Introduction to HIV, AIDS and STI Surveillance

HIV Clinical Staging and Case Reporting

Participant Manual

September 2009

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Table of Contents

Table of Contents, continued

Table of Contents, continued

Introduction

How to Study This Module

What you should know before the course

The information provided in this module is designed for national-level and district-level surveillance officers. As a participant, you should have a basic medical understanding of HIV and public health surveillance before taking the course.

Module structure

The module is divided into seven units. The units are convenient blocks of material and should be studied in the order they appear. After using this module you will have a better understanding of HIV case-based reporting and a complete (or nearly complete) action plan and operations manual. The last three appendices guide you through developing an action plan and operations manual for establishing and maintaining an HIV case-based reporting system. This module also can be used for self-study.

Because you already know quite a bit about HIV, we begin each unit with some warm-up questions. Some of the answers you may know. For other questions, your answer may be just 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 and you can check your work.

Appendices

More information is provided at the end of this module.

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
Appendix E, Action Plan for Implementing HIV Case Reporting
Appendix F, Developing a Draft Operational Manual
Appendix G, Operational Manual Checklist

Additions, Corrections, Suggestions

Do you have changes to this module? Is there additional information you'd like to see? Please write or email us. We'll collect your letters and email then consider your comments in the next update to this module.

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Unit 1

Overview of HIV Case Reporting

Overview

What this unit is about

This unit provides an overview of the history, purpose and importance of AIDS and HIV case reporting. It explains:

- The history of HIV case reporting and how changes in HIV treatments have affected it
- The natural history of HIV disease and disease stages that are important for surveillance
- The purpose of HIV case reporting
- How other types of HIV programmes can provide data for surveillance purposes.

Warm-up questions

1. What are the key differences between HIV sero-prevalence surveillance and HIV case reporting?

2. True or false? HIV testing of women seeking antenatal care is a component of HIV case reporting.

   True False

3. Which of the following is not a purpose of advanced HIV infection/AIDS case reporting?

   a. To determine the burden of disease attributable to advanced HIV infection in the region
   b. To assess trends in advanced HIV infection cases
   c. To provide information on the opportunistic infections associated with advanced HIV infection
   d. To measure the incidence of HIV.

4. List five surveillance target points in the natural history of HIV disease.

5. List three reasons for conducting HIV case reporting.

Introduction

What you will learn

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

- Describe the history of HIV and AIDS case reporting and how changes in HIV treatments have affected surveillance recommendations and practises
- Describe the stages in the natural history of HIV disease that can be useful in surveillance
- Describe the primary purposes of conducting HIV case reporting
- Describe the differences between HIV case reporting and HIV sero-prevalence surveillance (i.e. HIV sero-surveillance or HIV sentinel surveillance)
- List four types of HIV-related programmes that can provide data for HIV surveillance.

Historical overview of HIV and AIDS case surveillance

Soon after the emergence of the *acquired immunodeficiency syndrome* (AIDS) epidemic in 1981, many industrialised countries moved toward reporting cases of people who have AIDS to public health authorities. In the past, in developed countries, AIDS *case reporting* and active case-finding allowed AIDS notification and AIDS-specific *mortality* to be monitored. As the epidemic evolved and because AIDS *case reporting* had limitations in assessing current patterns of *human immunodeficiency syndrome* (HIV) transmission, the focus of *case reporting* shifted from AIDS as an end-stage disease to HIV infection. This change led many developed countries to make HIV infection reportable and today, many are reporting cases *confidentially*, either by name or by anonymous codes. In developed countries, it is generally agreed that HIV cases should be reported, but debate exists regarding, among other issues, *confidentiality*, how reporting should be done, how to avoid duplication and how to track people over time.

The situation is quite different in developing countries, where AIDS *case reporting* was introduced in most countries in the 1980s and early 1990s, depending on when the first AIDS case was reported. Reporting AIDS cases for *surveillance*, however, primarily has been through waiting for healthcare providers to make reports. This approach has generated incomplete and inaccurate data and has reduced the value of *case reporting*. The HIV *case reporting* system used in developed countries has not been introduced in most developing countries.

Historical overview of HIV and AIDS case surveillance, continued

In resource-constrained countries, under-reporting AIDS cases has been made worse by weak health care infrastructure. The situation has produced unreliable data of little use for monitoring trends or planning HIV prevention, care and treatment services. Thus, most countries have relied on HIV *sero-prevalence surveillance* in selected populations at *sentinel sites* to monitor HIV trends. Additionally, the *second-generation surveillance* system, which joins AIDS case reporting, HIV *sero-prevalence surveillance*, *sexually transmitted infection* (STI) surveillance and *risk-behaviour surveillance*, has aided estimations of the numbers of people living with HIV.

Impact of ART on AIDS case reporting

The increased availability of *antiretroviral therapy* (ART) may prevent or delay the onset of AIDS, as it was previously defined. Therefore, the advances of *ART* mean that public health *surveillance* alone does not provide reliable information on the scale and magnitude of the HIV epidemic. Data on HIV infection *cases* are more useful for determining the populations that need prevention and treatment services, as well as forecasting *ART* needs. Therefore, *surveillance* must move from reporting cases of AIDS to reporting cases HIV infection, which captures data on any *clinical stage* of HIV infection.

HIV case reporting terminology

HIV case reporting refers to the methods used to capture individual-level information about persons with HIV infection. Each person with HIV infection is reported using a single case report form which contains information pertaining only to that person. This type of reporting occurs at the level of the health facility and is forwarded to the local level as individual case reports. The local-level *surveillance* officers combine the data and forward them on to the national *surveillance* programme where they will be computerised.

The World Health Organization (WHO) refers to reporting all stages of HIV as "HIV infection reporting (all clinical stages)" and to reporting of advanced HIV (clinical stages 3 and 4 only) as "advanced HIV infection (disease) reporting." Reporting advanced HIV infection includes AIDS (clinical stage 4). Described in this module are updated methods for reporting persons with HIV infection. Specifically described is how countries can replace reporting AIDS cases (*HIV clinical stage* 4) with reporting *advanced HIV infection* (*clinical stages* 3 and 4) and *HIV infection reporting,* which includes reporting all persons with HIV regardless of their *clinical stage*.

The Relation Between the Natural History of HIV and Surveillance

Natural history of HIV and targets for surveillance

HIV infection results in a chronic condition. Shortly after becoming infected, an individual may experience signs and symptoms called *primary HIV infection* which may include fever, muscle aches and swollen glands. Often the symptoms go unnoticed by the infected person.

Following *primary infection*, most persons have mild or no symptoms for several years. Over time, their immune system weakens and they develop HIV-related illnesses which become increasingly severe as immune weakness progresses. The *clinical staging* method is a standardised way to describe progression through the increasing degrees of immune weakness. Without specific treatment, HIV-infected persons progress through all of the clinical stages. The end-stage of the disease is called AIDS (stage 4). and is defined by *opportunistic illnesses* that are associated with late-stage HIV infection. These illnesses are considered AIDS-related because they generally are uncommon in people with normally functioning immune systems.

The advent of effective *ART* has considerably reduced the rate of progression to AIDS and death from AIDS in areas where these drugs are available. It also has been associated with fewer AIDS-related *opportunistic illnesses*.

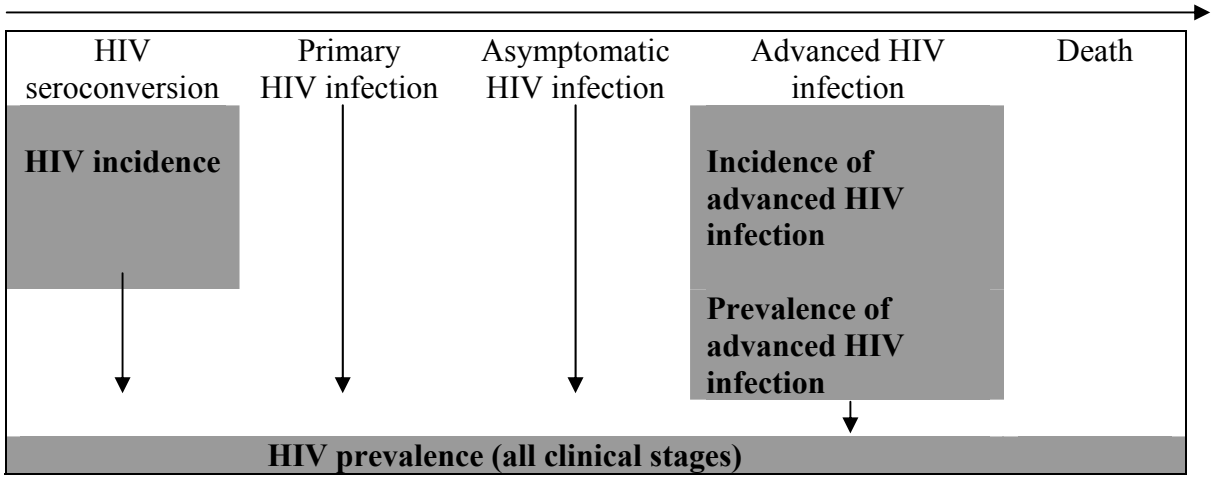
Natural history of HIV and targets for surveillance, continued

To fully understand the HIV epidemic, several key stages in the disease should be noted. These are depicted in Figure 1.1 and include:

- HIV *incidence* (the number or rate of new HIV infections)
- HIV *prevalence* (the number or rate of all persons living with HIV, regardless of how long they have been infected or whether or not they are aware of their infection)
- The *incidence* of *advanced HIV infection*
- The *prevalence* of *advanced HIV infection*
- Deaths from *advanced HIV infection*.

