of the over-all HIV prevalence in a population. *False. Sentinel surveys are easier because they involve surveys only a few defined locations. On the other hand, they do not represent the general population, since the individuals surveyed at sentinel sites often have unique behavioural risk factors (for example, STI clinic attendees).*

9. Selection bias is a big concern for _______ surveys. People who attend a particular facility may be different from those who do not use that site.
   a) *Population based*
   b) *Sentinel*

   *For this reason, data from sentinel surveys cannot usually be generalised to the broader population.*
Case study

You have recently assumed the position of surveillance officer for the Inyo district of the Yolo Republic, a midsized country in east Africa. You are charged with determining the surveillance activities for the district. The district conducted HIV seroprevalence surveys two years ago among women attending antenatal clinics in two urban areas of the district. The average seroprevalence from these sites was 2%. Five years ago, there was a country-wide Demographic Health Survey that collected blood for HIV testing (DHS+) and your district was included. The HIV prevalence was found to be 1%.

a. What type of surveillance do you think should be undertaken at this point and why?

The previous sero-surveys suggest a generalized epidemic and so sero-surveys among women attending antenatal clinics should be conducted. The results from the DHS also suggest a generalized epidemic.

You conduct sero-surveys in the two urban areas in which the earlier surveys were conducted and find that the prevalence is now 2.5%.

b. What other information can you use from this survey to help you understand what is happening with the epidemic in Inyo District?

Examination of the sero-prevalence by age group can be helpful in understanding changes in the epidemic. Specifically, increases in sero-prevalence in the youngest women suggests increases in new infections (HIV incidence).

You notice that the sero-prevalence among the youngest women is 2.8%.

c. What is a possible interpretation of this finding?

This may indicate increases in new infections in the general population.
Case study, continued

d. What additional information might be helpful to you?

Examination of data from other sources, as is recommended with Second Generation surveillance may help. This would include data from behavioural surveys and rates of sexually transmitted infections.

Population based surveys such as DHS or DHS+ can offer more representative information on the epidemic overall. If such surveys have been repeated the results should be examined and compared to the sero-prevalence findings from the antenatal clinics.

Expansion of sero-surveys to include rural areas and possibly high risk groups such as truck drivers and commercial sex workers may offer additional information on the factors that may be contributing to a worsening of the epidemic. It is particularly helpful when these surveys include behavioural data as well as HIV prevalence.

Results from the DHS+ show a slight increase in sero-prevalence. The sero-prevalence among truck drivers and commercial sex workers is higher than the prevalence from the DHS or from antenatal clinics. Among the truck drivers the prevalence is 2.6% and among commercial sex workers it is 3%.

e. What can you do with the information you have from these surveys?

These data should be summarized and shared with other public health and government officials and civil society for use with:

- Advocacy
- Targeting and evaluating prevention programs
- Resource allocation and programme planning (estimating the need for health care for HIV-infected persons)
- Mobilisation of political commitment.

The data can also be used to educate the public, to guide scientific research, and to make estimates and projections for new HIV infections and HIV-infected pregnant women (and to plan for programs to prevent mother to child transmission).
Unit 2 Answers

Warm up questions

1. True or false? In generalised HIV epidemics, surveillance activities should focus on groups that have high-risk behaviours. **False. In generalised epidemics, surveillance should focus on women at ANCs.**

2. Which of the following is a key consideration for selecting a sentinel population for HIV surveillance purposes?
   a. The local epidemiology of HIV and the major risk factors that drive HIV transmission
   b. The state of the epidemic
   c. Both of the above
   **The local epidemiology and risk factors should be considered. For example, if the main source of infection is injection drug use, you would focus on IDUs instead of truck drivers. Also, you should consider the epidemic state. For example, in a low-level epidemic, you would focus on high-risk groups instead of women at ANCs.**

3. True or false? In a concentrated epidemic, voluntary blood donors are an ideal sentinel population. **False. In this case, you should focus on the high-risk group in which infection is widespread. You should also include surveillance at ANCs, to monitor possible spread to the general population.**

4. Since the epidemic in Sub-Saharan Africa is generalised, the ideal sentinel population would be:
   a. Attendees at STI clinics
   b. Pregnant women visiting antenatal clinics
   c. Men who have sex with men
   d. All of the above
   **The focus should be women at ANCs, since they are most representative of the general population.**

5. True or false? When selecting sites for sentinel surveillance, the sites should be located in geographically diverse areas, both inside and outside of major cities and towns. **True. In this way, the sentinel sites will best reflect the country-wide epidemic.**

6. True or false? Provincial or district level staff should make decisions about the number and location of sentinel sites. **False. These decisions should be made by staff at the national level, in order to best coordinate surveillance activities.**
Case study

You are the surveillance officer for the Inyo district of the Yolo Republic. Your district is large and located on a major highway. It is on the border of a country with a large refugee population. New funding for surveillance has made possible the expansion of activities in your district.

Currently, two of the four ANCs in your district participate in the national HIV sentinel surveillance system. One is located in the main city of your district, Inyo Town. Inyo Town is also the provincial capital. The other ANC is in a rural area near the provincial capital. Of the remaining two ANCs, one is located far from the capital. It is far from the main highway, and near a refugee camp across the border. The other is in a private hospital funded by international charities in Inyo Town.