Measuring each of these points allows a complete HIV *surveillance* system for prevention or medical interventions and for monitoring the success of such programmes. In resource-constrained settings, including all of these target points in the *surveillance* system can be difficult, but HIV *case reporting* can provide information.

Figure 1.1. Target points for HIV surveillance within the natural history of HIV without treatment.



Discussing the figure

Look at Figure 1.1 and answer the following questions:

a) At which of the target points does your country monitor?

b) How many incidence points can be monitored? How do they differ?

Measuring new HIV infections

To know the direction of the HIV epidemic, information on HIV *incidence* is important. Only a few imperfect methods exist for measuring new HIV infections, but some tests can estimate the number and rate. One method is the *BED assay*—a serologic test that uses a modified version of a standard HIV test. Although it is not used to diagnose new HIV infections, it can be used as a *surveillance* tool.

Another more widely used method of measuring the rate of new HIV infections is monitoring trends in HIV *prevalence* among the youngest age group (15-19 or 15-24 years) of women attending *antenatal clinics* (ANCs). This use of *sentinel HIV sero-prevalence surveillance* has been the most common way of estimating HIV *incidence* in developing countries, although it is difficult to measure accurately, and is likely to become increasingly important in HIV *surveillance*.

Measurement of HIV prevalence

HIV *prevalence* is the number of persons living with HIV infection, including persons with any stage of HIV disease (newly acquired infections, long-standing asymptomatic infections and late-stage disease, including AIDS), whether or not they are aware of it. It does not include persons who have died from AIDS.

It is difficult to have a complete and accurate count of all persons infected with HIV. As a result, *prevalence* is often estimated using a variety of data sources, including HIV/AIDS case reports and results from surveys and special studies. In developing counties, *sentinel sero-prevalence surveys* of women attending *ANCs* have been the source of the most frequently used data for estimating *prevalence*.

Measurement of advanced HIV disease

Obtaining an accurate and complete count of persons with *advanced HIV infection* is an important way to anticipate the need for medical care and other support services and to estimate the success of treatment at earlier stages of the disease. In countries where *ART* is becoming increasingly available, the number of persons with *advanced HIV infection* should decline, even with ongoing HIV transmission, and they can be counted through *case reporting*. These people are symptomatic, and if they seek care they can be reported from healthcare facilities.

Measurement of HIV/AIDS mortality

Although many developing countries have successfully instituted *ART* programmes, many HIV-infected persons remain in need of *ART*. The number of deaths from *advanced HIV infection* has dropped dramatically in countries where *ART* has been used widely. Thus, tracking deaths from *advanced HIV infection* is an important measure of the success of treatment programmes. In addition, understanding the proportion of deaths from HIV and the age groups most severely affected reveals the magnitude of the problem. To count and track trends in HIV-related deaths accurately, however, countries must have well-functioning *vital statistics* registries. In developing countries, the report of AIDS deaths is incomplete due to the *stigma* associated with the disease. The use of alternative methods for mortality *surveillance* must be examined in countries where vital statistics registries are not in place or are incomplete because of issues such as *stigma*.

Purpose of HIV Case Reporting

Accurate, timely, and complete information on HIV cases can be used to:

- Determine the burden and impact of HIV on health services
- Provide information on the opportunistic infections associated with *advanced HIV infection*
- Determine the characteristics and *risk factors* (transmission categories) of persons with HIV infection
- Determine the region's *disease burden* that is attributable to HIV
- Assess trends in HIV *incidence* and *prevalence*, if reporting is nearly complete (>70%)
- Use data from HIV *case reporting* for the purposes of:
  - Advocacy
  - Resource mobilisation
  - Programme planning

Purpose of HIV Case Reporting, continued

- Targeting
- Monitoring and evaluation.

Surveillance terminology

Surveillance refers to many types of activities employed in the systematic collection of information about the HIV epidemic. Certain countries have relied primarily on blinded HIV *sero-prevalence surveys* and AIDS *case reporting* to measure the level and trends in HIV *prevalence*. Case reporting is used in tandem with HIV *sero-prevalence surveys*, as they provide different but complementary information.

Listed below are descriptions of the *surveillance* terms used in this module.

Table 1.1. Differences between HIV surveillance activities.

Activity	Characteristic
HIV sero-prevalence or *HIV sero-prevalence surveillance, or HIV sentinel surveillance*	▪ Measures the *prevalence* of HIV infection using serological survey methods ▪ Does not report on individual patients (as occurs with HIV *case surveillance*)
HIV infection reporting (all clinical stages)	▪ Reports all persons newly diagnosed with HIV, regardless of *clinical stage* or immunologic status
Advanced HIV infection reporting	▪ Reports the number of patients with *clinical stages* 3 and 4 or CD4 cell count <350 mm^3
AIDS *case reporting*	▪ Reports the number of patients with clinical stage 4 or CD4 cell count <200 mm^3

Discussing the table

Looking at Table 1.1, answer the following questions:

a. How do HIV *sero-prevalence surveys* and HIV *case reporting* differ?

b. Are serological survey methods used in HIV *case reporting*?

The need to replace AIDS case reporting

ART has dramatically altered the natural history of HIV disease: it delays progression from early HIV disease to advanced stages, which includes AIDS, and reduces HIV-related mortality.

The current *WHO* recommendation is to provide *ART* to all persons with *HIV clinical stage* 4, and to consider it for persons with clinical stage 3 and CD4 counts <350 mm^3 and with earlier stages of disease if CD4 counts are low (<200 mm^3). These changes in treatment have important implications for AIDS reporting. With *ART* given at earlier stages, fewer persons will progress to AIDS. Consequently, AIDS *case reporting* no longer can provide a stable way of monitoring the HIV epidemic. In addition, it is important to know how many people are currently in need of *ART*. *Case reporting* can provide this information. Because persons with clinical stages 3 and 4 may be offered ART, the *WHO* has changed its reporting recommendations to replace AIDS *case reporting* with either of the following:

- Reporting persons with *advanced HIV infection*
- Reporting persons with all clinical stages of HIV (this requires information on the clinical stage of HIV at diagnosis).

As HIV testing becomes more widespread, it provides the opportunity to monitor HIV infections that may occur prior to a person developing AIDS and thus allows asymptomatic HIV-infected persons to be counted. The expansion of AIDS *case reporting* to include adults and children who have not yet developed *advanced HIV infection* may provide a more complete picture of the epidemic.

Incorporating Data Collected from HIV Programmes into Case Reporting

Programmes with information for reporting

Although HIV *case reporting* is a newly recommended *surveillance* practise, reporting cases of AIDS has been recommended for many years. In some parts of the world, it has occurred primarily through healthcare providers. In addition, surveillance officers can assist directly to improve the effectiveness of *case reporting* by working closely with programmes that care for HIV-infected persons. Programmes that are likely to be good sources of HIV cases include:

- HIV care and *ART* programmes
- *Tuberculosis* (TB) programmes (especially those that conduct HIV testing among *TB* patients)
- Programmes that provide *ART* to pregnant women (*prevention of mother-to-child transmission* [PMTCT] programmes)
- Vital statistics registries (to capture information on persons who die with HIV disease).

How to use programme data for case reporting

Data collected from programmes that provide services or care to persons with HIV infection can be used for *surveillance* purposes in two ways:

- To supplement HIV *case reporting* data and data collected from HIV *sentinel sero-prevalence surveillance*
- To identify HIV-infected persons who should be reported to the *surveillance* programme.

You can use programme data for HIV case reporting only if:

- Programmes collect and retain patient-level information
- Methods exist to record cases that have been reported
- Programme staff are trained how to report cases and complete case report forms
- *Surveillance* officers provide guidance and technical assistance in completing case report forms.

How to use programme data for case reporting, continued

In addition, *case reporting* is more likely to occur if *surveillance* officers:

- Meet with programme managers to discuss the importance of reporting cases and provide forms and training
- Adequately assure the security and *confidentiality* of case data
- Provide regular feedback to the healthcare workers and providers about the results from case *surveillance*.

For efficient use of time and resources, programmes that serve the largest number of HIV-infected persons should be assisted with *case reporting*.

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 to discuss these questions:

1. Does your country have a functional HIV case reporting system?

2. If your country is not conducting HIV case reporting, discuss why it is not.

3. If your country does not have an HIV case reporting system, discuss current limitations to HIV case reporting. What are some possible solutions for these limitations?

4. Working alone or with others from your country, region or district, complete the following tables and then discuss your responses in your small group.

Small group discussion, continued

Table 1.2. HIV case reporting in your country.

Surveillance activities	**Is reporting conducted? (Tick one box)**	**If yes, how often?**	**Who is the responsible person/officer? (Name and title)**	**How can data from this activity be used and by whom?**
HIV infection *case reporting*	☐Yes ☐ No			
Case reporting for *advanced HIV infection*	☐Yes ☐ No			
Case *surveillance* for AIDS	☐Yes ☐ No			
Case *surveillance* of AIDS deaths	☐Yes ☐ No			
Tuberculosis (TB) *surveillance*: *case reporting* of diagnosed *TB* cases	☐Yes ☐ No			
Surveillance of death registration	☐Yes ☐ No			

Small group discussion, continued

If you answered "yes" to more than one of the questions on the previous page, please answer the following:

Is the *surveillance* system able to link case reports on one person who is reported multiple times or from multiple sources? If so, explain how this is done and at what level (for example, district or national). You will see more surveillance questions on the following pages.

Small group discussion, continued

Please indicate in the table below what types of HIV *sero-prevalence surveillance* are being conducted or have been conducted in your country.

Table 1.3. HIV sero-prevalence surveillance in your country.

Surveillance activities	**Surveillance ever conducted? (Tick one box)**	**If yes, how often?**	**When was the last survey conducted? (Record year)**	**Who is the responsible person/officer? (Name and title)**	**How are data distributed, and to whom?**
Antenatal clinic (ANC) attendees	☐Yes ☐ No				
Prisoners	☐Yes ☐ No				
Men who have sex with men (MSM)	☐Yes ☐ No				
Injection drug users (IDUs)	☐Yes ☐ No				
Commercial *sex workers*	☐Yes ☐ No				
Other populations Specify:	☐Yes ☐ No				

Small group discussion, continued

Please indicate which of the following programmes are conducted in your country.

Table 1.4. Prevention and control programmes in your country.

Programmes	**Does this programme exist in your country?**	**What year did the programme begin?**	**Who performs monitoring?**	**How often are indicators reported?**	**How are data delivered and to whom?**
Prevention of mother-to-child transmission (PMTCT)	☐Yes ☐ No				
HIV care	☐Yes ☐ No				
HIV treatment: *antiretroviral therapy* (ART)	☐Yes ☐ No				
Tuberculosis (*TB*) control and prevention	☐Yes ☐ No				

Small group discussion, continued

Programmes	**Does this programme exist in your country?**	**What year did the programme begin?**	**Who performs monitoring?**	**How often are indicators reported?**	**How are data delivered and to whom?**
Orphans and vulnerable children	☐Yes ☐ No				
Sexually transmitted infection (STI) prevention and control	☐Yes ☐ No				

Additional questions regarding *TB* control programmes:

i. Are *TB* patients routinely tested for HIV?

ii. If so, describe how to report these cases to the *surveillance* unit.

Small group discussion, continued

Please indicate in the table below which of the following special surveys are conducted in your country.

Table 1.5. Special surveys conducted in your country.

Survey type	**Is this conducted?**	**If so, how often?**	**When was the last survey conducted? (Record year)**	**Who is responsible? (Name and/or title)**	**How are data disseminated, and to whom?**
Health facility survey	☐Yes ☐ No				
Quality of service and care survey	☐Yes ☐ No				
Service availability mapping survey	☐Yes ☐ No				
Priorities for Local AIDS Control Efforts (PLACE) *survey*	☐Yes ☐ No				
Other: (specify)	☐Yes ☐ No				
Mortality surveys looking at HIV-related deaths	☐Yes ☐ No				

Small group discussion, continued

Survey Type	**Is this conducted?**	**If so, how often?**	**When was the last survey conducted? (Record year)**	**Who is responsible? (Name and/or title)**	**How are data disseminated, and to whom?**
Behavioural surveys (state with or without *biomarkers*)	☐Yes ☐ No				
Population-based surveys: Demographic Health Survey (DHS), *AIDS Indicator Survey* (AIS)	☐Yes ☐ No				

Apply what you've learned/ case study

Work on this case study independently.

1. You are the district surveillance officer for the Republic of Melabia in a resource-constrained country. The Republic of Melabia has been estimated to have one of the highest prevalence levels of HIV in the region. The national AIDS control programme is interested in expanding and improving its surveillance programme. The national surveillance officer is conducting site visits to various districts to discuss ways of improving surveillance. During your meeting with the national surveillance officer, you are asked to suggest additional surveillance activities in your district that you believe could be implemented successfully. Describe what these activities would be.

2. The national surveillance officer has indicated that there is interest in using data collected from HIV and other care programmes for reporting persons with advanced HIV infection. What programmes would you suggest using?

Unit 1 Summary

- For a full understanding of the HIV epidemic, you should monitor five key factors: HIV incidence, HIV prevalence, incidence of advanced HIV infection (and/or AIDS), prevalence of advanced HIV infection/AIDS, and deaths due to HIV disease.

- HIV case reporting is conducted to obtain accurate and timely information on the burden of disease. This is necessary to provide and measure the impact of programmes for HIV prevention, care and treatment.

- The 2006 WHO HIV surveillance recommendations call for replacing AIDS case reporting with reporting of persons with advanced HIV disease (clinical stages 3 and 4) to healthcare authorities. Countries may opt to report all persons with HIV infection, regardless of their clinical stage.

- Information collected as part of HIV-related programmes, including TB control programmes and HIV care and ART monitoring programmes, can be a source for identifying and reporting HIV-infected persons.

Unit 2

HIV Clinical Staging and Surveillance Case Definitions

Overview

What this unit is about

This unit provides an overview of the history and purpose of HIV clinical staging and HIV/AIDS surveillance case definitions. It includes:

- A brief history of HIV clinical staging systems and surveillance case definitions
- A description of the 2006 WHO HIV clinical staging criteria (the presumptive and definitive criteria) and the 2006 WHO surveillance case definitions
- Case reporting options and their advantages and disadvantages
- An explanation of the link between HIV clinical staging, ART recommendations and HIV case reporting.

Warm-up questions

1. True or false? In the revised (2006) adult and paediatric WHO HIV clinical staging systems, there are four clinical stages.

   True False

2. True or false? The revised (2006) WHO HIV surveillance case definition includes the same clinical stages for adults and infants.

   True False

3. List the two options for HIV case surveillance that WHO recommends.

   a.

   b.

4. True or false? The clinical criteria included in the revised (2006) WHO HIV surveillance case definition only include definitive diagnosis of clinical events.

   True False

5. List four reasons why HIV clinical staging systems were developed.

6. True or false? Previous surveillance case definitions in developing countries focused only on stage 4 (AIDS).

   True False

Introduction

What you will learn

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

- Describe the history of the HIV/AIDS clinical staging system and surveillance case definitions
- Describe the 2006 WHO HIV clinical staging criteria (the presumptive and definitive criteria) and the surveillance case definition for HIV infection, advanced HIV infection, and AIDS
- List at least one advantage and one disadvantage of HIV case reporting and advanced HIV case reporting
- Explain the link between HIV clinical staging, antiretroviral treatment recommendations, and HIV/AIDS case reporting.

Table 2.1. Unit 2 annexes

Annex	Information provided
2.1	Presumptive and definitive criteria for recognising HIV-related clinical events in adults (15 years or older) and children (younger than 15 years) with confirmed HIV infection
2.2	Presumptive diagnosis of severe HIV infection among HIV–sero-positive and HIV-exposed children

History of Clinical Staging and HIV/AIDS Case Surveillance Definitions

Previous clinical staging criteria

HIV clinical staging criteria were developed to:

- Provide uniformity for the clinical evaluation of persons with HIV infection
- Predict the progression to AIDS in persons with HIV infection
- Guide clinical management of patients
- Help people to study the natural history of HIV infection.