There is a rapidly growing town, Tehama, on the national border. Truck drivers wait long hours there as they pass customs inspections. Sex workers congregate in the border town, along the highway, and in two distinct areas of Inyo. There is also an STI clinic and outpatient TB programme in the hospital in Inyo Town. You have sufficient funds to add one additional HIV sentinel surveillance population.

a. In what populations might you consider doing the additional sero-survey?

Antenatal clinic patients, STI patients and TB patients are the most feasible given the access to patients, the drawing of blood, and their risk for HIV infection. Specific high-risk populations that might be considered are sex workers and mobile populations such as refugees, long-distance truck drivers, or mobile populations coming to Inyo. Given Inyo district’s situation, probably the most important high-risk populations are refugees and long-distance truck drivers. However, special community-based surveys may be needed to reach these populations.

b. What factors would you consider in selecting an appropriate population?

State of the epidemic (low-level, concentrated, generalised); how easily the population can be identified; if facility-based, whether blood is drawn routinely.
Case Study, continued

c. Are TB patients a suitable group for the additional sero-survey? Why or why not?

While TB patients are certainly at high risk for HIV infection (TB is the most common HIV-related opportunistic infection in Africa), they are likely not the best population to study in a generalised epidemic if only one additional site can be added. They can be identified fairly easily, especially if there are dedicated TB clinics, but they are not necessarily representative of the entire population – both with and without HIV infection – nor do they always have blood routinely drawn. Infections among TB patients may also be longer-standing infections rather than recent, and therefore less representative of the current patterns of transmission. For these reasons, they would likely not be the highest priority for sentinel surveillance expansion.

Because there is a generalised epidemic in the Yolo Republic, you have focused sentinel surveillance activities at ANCs. You make the decision to add one additional ANC site.

d. Which site would be the most suitable to add additional sentinel surveillance activities, and why?

Rural ANC located near refugee site.

e. What are the advantages and disadvantages of different site selections?

Advantages:
- Provides data on rural population not covered by current sites.
- May provide data on potential high-risk refugee population.
- Procedures for ANC sentinel surveillance are familiar and known.

Disadvantages:
- Logistically difficult given the long distance from provincial capital, in terms of transportation, supplies, and supervision.
- Does not necessarily provide information on specific high-risk populations. Attendance of the refugee populations should be confirmed.
- Review the additional criteria to determine what information is needed before selecting the ANC.

Time permitting, participants can discuss the relative advantages and disadvantages of the other options. Additionally, participants could consider, if a second new site were to be added, which they would choose and why.
Unit 3 Answers

Warm up questions

1. Which of the following is a reason to have inclusion and exclusion criteria?
   a. Include as few participants as possible in the survey
   b. Avoiding inclusion of the same person multiple times
   c. Both of the above
   One of the goals of inclusion and exclusion criteria, for example, only including a woman at an ANC if it is her first time attending, is to avoid including the same woman more than once.

2. True or false? The goal of sampling is to use the data from a sample of the population to estimate the HIV prevalence in the larger population.
   True. Since surveying the entire population is costly and impractical, sampling provides a less costly, more practical method of estimating prevalence.

3. Which of the following is a decision that needs to be made at the beginning of a sampling procedure?
   a. The sample size
   b. The sampling scheme
   c. The frequency of sampling
   d. All of the above
   All of the above factors need to be considered before sampling, in order to make sure that the survey will be representative and accurate.

4. True or false? As much as possible, the sampling period should be limited, in order to compare HIV prevalence over time. True. Because HIV prevalence changes over time (for example, people leave the area, new people become infected), it is best to limit the sampling duration in order to approximate a point estimate.
Warm up questions, continued

5. Match each sampling scheme with its description:

   _c_ Consecutive  a. Randomly selects the initial patient who meets inclusion criteria, and then selects every nth eligible patient thereafter

   _a_ Systematic  b. Uses a computer or other method to generate a list of random numbers that is used to identify patients to be included in the sample

   _b_ Simple random  c. Samples every patient that meets the inclusion criteria until the required sample size is achieved

6. Which of the above schemes is the most simple logistically, and best reduces the likelihood of selection bias? Consecutive. The other schemes require more complex methods, and are more prone to errors by clinic staff.

7. True or false? All subjects at the sentinel site who meet the inclusion criteria during the sampling period should be included in the survey. False. Individuals who meet the exclusion criteria should be excluded, even if they meet the inclusion criteria.

8. True or false? When surveys are repeated, they should be carried out in different sites from the initial survey and during a different time of the year. This helps give a clear picture of the epidemic’s scope. False. Surveys should be conducted at the same locations during the same time of year, so that the results can be meaningfully compared across time.

Case study

Using the formula for sample size estimation based on the precision of a point estimate, calculate the sample size required for the following scenarios.

\[ N = 4 z^2 \sigma^2 \frac{P(1-P)}{W^2} \]

a. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 10% within +/- 5%. Remember that P and W are expressed as decimals (that is, P = 0.10 and W = 0.10)

138 subjects

\[ N = 4 \times 1.96^2 \times 0.1 \times (1 - 0.1) \div 0.1^2 = 138 \]
Case study, continued

b. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 10% within +/- 2.5%.