The Walter Reed clinical staging classification system was developed in 1986 for use among United States military personnel. It included both clinical and laboratory manifestations of HIV infection. The inclusion of a laboratory component and the list of AIDS-related *opportunistic illnesses* in the classification system worked well in developed countries, but proved to be less suitable for developing countries where certain diagnostic methods were unavailable.

Previous clinical staging criteria, continued

To provide an *HIV clinical staging* system that could be used worldwide, the *World Health Organization* (WHO) convened a panel of experts and developed the 1990 staging system for adults. The 1990 staging system is simple and prognostic, predicts progression to AIDS and uses CD4 cell count and other simple clinical variables, such as night sweats and oral thrush. A paediatric staging system was adopted in 2003.

Previous surveillance case definitions

Several AIDS *surveillance case definitions* are used throughout the world. The initial definition (*Bangui*) was developed in 1985 and formalised in 1986 for developing countries. It was modified in 1989 to include HIV serologic criteria for adults in areas with laboratory capacity. Additional regional *surveillance case definitions* were developed by the Pan American Health Organization (the Caracas definition), the European Centers for Disease Control and Prevention, and the United States *Centers for Disease Control and Prevention* (CDC). Each of these definitions was modified as laboratory testing became available and as additional information regarding the clinical manifestations of *advanced HIV infection* became known. In addition to modifications of the AIDS *surveillance* definitions, some regions developed *surveillance case definitions* for HIV infection not yet meeting the criteria for AIDS, which the *WHO* had not previously done.

The 2006 HIV Clinical Staging System and Surveillance Case Definitions

Updated clinical staging system

The increased availability of *anti-retroviral treatment* (ART) has resulted in the need for an updated *HIV clinical staging* system that:

- Harmonises the 2002 three-stage paediatric staging system with the 1990 four-stage adult system
- Includes stages at which *prophylaxis* and *ART* should be considered and recommended
- Updates clinical conditions
- Harmonises *HIV clinical staging* and *surveillance case definitions*
- Includes immunologic criteria for *HIV clinical staging* and *surveillance case definitions*.

Anticipating the greater availability of *ART*, the *WHO* and *CDC* convened a panel of experts in 2004 to develop updated *HIV clinical staging* systems for adults and children. Regional consultations were held in all WHO regions in 2004 and 2005. The *HIV clinical staging* criteria and *surveillance case definitions* were adopted in 2006. The revisions were to show that HIV infection is treatable in the presence of *ART*. Clinical staging should be done at the time of the initial HIV diagnosis, upon entry into clinical care for HIV infection and at each clinical visit.

Table 2.2. WHO clinical classification of established HIV-infection.

HIV-associated symptomatology	WHO clinical stage
Asymptomatic	1
Mild symptoms	2
Advanced symptoms	3
Severe symptoms	4

The revised staging systems include:

- *Presumptive clinical diagnosis* criteria that can be made in the absence of sophisticated laboratory tests
- *Definitive clinical diagnosis* criteria that require confirmatory laboratory tests.

Updated clinical staging system, continued

With more laboratory capacity in developing countries, the *WHO* developed an immunologic classification system for HIV infection based on the known decline in CD4 cells with the progression of HIV infection. Listed below are the age-related values and associated degree of immunodeficiency. Note that for children less than five years of age, CD4 percentage should be used rather than absolute cell count.

Table 2.3. WHO-proposed immunologic classification for established HIV infection.

HIV-associated immunodeficiency	**Age-related CD4 values**			
	< 11 mo (%)	**12-35 mo (%)**	**36-59 mo (%)**	**≥ 5 yrs (mm^3)**
None/not significant	> 35	> 30	> 25	> 500
Mild	30-35	25-30	20-25	350-499
Advanced	25-30	20-25	15-20	200-349
Severe	< 25	< 20	< 15	< 200 or < 15%

WHO clinical staging of HIV/AIDS

Table 2.4. WHO clinical staging of HIV/AIDS for adults and adolescents with confirmed HIV infection.

Clinical stage 1

Asymptomatic
Persistent generalised lymphadenopathy

Clinical stage 2

Moderate unexplained weight loss (<10% of presumed or measured body weight)[1]
Recurrent respiratory tract infections (sinusitis, tonsillitis, bronchitis, otitis media, pharyngitis)
Herpes zoster
Angular cheilitis
Recurrent oral ulceration
Papular pruritic eruptions
Seborrhoeic dermatitis
Fungal nail infections

Clinical stage 3

Unexplained[2] severe weight loss (>10% of presumed or measured body weight)[1]
Unexplained chronic diarrhoea for longer than one month
Unexplained persistent fever (intermittent or constant for longer than one month)
Persistent oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis
Lymph node TB
Severe bacterial infections (for example, pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Unexplained anaemia (<8 g/dl), neutropenia (< 0.5 x 10^9 /L) and/or chronic thrombocytopenia (< 50 X 10^9 /L^3)

Clinical stage 4[3]

HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Extrapulmonary tuberculosis
Kaposi's sarcoma
Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacteria infection
Progressive multifocal leukoencephalopathy
Chronic cryptosporidiosis
Chronic isosporiasis
Disseminated mycosis (extrapulmonary histoplasmosis or coccidiomycosis)
Recurrent septicaemia (including non-typhoidal *Salmonella*)
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

[1] Assessment of body weight in pregnant woman must consider expected weight gain of pregnancy.
[2] Unexplained refers to those cases in which the condition is not explained by other conditions.
[3] Some additional specific conditions also can be included in regional classifications (for example, American trypanosomiasis reactivation in Americas region).

WHO clinical staging of HIV/AIDS, continued

Table 2.5. WHO clinical staging of HIV/AIDS for children with confirmed HIV infection.

Clinical Stage 1

- Asymptomatic
- Persistent generalised lymphadenopathy

Clinical Stage 2

- Unexplained persistent hepatosplenomegaly
- Papular pruritic eruptions
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Fungal nail infections
- Recurrent oral ulcerations
- Unexplained persistent Parotid enlargement
- Lineal gingival erythema
- Herpes zoster
- Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)

Clinical Stage 3

- Moderate unexplained[1] malnutrition not adequately responding to standard therapy
- Unexplained persistent diarrhoea (14 days or more)
- Unexplained persistent fever (above 37.5 intermittent or constant, for longer than one month)
- Persistent oral candidiasis (after first 6-8 weeks of life)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis/periodontitis
- Lymph node tuberculosis
- Pulmonary tuberculosis
- Severe recurrent bacterial pneumonia
- Symptomatic lymphoid interstitial pneumonitis
- Chronic HIV-associated lung disease including brochiectasis
- Unexplained anaemia (< 8g/dl), neutropenia (<$0.5x10^9/L^3$) or chronic thrombocytopenia (< $50x10^9/L^3$)

Clinical Stage 4[2]

- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia
- Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration or visceral at any site)
- Extrapulmonary tuberculosis
- Kaposi's sarcoma
- Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
- Central nervous system toxoplasmosis (after one month of life)
- HIV encephalopathy
- Cytomegalovirus infection retinitis or CMV infection affecting another organ, with onset at age over one month.
- Extrapulmonary cryptococcosis (including meningitis)
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis, penicilliosis)
- Chronic cryptosporidiosis
- Chronic isosporiasis
- Disseminated non-tuberculous mycobacteria infection
- Cerebral or B cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy
- Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

Updated WHO surveillance case definitions

Changes to the clinical staging of HIV infection combined with the greater use of *ART* have resulted in a need to revise case *surveillance* recommendations. Previous *case definitions* have focused exclusively on reporting persons who met the *Bangui* or expanded AIDS *case definition*. The following tables present the *case definitions* for HIV infection and *advanced HIV infection*.

Table 2.6. WHO case definition for HIV infection.

Adults and adolescents and children ≥18 months
HIV infection is diagnosed based on: ▪ A positive HIV antibody testing (rapid or laboratory-based enzyme immunoassay). The test is usually confirmed using a second HIV antibody test (rapid or laboratory-based enzyme immunoassay) relying on different antigens or different operating characteristics than in the initial test And/or ▪ A positive virologic test for HIV or its components (HIV-RNA or HIV-DNA or ultrasensitive HIV *p24 antigen*) confirmed by a second virologic test obtained from a separate determination.
Children younger than 18 months
HIV infection is diagnosed based on: ▪ A positive virologic test for HIV or its components (HIV-RNA or HIV-DNA or ultrasensitive HIV *p24 antigen*) confirmed by a second virologic test obtained from a separate determination taken more than four weeks after birth.

Updated WHO surveillance case definitions, continued

Table 2.7. Criteria for diagnosis of advanced HIV infection (including AIDS[a]) for reporting adults and children.

Clinical criteria for a diagnosis of advanced HIV in adults and children with confirmed HIV infection
Presumptive or *definitive diagnosis* of any one stage 3 or 4 condition
Immunological criteria for diagnosing *advanced HIV infection* in adults and children five years or older with confirmed HIV infection
CD4 count of <350/mm^3 in an adult or child
Immunological criteria for diagnosis in a child younger than five years with confirmed HIV infection
%CD4 <30 among those younger than 12 months of age; %CD4 <25 among those aged 12-35 months, %CD4 <20 among those aged 35-59 months.

[a] AIDS in adults and children of any age is defined as: clinical diagnosis (presumptive or definitive) of any stage 4 condition with confirmed HIV infection; OR immunologic criteria in adults and children with confirmed HIV infection and ≥5 years of age; first-ever documented % CD4 count <200 per mm^3 or % CD4 + <15; or among children aged 12-35 months first-ever documented % CD4+ <20; or among infants <12 months of age first-ever documented % CD4+ <25.

Reporting primary HIV infection

Primary HIV infection has no standard *case definition*, although it is recently acquired and highly contagious and therefore important to report. Reporting persons with primary HIV infection is one method of capturing the leading edge of the epidemic. In certain settings these persons are not likely to seek medical care; reporting them probably is of limited value and is not recommended. Rather, they should be reported as HIV infected.

Symptomatic primary HIV infection presents two to four weeks after HIV acquisition and may include any of the following symptoms:

- Lymphadenopathy
- Pharyngitis
- Maculopapular rash
- Orogenital ulcers
- Menigoencephalitis
- Lymphopaenia (including low CD4 cell count)
- *Opportunistic infections*.

Reporting primary HIV infection, continued

These clinical conditions should not be confused with *HIV clinical staging* criteria. Primary HIV infection can be diagnosed by recent HIV *sero-conversion* or by identifying HIV products (HIV-RNA or HIV-DNA and/or ultrasensitive HIV *p24 antigen* with a negative HIV antibody test).

WHO HIV case reporting recommendations

Due to the revisions in *case definitions*, *WHO* recommends that countries standardise their *surveillance* practises and definitions to report HIV-infected persons not previously reported. A case of HIV infection includes all stages of HIV infection (*HIV clinical stages* 1-4).

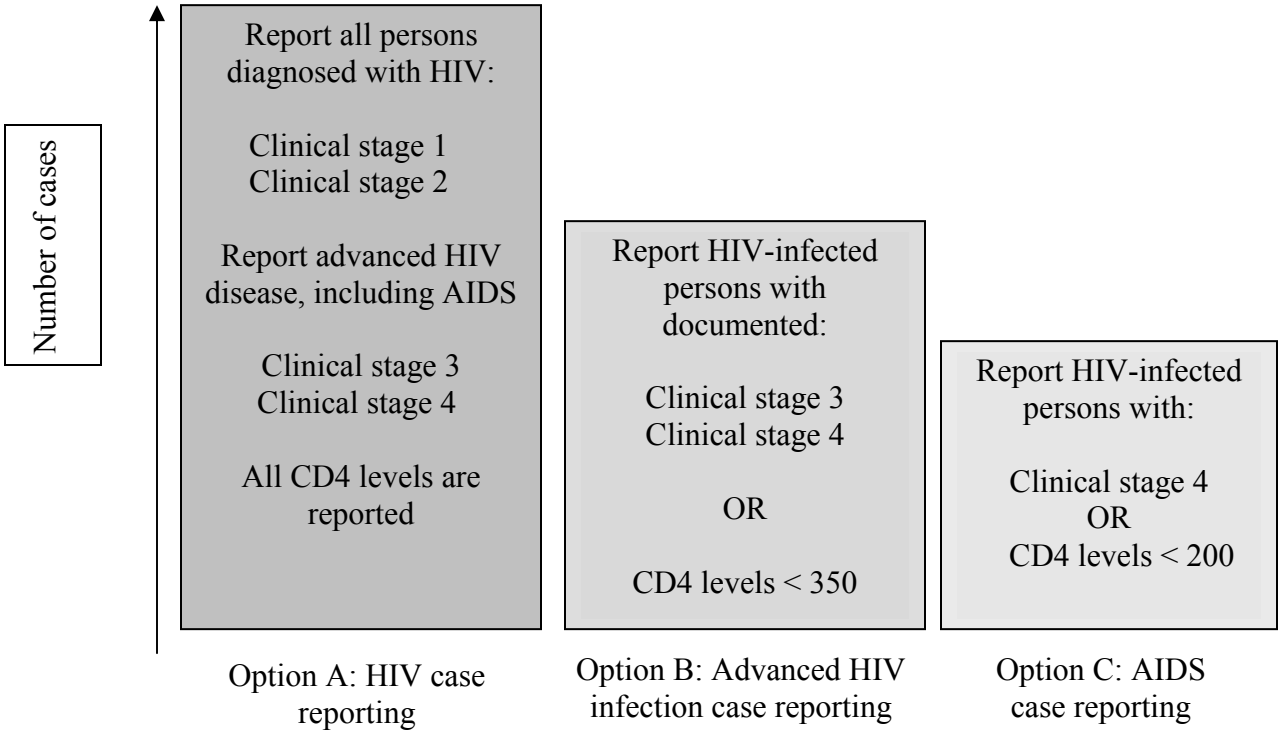
Countries may choose to report all persons diagnosed with HIV and will report persons at any clinical stage of infection and *advanced HIV infection* (clinical stages 3 and 4). This means that those who are initially diagnosed with HIV at stages 1 or 2 and progress to later clinical stages will be reported twice. Persons who are first diagnosed with HIV at clinical stage 3 or 4 will be reported as having *advanced HIV infection* and will be reported only once.

If countries cannot report all cases of HIV, they may choose to report only people diagnosed with *advanced HIV infection*, which includes AIDS cases and does not require separate AIDS *case reporting*.

The graphic on the next page illustrates what your *surveillance* system will yield, depending on what you report.

WHO HIV case reporting recommendations, continued

Figure 2.1. Levels of case reporting.



Advantages and disadvantages of case reporting options

WHO recommendations on *case reporting* are:

1. Countries should replace AIDS *case reporting* (option C) with reporting *advanced HIV infection* cases (option B). Once this is begun, countries may choose to continue to monitor trends, particularly if the *completeness of reporting* was 70% or more.
2. Option A is the ultimate goal. As a long-term strategy, countries should report all cases of HIV infection to obtain a complete picture of the epidemic. Countries should implement pilot projects to gain experience in reporting all cases of HIV infection so that a system of HIV *case reporting* on a national scale can be planned.

Advantages and disadvantages of case reporting options, continued

Selecting the type of *case reporting* should be based on understanding the advantages and disadvantages and the resources needed to collect, analyse and interpret *surveillance* data. Regardless of the type, reporting should be complete, timely and consistent, and able to accommodate change.

Look at Tables 2.8, 2.9, and 2.10 on this page and the next page to consider *case reporting* options:

Table 2.8. HIV case reporting, all clinical stages (1-4).

Advantages
▪ Can provide information on the current and future need for *ART* and prevention services ▪ In situations where a large proportion of the population tests regularly, reporting can estimate the levels and trends in HIV *prevalence* and provide information on persons more recently infected ▪ Provides a complete picture of the HIV-infected population ▪ Includes reporting people with *advanced HIV infection*
Disadvantages
▪ Cannot determine the rate of newly acquired infections (*incidence*) ▪ Requires frequent and widespread HIV testing among *at-risk* persons to yield complete counts of HIV-infected persons ▪ In countries with mature epidemics, initial HIV *case reporting* will result in more persons reported with *WHO HIV clinical stage* 3 and 4 disease ▪ If clinical stages are not included in reporting, it will be difficult to compare trends in countries in which it has been functioning well

Table 2.9. Advanced HIV infection case reporting (includes AIDS) (Clinical stages 3 and 4).

Advantages
▪ Likely to provide a complete picture of persons with *advanced HIV infection*, because they seek care for symptoms and are diagnosed and can be reported by the healthcare provider ▪ Provides information on the number of diagnosed persons on *ART* and information on the number of those in need of *ART* (assists with programme planning efforts) ▪ Provides complete reporting because persons receiving *ART* are in care settings where *surveillance* officers can assist with case reporting and can train clinic staff to report cases ▪ In countries with mature epidemics and decreasing *incidence*, is likely to include a large proportion of the total number of cases

Disadvantages
▪ Cannot determine the rate of newly acquired infections (*incidence*) ▪ Will not be useful for planning for *ART* should treatment guidelines change to include the provision of *ART* to persons in earlier clinical stages ▪ Cannot provide information on all persons diagnosed with HIV ▪ In areas with changing epidemics, cannot provide information on populations newly infected and diagnosed

Table 2.10. AIDS case reporting (clinical stage 4).