553 subjects

\[ N = 4 \times 1.96^2 \times 0.1 \times (1 - 0.1) \div 0.05^2 = 553 \]

c. What happens to the required sample size as the width of the margin of error gets smaller?

For the same estimated prevalence, the sample size needed is larger in order to have better precision.

d. You wish to have a sufficient sample size to estimate an expected HIV prevalence of 35% within +/- 5%.

350 subjects

\[ N = 4 \times 1.96^2 \times 0.35 \times (1 - 0.35) \div 0.1^2 = 350 \]

e. What happens to the required sample size as the estimated prevalence gets closer to 50%?

For the same level of precision, the sample size required for the same precision increases as the estimated prevalence gets closer to 50%.

Unit 4 Answers

Warm up questions

1. True or false? In unlinked anonymous testing, information about the identity of patients is kept in order to tell them about their results if they test positive. False. All personal identifying information should be removed, since testing is unlinked and anonymous.

2. Place the following events in the correct order, corresponding to the proper procedure for unlinked anonymous testing:

a. Blood is collected and labelled with a code
b. Specimen is tested for HIV
c. Personal identifying information is removed from specimen
d. An aliquot is removed into new tube for HIV testing.

\[ a, d, c, b \]
Warm up questions, continued

3. True or false? Unlinked anonymous testing without informed consent can sharply reduce participation bias. True. In this way, patients do not have a choice about whether their sample will be included.

4. Place the following events in the correct order, corresponding to the preferred data collection method for unlinked anonymous testing:
   a. Send form to laboratory
   b. Add HIV test result to form
   c. Add demographic data to form
   d. Remove demographic section of form and send to data manager.
   
   \[ c, d, a, b \]

5. Which of the following is not a reason for the use of standardised data collection forms?
   a. To ensure that the necessary information is obtained
   b. To ensure that data from different sites can be easily compared
   c. To ensure that a patient’s personal information can be matched with their test result
   d. None of the above

   Standardised data collection forms allow for greater ease in data collection. Matching a patient’s information to their test result is irrelevant, and sometimes is even undesired.

6. True or false? For linked confidential surveys, a separate laboratory form for serologic results should be used so that laboratory personnel do not have access to the patient’s personal identifying information. True. Since testing is confidential, laboratory personnel should not be able to identify the patient with his or her test result.

7. For unlinked anonymous testing, as is used in sentinel surveillance, which of the following variables would be inappropriate to collect:
   a. Patient age
   b. Patient marital status
   c. Patient’s number of children
   d. None of the above

   Knowing the patient’s number of children is not necessary.
Case study

You identify an STI clinic in your district that serves a population located on the border area of a country with high HIV prevalence and a large refugee population. It is located on a major highway. You wish to determine HIV prevalence in the STI clinic population. Funding to establish the clinic as a sentinel surveillance site will be available starting next year.

You visit the hospital laboratory that conducts syphilis testing for the STI clinic. The laboratory director tells you that she has saved blood specimens from the clinic for the last six months. She was about to discard them, but asks whether these specimens could be tested for HIV to determine the prevalence in the clinic population.

a. Do you think that testing these specimens would produce an estimate of HIV prevalence that could be compared to the sentinel surveillance estimate planned for the following year?

It is possible that these specimens could produce an estimate of HIV prevalence that is comparable to sentinel surveillance - providing that certain information is available and procedures for unlinking personal information from HIV results can be established. Because sentinel surveillance at facilities is based on the use of available information and blood collected for other purposes, on the face of it these specimens could be used to produce an estimate of HIV prevalence in a cross-section of the clinic population in a manner similar to one planned for next year.

b. What information do you need to know about the specimens and their source in order to assess their suitability for estimating HIV prevalence?

Do the stored specimens represent a complete, consecutive sample of STI clinic patients? During what time-period were they collected? Are specimens missing? Are specimen volumes sufficient? Were the specimens stored adequately?

Are the specimens linked to clinic records that contain a minimum amount of information on the patients needed for interpreting data? Can the eligibility of the patients be determined? Do the records completely record date of clinic visit, repeat or first time visit, age, sex, residence? Are additional information required by sentinel surveillance also available (for instance, marital status, education, occupation)?
Case study, continued

c. Describe the steps you would take to ensure that HIV test results could not be linked back to clinic patients.