Advantages
▪ Allows for monitoring trends in countries where AIDS *case reporting* has been complete (at least 70% complete for the last five years or more) ▪ Can be used to measure the success of *ART* programmes (number of living AIDS cases should increase and number of newly diagnosed AIDS cases should decrease) ▪ In countries where people wait until they are severely ill to seek care, this may be the only type of reporting that can be complete
Disadvantages
▪ Does not provide adequate information for planning *ART* and prevention services ▪ Provides an incomplete picture of the number of persons diagnosed with HIV infection

Linking HIV Clinical Staging, ART Use and HIV Case Reporting

Initiating ART

WHO has specified the best times to initiate *ART* based on *HIV clinical staging* and CD4 count, when available.

Table 2.11. WHO recommendations for initiating ART based on clinical staging and CD4 count testing.

Clinical stage	CD4 available	CD4 not available
1	Treat if CD4 cell count <200 Consider treating if CD4 <350	Do not treat
2	Treat if CD4 <200 Consider treating if CD4 <350	Do not treat
3	Consider treating if CD4 <350 Treat CD4 <350, or pregnant or had pulmonary *TB*	Treat
4	Treat	Treat

ART is recommended for children and infants with clinical stages 3 and 4, regardless of CD4 cell count or percentage. Results from CD4 testing are used to guide decisions on beginning *ART* in children and infants with clinical stages 1 and 2.

Linking HIV clinical staging, ART use, and case surveillance

As described above, *HIV clinical staging* is:

- Used to determine the best time to begin treatment for HIV infection
- A key component of the *surveillance case definitions*.

The link between these factors is useful for *surveillance* purposes. HIV *case reporting* is usually conducted in hospitals and clinics that provide *ART* and by healthcare providers who conduct reporting. Therefore, patients who receive *ART* probably will have their clinical stage determined. This is particularly useful in countries where *advanced HIV infection* is reported. In healthcare facilities, *ART* programmes may use monitoring to identify and provide all the information needed to report these persons to the health authorities. The new *HIV clinical staging system*, HIV treatment recommendations, and *surveillance case definition* and reporting recommendations should improve *case reporting* and enable the best care of HIV-infected persons.

Annex 2.1. Presumptive and definitive criteria for recognising HIV-related clinical events in adults (15 years or older) and children (younger than 15 years) with confirmed HIV infection

Adults (15 years or older)

CLINICAL EVENT	CLINICAL DIAGNOSIS	DEFINITIVE DIAGNOSIS
Clinical Stage 1		
Asymptomatic	No HIV-related symptoms reported and no signs on examination.	Not applicable
Persistent generalised lymphadenopathy	Painless enlarged lymph nodes >1 cm, in two or more non-contiguous sites (excluding inguinal), in absence of known cause & persisting for ≥3 months	Histology
Clinical Stage 2		
Moderate unexplained weight loss (10% of body weight)	Reported unexplained involuntary weight loss. In pregnancy, failure to gain weight.	Documented weight loss of <10% of body weight.
Recurrent bacterial upper respiratory tract infections (current event plus one or more in last six-month period)	Symptom complex; for example, unilateral face pain with nasal discharge (sinusitis), painful inflamed eardrum (otitis media), or tonsillo-pharyngitis without features of viral infection (such as coryza, cough)	Laboratory studies where available; for example, culture of suitable body fluid
Herpes zoster	Painful vesicular rash in dermatomal distribution of a nerve supply that does not cross midline	Clinical diagnosis
Angular cheilitis	Splits or cracks at the angle of the mouth not due to iron or vitamin deficiency; usually responds to antifungal treatment	Clinical diagnosis
Recurrent oral ulcerations (two or more episodes in last six months)	Aphthous ulceration, typically painful with a halo of inflammation and a yellow-grey pseudo-membrane	Clinical diagnosis
Papular pruritic eruption	Papular pruritic lesions, often with marked post-inflammatory pigmentation	Clinical diagnosis
Seborrhoeic dermatitis	Itchy scaly skin condition, particularly affecting hairy areas (scalp, axillae, upper trunk and groin)	Clinical diagnosis
Fungal nail infections	Paronychia (painful red and swollen nail bed) or onycholysis (separation of the nail from the nail bed) of the fingernails (white discolouration—especially involving proximal part of nail plate—with thickening and separation of nail from nail bed)	Fungal culture of nail/nail plate material

Clinical Stage 3		
Unexplained severe weight loss (≥10% of body weight)	Reported unexplained involuntary weight loss (> 10% of body weight) and visible thinning of face, waist and extremities, with obvious wasting or body mass index < 18.5 In pregnancy weight loss may be masked	Documented loss of more than 10% of body weight
Unexplained chronic diarrhoea for longer than one month	Chronic diarrhoea (loose or watery stools three or more times daily) reported for longer than one month	Three or more stools observed and documented as unformed, and two or more stool tests reveal no pathogens
Unexplained persistent fever (intermittent or constant and lasting for longer than one month)	Fever or night sweats for more than one month, either intermittent or constant with reported lack of response to antibiotics or anti-malaria agents, without other obvious foci of disease reported or found on examination Malaria must be excluded in malarial areas	Documented fever >37.5 ^{o}C with negative blood culture, negative Ziehl-Nielsen (ZN) stain, negative malaria slide, normal or unchanged chest X-ray and no other obvious focus of infection
Persistent oral candidiasis	Persistent or recurring creamy white curd-like plaques which can be scraped off (pseudo-membranous), or red patches on tongue, palate or lining of mouth, usually painful or tender (erythematous form)	Clinical diagnosis
Oral hairy leukoplakia	Fine white small linear or corrugated lesions on the lateral borders of the tongue which do not scrape off	Clinical diagnosis
Pulmonary tuberculosis (current)	Chronic symptoms: (lasting ≥ 2-3 weeks) cough, haemoptysis, shortness of breath, chest pain, weight loss, fever, night sweats; PLUS EITHER positive sputum smear; OR negative sputum smear; AND compatible chest radiograph (including but not restricted to upper lobe infiltrates, caritation, pulmonary fibrosist shrinkage. No evidence of extrapulmonary disease.	Isolation of *M. tuberculosis* on sputum culture or histology of lung biopsy (with compatible symptoms)
Severe bacterial infection (for example, pneumonia, meningitis, empyema, pyomyositis, bone or joint infection, bacteraemia or severe pelvic inflammatory disease)	Fever accompanied by specific symptoms or signs that localize infection, and response to appropriate antibiotic	Isolation of bacteria from appropriate clinical specimens (usually sterile sites)

Acute necrotizing ulcerative gingivitis or necrotizing ulcerative periodontitis	Severe pain, ulcerated gingival papillae, loosening of teeth, spontaneous bleeding, bad odour and rapid loss of bone and/or soft tissue	Clinical diagnosis
Unexplained anaemia (<8g/dL), neutropenia (<0.5 $\times 10^9$/L or chronic (more than one month) thrombocytopaenia (<5 0 $\times 10^9$/L)	Not presumptive clinical diagnosis	Diagnosed on laboratory testing and not explained by other non-HIV conditions Not responding to standard therapy with haematinics, anti-malarials or anti-helminthics as outlined in relevant national treatment guidelines, WHO Integrated Management of Childhood Illness guidelines or other relevant guidelines
Clinical Stage 4		
HIV wasting syndrome	Unexplained involuntary weight loss (>10% body weight), with obvious wasting or body mass index <18.5. PLUS EITHER unexplained chronic diarrhoea (loose or watery stools three or more times daily) reported for longer than one month OR reports of fever or night sweats for more than one month without other cause and lack of response to antibiotics or anti-malarials; malaria must be excluded in malarias areas	Documented weight loss >10% of body weight; PLUS EITHER two or more unformed stools negative for pathogens OR documented temperature of >37.5 ^oC with no other cause of disease, negative blood culture, negative malaria slide and normal or unchanged chest X-ray
Pneumocystis pneumonia	Dyspnoea on exertion or non-productive cough of recent onset (within the past three months) , tachypnoea and fever AND Chest X-ray evidence of diffuse bilateral interstitial infiltrates AND No evidence of bacterial pneumonia; bilateral crepitations on auscultation with or without reduced air entry	Cytology or immunofluorescent microscopy of induced sputum or bronchoalveolar lavage, or histology of lung tissue
Recurrent bacterial pneumonia	Current episode plus one or more previous episodes in last six months; acute onset (< 2 weeks) of severe symptoms (such as fever, cough, dyspnoea and chest pain) PLUS New consolidation on clinical examination or chest X-ray; response to antibiotics	
Chronic herpes simplex virus (HSV) infection (orolabial, genital or anorectal) of more than one month, or visceral of any duration	Positive culture or antigen test of a compatible organism Painful, progressive anogenital or orolabial ulceration; lesions caused by recurrent herpes simplex virus infection and reported for more than one month; history of previous episodes Visceral herpes simplex virus requires definitive diagnosis Positive culture or DNA (by polymerase chain reaction) of herpes simplex virus or compatible cytology/histology	