Of note, as an effort that differs from the planned sentinel surveillance activity, it may first require consideration for ethical review and, at a minimum, a fully written and detailed protocol. The actually steps taken to conduct this effort may vary, but will closely parallel the steps outlined in this unit. Participants should clearly detail how information from medical records will be permanently unlinked from HIV test results prior to HIV testing of specimens. The following is one example:

- Identify the time-period to be used. This should correspond to the same consecutive time-period planned for next year’s sentinel surveillance effort. The period should include enough saved specimens to complete the same sample size projected for next year.
- Confirm that all the specimens collected during the time-period are available. This may be accomplished by comparing actual stored specimens with labels to laboratory records of syphilis test results.
- Create a temporary database that lists all specimens to be included. The database will temporarily include the original specimen identification number. A new, unique non-identifying study identification number is then assigned to each specimen number. The database also temporarily includes the patient medical record number.
- Data from the medical records are abstracted onto a data abstraction for (preferable the same form used for routine sentinel surveillance as planned next year). One part of the form contains the patient medical record number. This form does not personally identify information on the patients, but does include the required demographic characteristics and other routine data collected for surveillance.
- Data are entered into the database and checked for errors.
- Aliquots of stored blood are placed in tubes labelled only with the new, non-identifying study numbers corresponding to their original specimen numbers.
- Ensure that all linking information is destroyed. This includes: removal of medical record numbers from the data abstraction form (for instance, physically cutting off the portion and destroying them), deletion of original laboratory specimen numbers from the database, and permanently discarding (or replacing in storage) the original specimen tubes.
- Once unlinking is confirmed, HIV testing is done. Test results are entered into the database according to their unique, non-identifying study numbers.
Case study, continued

d. The laboratory director indicates that they also conduct voluntary HIV testing on STI clinic patients when recommended by the physician and consented to by the patient. HIV prevalence among clinic patients voluntarily tested is 50%. Based on this information, what HIV testing strategy would you use to determine HIV prevalence as a surveillance exercise?

As a surveillance activity, the same testing strategy planned for next year should be used for comparability of results. Strategy I (a single test) is the most appropriate strategy given the surveillance purpose and the likely high prevalence of infection. Of note, the selective testing of some patients may mean the 50% prevalence of HIV is a biased estimate, although true prevalence in the clinic population is likely to be above 10%. Also of note, the testing strategy for diagnosing HIV infection among patients may differ from the sentinel surveillance testing strategy.

e. Would you use the voluntary HIV testing data from the STI clinic as a measure of prevalence? Why or why not?

While the data from voluntary HIV testing may be informative, it is subject to many potential biases. For example, persons who already know they are infected may not choose to test thus lowering prevalence. On the other hand, physicians noting signs and symptoms of HIV infection may only test those most likely to be infected. The unlinked, anonymous approach eliminates many of these potential biases. Nonetheless, voluntary HIV testing data may be useful in certain situations. For example, if HIV testing is nearly 100% in the clinic, then the estimate of HIV prevalence should be comparable to unlinked anonymous testing. However, interpretation of voluntary testing data should be done very cautiously.

Unit 5 Answers

Warm up questions

1. Which of the following factors are involved in the decision to select an HIV testing strategy?
   a. Sensitivity and specificity of test being used
   b. Objective of the test
   c. HIV prevalence in the population being tested
   d. All of the above

   All of the above are required in order to select an appropriate test that maximises sensitivity and specificity while minimising cost.
Warm up questions, continued

2. Match each phase of the HIV testing process with the components it includes:

   _b_ Pre-analytical  a. Interpreting results, entering data into tracking system, reviewing quality control

   _c_ Analytical      b. Training, laboratory safety, selection of test kits

   _a_ Post-analytical c. Specimen processing and storage, analysis of testing performance, reagent preparation

3. The process by which reference specimens are tested externally to ensure accuracy of a technician’s or laboratory’s performance is known as:
   a. Internal quality assurance
   b. External quality assurance
   c. Quality performance
   d. None of the above.

   Laboratories conducting HIV testing should work with a national or international reference laboratory to conduct proficiency testing in order to verify the accuracy of their instruments and methods.

Case study

You are the newly hired district surveillance officer for Inyo district in the Yolo Republic, and are charged with co-ordinating HIV sero-prevalence studies. You have been asked to help set up a new laboratory at an ANC in Tehama, a town near the border. Prevalence at other ANC sentinel surveillance sites in the district has run approximately 8% for the last three years. You choose a test that has a sensitivity of 0.9995 and a specificity of 0.995.

a. What is the positive predictive value of the test?

   95%. Assume 100 people in the population. Prevalence = a+c = 8 persons who truly have HIV; b+d = 92 persons who truly do not have HIV.

   \[
a/a+c = 0.9995, \text{ so } a = 7.996
\]

   \[
d/b+d = 0.995, \text{ so } d = 91.54 \text{ and } b = 0.46
\]

   Positive predictive value = a/a+b = 95%

b. What testing algorithm would seem most appropriate for testing for HIV as part of the next HIV sentinel surveillance round at this new laboratory?
Dual test strategy because it is used for UAT, and prevalence is <10%.
Case study, continued

c. What are five steps that you would do to ensure quality of the laboratory before the first test was run?

Establish a quality assurance programme. Pre-analytic activities include training, having a laboratory safety programme, having trained staff to perform the tests, working out specimen collection, labelling and transport, selecting test kits and checking their expiration dates, ordering HIV test kit reagents.

Unit 6 Answers

Warm up questions

1. Which staff members should be trained prior to conducting sero-surveys?
   a. Supervisors and managerial staff
   b. Laboratory staff
   c. Clinic staff
   d. All of the above

   All staff should be trained so that they know the proper procedures and their responsibilities in conducting the survey.

2. True or false? When planning for the supervision of testing facilities, the national surveillance organisers should hire an outside supervisor to staff each of the facilities where HIV testing occurs. False. This role should be assigned to someone in the existing management structure, in order to minimise conflicts, encourage a sense of ownership, and encourage effective management.

3. List three types of personnel necessary to conduct an HIV sero-survey.
   Clinic staff, laboratory technicians, supervisory staff, etc.

4. The national surveillance supervisor should be responsible for supervision of:
   a. Specimen collection
   b. Data management
   c. Laboratory equipment
   d. Sampling
   e. All of the above.

   At the national level, there must always be a person responsible for ensuring that all the required activities take place, and that surveillance is conducted uniformly in all sites.
Case study

As part of your duties as the Inyo District HIV surveillance officer, you are charged with assisting central Ministry of Health staff in training personnel for a new ANC sentinel surveillance site. You have been asked to invite appropriate people to the training.

a. Identify the types of participants you plan to invite.

*Trainings should include clinic supervisors, laboratory staff, clinic staff and district surveillance staff. There will likely be a mix of persons identified that work at the clinic site or who work at the district level. The important point to emphasise is that the training (or trainings) need to encompass both the staff working at the clinic and the clinic’s laboratory and the staff responsible for supervision, data management and transfer and laboratory testing (if applicable) at the district level.*

b. What elements of sentinel surveillance do you think need to be covered in this training?

*Training should include a review of operational procedures, field protocol and previous sero-survey findings (see figure). Please emphasise the need to communicate results during the training to motivate staff to ‘own’ the project. Even if sentinel surveillance has not been conducted at this site previously, results from other sites and how they have been used should be conveyed. An important part of surveillance is the feedback of results to the people who collected them.*

c. A staff member asks a question about the difference between linked and unlinked testing and why unlinked testing is being done at the clinic. How do you respond?

*It is important for staff to have the opportunity to discuss concerns and obtain further clarification of sero-survey operations during training. Presumably the question refers to the choice between unlinked anonymous testing without informed consent and linked non-anonymous testing with informed consent. While unlinked non-anonymous testing with informed consent is a possibility, it would be unlikely to be used in this setting. Unlinked anonymous testing refers to HIV testing done on left-over specimens of blood drawn for other clinical reasons in which the patient’s identifying information is permanently removed; there is no way to link test results with an individual patient. This is done for surveillance purposes only. Linked non-anonymous testing with informed consent refers to standard clinical testing where patients are informed of test results and the results are recorded in their charts.*
Module 3, HIV Surveillance

Case study, continued

The reason the surveillance system will likely opt for unlinked anonymous HIV testing is because the prevalence estimates derived from this survey will have minimum participation bias and the costs of the survey are relatively lower because there is no cost for counselling about HIV test results. Additionally because the testing is anonymous, the privacy of the individual is maintained, informed consent is not required and the person who is tested does not have to return to be counselled about the test result. The obvious disadvantage is that there is no opportunity to counsel HIV-infected individuals about prevention (especially important in ANC settings) and care. This can be offset somewhat by offering voluntary counselling and testing at the site or nearby.

d. You receive a report that an individual patient’s results were released inadvertently to clinic staff. You view this as a serious breach in study procedures. How would you investigate this, and what would you do?

Breaching patient confidentiality is a serious matter and one that unlinked anonymous testing was specifically designed to avoid. You need to immediately and carefully review procedures for unlinking identifiers at the clinic and laboratory levels, interview staff about where the breach may have occurred and retrain staff on how to unlink identifiers from specimens. You may choose to stop data collection altogether for a period of days during which you conduct intensive retraining of clinic and laboratory staff on the reasons, rationale and procedures for unlinked anonymous testing.

e. At the end of the surveillance cycle, you discover that the clinic did not report any data for the last month of the survey period. How do you address this problem?

You should first be certain that the data truly were not reported to the district level (that is, be sure that they were not misplaced or went to the wrong person). After you are certain that the problem does not lay on your end, you should discuss the matter with the clinic supervisor. Data may be available and just not sent yet or may have been sent mistakenly to the provincial level, bypassing the district. If you establish that this is not a simple data transmission problem, you need to ascertain if blood specimens were sent to the laboratory and if the laboratory tested them. One reason for non-reporting is that the laboratory ran out of supplies and is holding the specimens until new test kits arrive. Another reason may be that clinic personnel changed, and the new personnel were unaware of the survey and/or the survey procedures.
Case study, continued

You need to emphasise to clinic and laboratory staff the need to keep you informed of problems with the surveys on a real time basis. You could, for instance, have done a special training for the new personnel or assisted the laboratory with obtaining new test kits from the Ministry. You also need to accept some responsibility for this yourself. Closer monitoring of data, for instance on a weekly basis, may have led to more rapid identification of this problem before four weeks’ worth of data was lost. You should plan on emphasizing in the next cycle the need for closer communication with the clinic and laboratory and the need on your part for more frequent examination of data at the district level.

Unit 7 Answers

Warm up questions

1. Data entry is the process of entering paper records into a computerised database.
   In the case of HIV surveillance, data entry involves entering merged demographic data and HIV test results into a database.