Chronic herpes simplex virus (HSV) infection (orolabial, genital or anorectal) of more than one month, or visceral of any duration	Painful, progressive anogenital or orolabial ulceration; lesions caused by recurrent herpes simplex virus infection and reported for more than one month; history of previous episodes Visceral herpes simplex virus requires definitive diagnosis	Positive culture or DNA (by polymerase chain reaction) of herpes simplex virus or compatible cytology/histology
Oesophageal candidiasis	Recent onset of retrosternal pain or difficulty in swallowing (food and fluids) together with oral candidiasis	Macroscopic appearance at endoscopy or bronchoscopy, or by microscopy/histology

Extrapulmonary tuberculosis	Systemic illness (such as fever, night sweats, weakness and weight loss) Other evidence for extrapulmonary or disseminated TB varies by site, such as pleural, pericardial, peritoneal involvement, meningitis, mediastinal or abdominal Discrete peripheral lymph node *Mycobacterium tuberculosis* infection (especially cervical) is usually considered a less severe form of extrapulmonary tuberculosis	*M. tuberculosis* isolation or compatible histology from appropriate site or radiological evidence of miliary TB (diffuse, uniformly distributed small miliary shadows or micronodules on chest X-ray)
Kaposi's sarcoma	Typical gross appearance in skin or oropharynx of persistent, initially flat, patches with a pink or violaceaous colour, skin lesions that usually develop into plaques or nodules	Macroscopic appearance at endoscopy or bronchoscopy, or by histology
Cytomegalovirus disease (other than liver, spleen or lymph node).	Retinitis only: may be diagnosed by experienced clinicians. Typical eye lesions on fundoscopic examination: discrete patches of retinal whitening with distinct borders, spreading centrifugally, often following blood vessels, associated with retinal vasculitis, haemorrhage and necrosis.	Compatible histology or cytomegalovirus demonstrated in cerebrospinal fluid by culture or DNA (by polymerase chain reaction).
Central nervous system toxoplasmosis	Recent onset of a focal nervous system abnormality consistent with intracranial disease or reduced level of consciousness AND response within 10 days to specific therapy.	Positive serum toxoplasma antibody AND (if available) single/multiple intracranial mass lesion on neuro-imaging (computed tomography or magnetic resonance imaging)
HIV encephalopathy	Disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks or months in the absence of a concurrent illness or condition other than HIV infection which might explain the findings.	Diagnosis of exclusion: and (if available) neuro-imaging (computed tomography or magnetic resonance imaging)
Extrapulmonary cryptococcosis (including meningitis)	Meningitis: usually subacute, fever with increasing severe headache, meningism, confusion, behavioural changes that respond to cryptococcal therapy.	Isolation of *Cryptococcus neoformans* from extrapulmonary site or positive cryptococcal antigen test on cerebrospinal fluid or blood.

Disseminated non-tuberculous mycobacteria infection	No presumptive clinical diagnosis.	Diagnosed by finding atypical mycobacterial species from stool, blood, body fluid or other body tissue, excluding lung.
Progressive multi focal leukoencephalopathy	No presumptive clinical diagnosis	Progressive neurological disorder (cognitive dysfunction, gait/speech disorder, visual loss, limb weakness and cranial nerve palsies) together with hypodense white matter lesions on neuro-imaging or positive polyomavirus JC polymerase chain reaction on cerebrospinal fluid.
Cryptosporidiosis (with diarrhoea lasting more than one month)	No presumptive clinical diagnosis.	Cysts identified on modified Ziehl-Nielsen stain microscopic examination of unformed stool.
Chronic isosporiasis	No presumptive clinical diagnosis.	Identification of *Isospora*
Disseminated mycosis (coccidiomycosis, histoplasmosis)	No presumptive clinical diagnosis.	Histology, antigen detection or culture from clinical specimen or blood culture.
Recurrent non-typhoid *Salmonella* bacteraemia	No presumptive clinical diagnosis.	Blood culture.
Lymphoma (cerebral or B cell non-Hodgkin)	No presumptive clinical diagnosis	Histology of relevant specimen or, for CNS tumours, neuroimaging techniques
Invasive cervical carcinoma	No presumptive clinical diagnosis.	Histology or cytology.
Atypical disseminated leishmaniasis	No presumptive clinical diagnosis.	Diagnosed by histology (amastigotes visualized) or culture from any appropriate clinical specimen.
Symptomatic HIV-associated nephropathy	No presumptive clinical diagnosis	Renal biopsy
Symptomatic HIV-associated cardiomyopathy	No presumptive clinical diagnosis	Cardiomegaly and evidence of poor left ventricular function confirmed by echocardiography

Children (younger than 15 years)

Clinical Event	Clinical Diagnosis	Definitive Diagnosis
Clinical Stage 1		
Asymptomatic	No HIV related symptoms reported and no clinical signs on examination.	Not applicable
Persistent generalised lymphadenopathy	Persistent swollen or enlarged lymph nodes >1 cm at two or more non-contiguous sites (excluding inguinal), without known cause.	Clinical diagnosis
Clinical Stage 2		
Unexplained persistent hepatosplenomegaly	Enlarged liver and spleen without obvious cause.	Clinical diagnosis
Papular pruritic eruptions	Papular pruritic vesicular lesions	Clinical diagnosis
Fungal nail infections	Fungal paronychia (painful, red and swollen nail bed) or onycholysis (painless separation of the nail from the nail bed). Proximal white subungual onchomycosis is uncommon without immunodeficiency.	Clinical diagnosis
Angular cheilitis	Splits or cracks at the angle of the mouth not attributable to iron or vitamin deficiency, and usually responding to antifungal treatment.	Clinical diagnosis
Lineal gingival erythema	Erythematous band that follows the contour of the free gingival line; may be associated with spontaneous bleeding.	Clinical diagnosis
Extensive wart virus infection	Characteristic warty skin lesions; small fleshy grainy bumps, often rough, flat on sole of feet (plantar warts); facial, more than 5% of body area or disfiguring.	Clinical diagnosis
Extensive molluscum contagiosum infection	Characteristic skin lesions: small flesh-coloured, pearly or pink, dome-shaped or umbilicated growths, may be inflamed or red; facial, more than 5% of body area or disfiguring. Giant molluscum may indicate more advanced immunodeficiency.	Clinical diagnosis
Recurrent oral ulceration	Current event plus at least one previous episode in past six months. Aphthous ulceration, typically with a halo of inflammation and yellow-grey pseudo-membrane	Clinical diagnosis
Unexplained persistent parotid enlargement	Asymptomatic bilateral swelling that may spontaneously resolve and recur, in absence of other	Clinical diagnosis

	know cause, usually painless	
Herpes zoster	Painful rash with fluid-filled blisters, dermatomal distribution, can be haemorrhagic on erythematous background, and can become large and confluent. Does not cross the midline.	Clinical diagnosis
Recurrent or chronic upper respiratory tract infection (URTI)	Current event with at least one episode in past 6 months. Symptom complex; fever with unilateral face pain and nasal discharge (sinusitis) or painful swollen eardrum (otitis media), sore throat with productive cough (bronchitis), sore throat (pharyngitis) and barking croup-like cough (laryngotracheal bronchitis). Persistent or recurrent ear discharge.	Clinical diagnosis
Clinical Stage 3		
Unexplained moderate malnutrition or wasting	Weight loss: low weight-for-age, up to −2 standard deviations from the mean, not explained by poor or inadequate feeding and or other infections, and not adequately responding to standard management.	Documented loss of body weight of –2 standard deviations from the mean, failure to gain weight on standard management and no other cause identified during investigation.
Unexplained persistent diarrhoea	Unexplained persistent (14 days or more) diarrhoea (loose or watery stool, three or more times daily), not responding to standard treatment.	Stools observed and documented as unformed. Culture and microscopy reveal no pathogens.
Unexplained persistent fever (>37.5ºC intermittent or constant, for longer than one month)	Reports of fever or night sweats for longer than one month, either intermittent or constant, with reported lack of response to antibiotics or antimalarial agents. No other obvious foci of disease reported or found on examination. Malaria must be excluded in malarious areas.	Documented fever of >37.5 ^{0}C with negative blood culture, negative malaria slide and normal or unchanged chest X-ray, and no other obvious foci of disease.
Oral candidiasis (after first 6-8 weeks of life)	Persistent or recurring creamy white to yellow soft small plaques which can be scraped off (pseudomembranous), or red patches on tongue, palate or lining of mouth, usually painful or tender (erythematous form).	Microscopy or culture.
Oral hairy leukoplakia	Fine small linear patches on lateral borders of tongue, generally bilaterally, which do not scrape off.	Clinical diagnosis