2. True or false? The best way to summarise sentinel surveillance data is by calculating a single prevalence figure for the whole survey. False. Data should be analysed by each of the variables collected (for example, by gender, risk behaviour or district).

3. True or false? Data dictionaries (electronic files that describe the basic organization of a project or database) should be developed at the local clinic level. False. Data dictionaries should be developed at a national level in order to ensure consistency across sites.

Case study

You are the newly hired district surveillance officer for Inyo district in the Yolo Republic, and are charged with co-ordinating HIV sero-prevalence studies. Unlinked, anonymous annual HIV sero-prevalence studies have been conducted in all five ANCs in this district for the past seven years. You decide to examine the trends in HIV prevalence at the ANCs to assess the status of the HIV epidemic in your district. Since you have included all the ANCs in the district in your survey, it is appropriate to calculate single prevalence values for the district.
Case study, continued

The following data are available for you to examine:

Number of HIV tests and positive results for Inyo District, by year.

<table>
<thead>
<tr>
<th>Year</th>
<th>Number HIV tests done</th>
<th>Number tests HIV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>400</td>
<td>76</td>
</tr>
<tr>
<td>1998</td>
<td>450</td>
<td>81</td>
</tr>
<tr>
<td>1999</td>
<td>500</td>
<td>90</td>
</tr>
<tr>
<td>2000</td>
<td>475</td>
<td>71</td>
</tr>
<tr>
<td>2001</td>
<td>425</td>
<td>60</td>
</tr>
<tr>
<td>2002</td>
<td>486</td>
<td>54</td>
</tr>
<tr>
<td>2003</td>
<td>499</td>
<td>55</td>
</tr>
</tbody>
</table>

Use these data to calculate the annual HIV prevalence and develop a figure or graph that you think would explain the trends.


*Figure. HIV prevalence for Inyo District, by year.*

a. What do you observe in sero-prevalence trends and what might these trends mean?

*Sero-prevalence is declining from 19% in 1997 to approximately 11% in 2003. Sero-prevalence is a function of the number of people who are becoming newly infected and the number of people who are dying. When sero-prevalence declines, the number of people dying is greater than the number of people becoming newly infected. Whatever the reason, the burden of disease in the population is decreasing.*

b. What additional information would be helpful in understanding these trends?

*The mortality rate among persons with HIV infection (both HIV-related and non-HIV-related mortality) and the HIV incidence rate.*
Case study, continued

c. Are there additional ways to examine these data to assess the epidemic?

Yes, one of the easiest ways is to look at the youngest cohorts of adult patients (15-24 years old) who presumably would have been infected relatively recently. When divided by the time period of observation, these ‘rates’ can be roughly interpreted as incidence rates in this age group. Other more sophisticated analyses can examine prevalence trends over time in specific age strata and, if mortality rates are known, can estimate incidence trends.

Unit 8 Answers

Warm up questions

1. True or false? Reading or hearing about HIV in the media strengthens basic information and prevention messages. True. This helps to give people a realistic perception of their risk for infection, and it also helps to reduce stigma.

2. List two potential audiences for surveillance data. Technical professionals, NGOs, policy-makers, journalists, etc.

3. List three potential uses of HIV surveillance data. Targeting intervention activities, programme monitoring and evaluation, resource allocation, political mobilisation, etc.

4. True or false? When disseminating HIV surveillance results, a single message that can be used for all target audiences is the best way to transmit the information. False. Based on the target audience, the message can differ in terms of its content (for example, the level of technicality), the method of dissemination (for example, radio versus written material), etc.

Case study

You are the HIV sero-prevalence co-ordinator for a province in the Yolo Republic. Annual sero-surveys have been conducted at five ANCs in three districts of the province for the past 4 four years. You are in the process of analysing your province’s local data and preparing the information for dissemination. The following table summarises your analysis so far:
Case study, continued

Number of women (total and HIV+) at ANC sites.

<table>
<thead>
<tr>
<th>Women</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women, all sites</td>
<td>2 009</td>
<td>1 993</td>
<td>2 003</td>
<td>1 999</td>
</tr>
<tr>
<td>All HIV+ women, all sites</td>
<td>299</td>
<td>277</td>
<td>305</td>
<td>290</td>
</tr>
<tr>
<td>Women age 15-24 years old, all sites</td>
<td>491</td>
<td>507</td>
<td>497</td>
<td>501</td>
</tr>
<tr>
<td>HIV+ women, age 15-24 years old, all sites</td>
<td>39</td>
<td>31</td>
<td>25</td>
<td>19</td>
</tr>
</tbody>
</table>

a. At a local meeting of NGO directors, you are asked whether or not there is any indication that the money and effort spent on HIV prevention in the province has been successful. They request a brief summary of the antenatal sentinel surveillance data for their next meeting. What data would you include in this summary?

Total numbers of women tested and prevalence over-all and in 15-24 year old age group (that is, report prevalence and not raw numbers of HIV-infected women).

How would you present the data?

You could either present it in a table (such as the one below) or a graph with time on the x-axis. Given that these data are being analysed for a non-governmental organisation, a figure with trends over time both over-all and in the 15- to 24-year-old age group may be most appropriate.

Table. HIV prevalence by year.

<table>
<thead>
<tr>
<th>Women</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women, all sites</td>
<td>2 009</td>
<td>1 993</td>
<td>2 003</td>
<td>1 999</td>
</tr>
<tr>
<td>HIV prevalence, all sites</td>
<td>14.9%</td>
<td>13.9%</td>
<td>15.2%</td>
<td>14.5%</td>
</tr>
<tr>
<td>Women age 15-24 years old, all sites</td>
<td>491</td>
<td>507</td>
<td>497</td>
<td>501</td>
</tr>
<tr>
<td>HIV+ women, age 15-24 years old, all sites</td>
<td>7.9%</td>
<td>6.1%</td>
<td>5.0%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

What data other than HIV prevalence would be useful to include?

Year. You may also decide to present the over-all number of women tested to show that the denominator remained relatively stable year to year. However, the graph would then have three lines and would also need two y-axes (one for prevalence – a proportion – and the other for numbers tested per year). It is probably wisest to leave off the number of women tested.

F-23
Case study, continued

What conclusion do you present to NGO directors?

While the prevalence among all women has remained relatively stable over the four-year period, there has been a steady and marked (48.1%) decrease in prevalence among 15- to 24-year-old women, suggesting a declining incidence.

b. The Ministry of Health and the NACP inform you that the budgets for HIV prevention and care for your province are going to be reduced to US$300 000 for the coming year. Their policy is that money should be concentrated in the health districts in greatest need and that half should be spent on prevention and half on care programmes. They ask you to plan how you will allocate the $300 000 in the three districts within your province. You start by examining the ANC data by district and site and find the following:

Number of women, by district site, age group and sero-status.

<table>
<thead>
<tr>
<th>Women</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women</td>
<td>2 009</td>
<td>1 993</td>
<td>2 003</td>
<td>1 999</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>398</td>
<td>401</td>
<td>400</td>
<td>402</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>402</td>
<td>401</td>
<td>398</td>
<td>396</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>404</td>
<td>389</td>
<td>401</td>
<td>403</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>397</td>
<td>399</td>
<td>391</td>
<td>399</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>408</td>
<td>403</td>
<td>413</td>
<td>399</td>
</tr>
<tr>
<td>All HIV+ women</td>
<td>299</td>
<td>277</td>
<td>305</td>
<td>290</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>99</td>
<td>91</td>
<td>97</td>
<td>93</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>31</td>
<td>42</td>
<td>60</td>
<td>67</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>36</td>
<td>33</td>
<td>30</td>
<td>23</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>97</td>
<td>88</td>
<td>97</td>
<td>88</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>36</td>
<td>23</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Women age 15-24 years old</td>
<td>491</td>
<td>507</td>
<td>497</td>
<td>501</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>98</td>
<td>99</td>
<td>101</td>
<td>102</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>99</td>
<td>97</td>
<td>102</td>
<td>97</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>101</td>
<td>104</td>
<td>93</td>
<td>99</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>100</td>
<td>103</td>
<td>99</td>
<td>103</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>93</td>
<td>104</td>
<td>102</td>
<td>100</td>
</tr>
<tr>
<td>HIV+ women, age 15-24 years old</td>
<td>39</td>
<td>31</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>District A, urban site</td>
<td>10</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>District A, rural site</td>
<td>3</td>
<td>4</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>District B, rural site</td>
<td>9</td>
<td>6</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>District C, urban site</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>District C, rural site</td>
<td>9</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>
Case study, continued

Using the HIV sentinel surveillance data above, what are your recommendations on where the $150 000 for HIV prevention should be spent?

- District A (rural), because prevalence among 15- to 24-year old women is increasing.
- Districts A and C (urban), because prevalence is high.

Using the HIV sentinel surveillance data above, what are your recommendations on where the $150 000 for HIV care should be spent?

Same as above because of high disease burden.

What other factors would you consider before making your recommendations?

You should also examine CD4 levels to decide who among the HIV-positive patients needs antiretroviral treatment.

c. You receive a call from a reporter working for your national newspaper. She says that she heard a rumour that HIV has gone down in your province and would like your comments. You tell her that you are on your way to a meeting right now, but promise to call her back as soon as possible and also prepare a written press release.

Using the data presented above, what would you include in the press release? What further explanation would you provide? Whom would you contact before returning the call?

Calculate the HIV prevalence in your province (without regard to district), and plot it on a graph with time on the X-axis.

1999: 299/2009 = 14.9%
2000: 277/1993 = 13.9%
2001: 305/2003 = 15.2%
2002: 290/1999 = 14.5%
Case study, continued

Figure. HIV prevalence by year.

In your press release, you could further explain possible sources of error, the trend in prevalence (that is, varying by year but relatively stable), etc. Before returning the call, however, you need to call the provincial and district health officers to tell them what you are going to say.
Final Case Study

1. You are the HIV surveillance officer for Inyo Province in the Yolo Republic. Inyo Province currently conducts HIV sentinel surveillance at antenatal and STI clinics serving female sex workers. You are considering adding more sites to the province’s sentinel surveillance system.

   a. What must you consider when selecting sites for sentinel surveillance?

   The selection of sites for HIV sentinel surveillance is a balance between including as much of the selected population as possible and logistical necessities. In order to ensure success, sentinel surveillance should be implemented in facilities with enough personnel and laboratory capacity to conduct a successful survey. Other factors to consider include, the populations being served by the site, whether blood samples are routinely collected at the site, the laboratory facilities available, the size of the client base, and the geographic diversity of sites.

   b. In Inyo Province, the estimated prevalence of HIV is 35% among female sex workers. What would be an adequate sample size to measure HIV prevalence within a margin or error of +/- 5%?

   Using the following formula:

   \[ N = 4z^2\alpha^2 P (1-P) \div W^2 \]

   The calculation would look like this:

   \[ N = [4 \times (1.96)^2 \times 0.35 \times (1 - 0.35)] \div (0.10)^2 \]

   \[ N = 350 \text{ people} \]

   Therefore you need 350 people in your sample in order to achieve the confidence interval that you want.
Final Case Study, continued

c. What method of HIV testing would be most appropriate in conducting sentinel surveillance of female sex workers attending STI clinics?

*Unlinked anonymous testing or linked testing with informed consent.* Unlinked anonymous testing may be appropriate in this situation as UAT relies on blood that is left over from specimens that are regularly collected for other purposes (such as syphilis testing). The major disadvantage of unlinked anonymous testing is that persons do not get their test results. Since such information may directly impact their health and risk of acquiring or transmitting HIV, unlinked anonymous testing should be done in settings where patients can be referred to voluntary counselling and HIV testing programmes. The benefit of unlinked surveys is that it minimizes participation bias. In settings where treatment is available or when the target population is not easily accessed in health settings, linked testing (confidential or anonymous) with informed consent is preferred as patients receive their test results.

d. Inyo Province conducts HIV surveillance at 20 sentinel sites. As the HIV surveillance officer for Inyo Province, you are charged with supervising the staff at all sentinel sites. How would you ensure that sentinel site staff are adequately trained and that surveillance is conducted in the same manner at all sentinel sites?

*To ensure that the surveillance process is smooth and effective, be sure that all staff undergo the necessary training.* As the HIV surveillance officer in charge of supervising staff at all sentinel sites, you should monitor all aspects of sentinel surveillance, including: sampling, data and specimen collection and management and laboratory equipment. As it is impossible for you to be present to supervise at all facilities, you may delegate to other supervisors. These other supervisors may then delegate, if need be, to a supervisor at the facility level.
Final Case Study, continued

2. HIV surveillance at various sentinel sites between 1999 and 2005 found the following data:

HIV Prevalence at select sentinel site in Inyo Province, 1999-2005.

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of sites</th>
<th>Area</th>
<th>1999</th>
<th>2001</th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant women</td>
<td>6</td>
<td>urban</td>
<td>32%</td>
<td>30%</td>
<td>23%</td>
<td>21%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>2</td>
<td>rural</td>
<td>17%</td>
<td>19%</td>
<td>20%</td>
<td>22%</td>
</tr>
<tr>
<td>STI patients</td>
<td>2</td>
<td>urban</td>
<td>52%</td>
<td>57%</td>
<td>54%</td>
<td>51%</td>
</tr>
<tr>
<td>Sex workers</td>
<td>5</td>
<td>urban</td>
<td>63%</td>
<td>66%</td>
<td>61%</td>
<td>55%</td>
</tr>
<tr>
<td>Tuberculosis patients</td>
<td>1</td>
<td>urban</td>
<td>-</td>
<td>-</td>
<td>73%</td>
<td>82%</td>
</tr>
<tr>
<td>Tuberculosis patients</td>
<td>1</td>
<td>rural</td>
<td>-</td>
<td>-</td>
<td>32%</td>
<td>36%</td>
</tr>
</tbody>
</table>

a. What trends do you see? At which sites would you expect HIV prevalence to be the highest in 2006?

Among urban pregnant women HIV prevalence peaked in 1999 and decreased between 1999 and 2005. Among urban pregnant women, the greatest decrease was observed between 2001 and 2003. Rural pregnant women consistently had a lower mean prevalence compared to urban pregnant women. HIV prevalence among STI patients and sex workers peaked in 2001 and decreased thereafter. Among TB patients, the prevalence of HIV increased between 2003 and 2005 and was highest in TB patients in urban areas. In 2006, HIV prevalence will probably be highest among urban TB patients.

b. What are the limitations of the above data? What are the limitations of sentinel surveillance?

Limitations of the above data include: No data on TB patients until 2003. Only two data points sero-surveillance in TB patients make it difficult to determine a trend for TB patients. The small number of site, particularly for TB and STI patients limits the ability to generalise findings from sentinel surveillance.

Limitations of sentinel surveillance data include: most sentinel surveillance is conducted among pregnant women attending ANCS and thus do not provide information about non-pregnant women or men. Additionally, because coverage of rural areas by the sentinel surveillance system in most countries in incomplete, the assumptions and validity of estimates derived from sentinel surveillance are often questionable.