Acute necrotizing ulcerative gingivitis or stomatitis, or acute necrotizing ulcerative periodontitis	Severe pain, ulcerated gingival papillae, loosening of teeth, spontaneous bleeding, bad odour, and rapid loss of bone and/or soft tissue.	Clinical diagnosis
Lymph node tuberculosis	Non acute, painless "cold" enlargement of peripheral lymph nodes. Response to standard anti-tuberculosis treatment in one month.	Histology or fine needle aspirate for Ziehl-Nielsen stain or culture.
Pulmonary tuberculosis	Nonspecific symptoms, e.g. chronic cough, fever, night sweats, anorexia and weight loss. In the older child also productive cough and haemoptysis. History of contact with adult with smear positive pulmonary tuberculosis. No response to standard broad spectrum antibiotic treatment	One or more sputum smear positive for acid-fast bacilli and/or radiographic abnormalities consistent with active tuberculosis and/or culture-positive for *Mycobacterium*.
Severe recurrent bacterial pneumonia	Cough with fast breathing, chest indrawing, nasal flaring, wheezing, and grunting. Crackles or consolidation on auscultation. Responds to course of antibiotics. Current episode plus one or more in previous 6 months	Isolation of bacteria from appropriate clinical specimens (induced sputum, bronchoalveolar lavage, and lung aspirate).
Symptomatic lymphocytic interstitial pneumonia	No presumptive clinical diagnosis.	Chest X-ray: bilateral reticulonodular interstitial pulmonary infiltrates present for more than two months with no response to antibiotic treatment and no other pathogen found. Oxygen saturation persistently <90%. Cor pulmonale and increased exercise-induced fatigue. Characteristic histology.
Chronic HIV-associated lung disease (including bronchiectasis)	History of cough productive of copious amounts of purulent sputum (bronchiectasis only), with or without clubbing, halitosis, and crepitations and/or wheezes on auscultation	Chest X-ray may show honeycomb appearance (small cysts) and/or persistent areas of opacification and/or widespread lung destruction, with fibrosis and loss of volume.
Unexplained anaemia (<8g/dl), neutropaenia (<0.5 x $10^9/L^3$) and/or chronic thrombocytopaenia (<50 x $10^9/L^3$)	No presumptive clinical diagnosis.	Laboratory testing, not explained by other non-HIV conditions, not responding to standard therapy with haematinics, antimalarial agents or anthelminthics as outlined in WHO Integrated Management of Childhood Illnesses guidelines.

Clinical Stage 4		
Unexplained severe wasting, stunting or severe malnutrition not adequately responding to standard therapy	Persistent weight loss, stunting, wasting, or malnutrition not explained by poor or inadequate feeding, other infections and not adequately responding in two weeks to standard therapy. Visible severe wasting of muscles, with or without oedema of both feet, and/or weight-for-height of –3 standard deviations from the mean, as defined by WHO Integrated Management of Childhood Illnesses guidelines.	Documented weight loss of ≥3 standard deviations from the mean with or without oedema
Pneumocystis pneumonia	Dry cough, progressive difficulty breathing, cyanosis, tachypnoea and fever; chest indrawing or stridor. (Severe or very severe pneumonia re WHO Integrated Management of Childhood Illnesses guidelines.) Rapid onset especially in infants <six months of age. Response to high-dose co-trimoxazole with or without-prednisolone. Chest X-ray typical bilateral perihilar diffuse infiltrates	Cytology or immunofluorescent microscopy of induced sputum or bronchoalveolar lavage, or histology of lung tissue.
Recurrent severe bacterial infection, e.g. empyema, pyomyositis, bone or joint infection, or meningitis but excluding pneumonia	Fever accompanied by specific symptoms or signs that localize infection. Responds to antibiotics. Current episode plus one or more in previous 6 months	Culture of appropriate clinical specimen.
Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration or visceral at any site)	Severe and progressive painful orolabial, genital, or anorectal lesions caused by herpes simplex virus infection present for more than one month.	Culture and/or histology
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs).	Difficulty in swallowing, or pain on swallowing (food and fluids). In young children, suspect particularly if oral *Candida* observed and food refusal occurs and/or difficulty or crying when feeding.	Macroscopic appearance at endoscopy, microscopy of specimen from tissue or macroscopic appearance at bronchoscopy or histology.
Extrapulmonary tuberculosis	Systemic illness usually with prolonged fever, night sweats, weight loss. Clinical features of organs, e.g. sterile pyuria, pericarditis, ascites, pleural effusion, meningitis, arthritis, orchitis., pericardial or abdominal	Positive microscopy showing acid-fast bacilli or culture of *Mycobacterium* tuberculosis from blood or other relevant specimen except sputum or bronchoalveolar lavage. Biopsy and histology.

Kaposi's sarcoma	Typical appearance in skin or oropharynx of persistent, initially flat, patches with a pink or blood-bruise colour, skin lesions that usually develop into nodules.	Macroscopic appearance or by histology.
Cytomegalovirus retinitis or cytomegalovirus infection affecting another organ, with onset at age over 1 month.	Retinitis only. Cytomegalovirus retinitis may be diagnosed by experienced clinicians: typical eye lesions on serial fundoscopic examination; discrete patches of retinal whitening with distinct borders, spreading centrifugally, often following blood vessels, associated with retinal vasculitis, haemorrhage and necrosis.	Definitive diagnosis required for other sites. Histology or cytomegalovirus demonstrated in cerebrospinal fluid by polymerase chain reaction..
Central nervous system toxoplasmosis onset after age 1 month.	Fever, headache, focal neurological signs, convulsions. Usually responds within 10 days to specific therapy.	Computed tomography scan (or other neuroimaging) showing single/multiple lesions with mass effect or enhancing with contrast.
Extrapulmonary cryptococcosis (including meningitis)	Meningitis: usually subacute, fever with increasing severe headache, meningism, confusion, and behavioural changes that responds to cryptococcal therapy.	Cerebrospinal fluid microscopy (India ink or Gram stain), serum or cerebrospinal fluid cryptococcal antigen test or culture.
HIV encephalopathy	At least one of the following, progressing over at least two months in the absence of another illness: - failure to attain, or loss of, developmental milestones, loss of intellectual ability; OR - progressive impaired brain growth demonstrated by stagnation of head circumference; OR - acquired symmetric motor deficit accompanied by two or more of the following: paresis, pathological reflexes, ataxia, and gait disturbances	Neuroimaging demonstrating atrophy and basal ganglia calcification and excluding other causes.
Disseminated mycosis (coccidiomycosis or histoplasmosis)	No presumptive clinical diagnosis.	Histology: usually granuloma formation. Isolation: antigen detection from affected tissue; culture or microscopy from clinical specimen or blood culture.
Disseminated mycobacteriosis, other than TB	No presumptive clinical diagnosis.	Nonspecific clinical symptoms including progressive weight loss, fever, anaemia, night sweats, fatigue or diarrhoea; plus culture of atypical mycobacterial species from stool, blood, body fluid or other body tissue, excluding lung.
Chronic isosporiasis	No presumptive clinical diagnosis.	Identification of *Isospora*

Cerebral or B cell non-Hodgkin lymphoma	No presumptive clinical diagnosis.	Diagnosed by central nervous system neuroimaging; histology of relevant specimen
Progressive multi focal leukoencephalopathy	No presumptive clinical diagnosis.	Progression nervous system disorder (cognitive dysfunction, gait or speech disorder, visual loss, limb weakness and cranial nerve palsies) together with hypodense white matter lesions on neuroimaging or positive polyomavirus JC (JCV)

		polymerase chain reaction on cerebrospinal fluid
Symptomatic HIV-associated nephropathy	No presumptive clinical diagnosis	Renal biopsy
Symptomatic HIV-associated cardiomyopathy	No presumptive clinical diagnosis	Cardiomegaly and evidence of poor left ventricular function confirmed by echocardiography

Annex 2.2. Presumptive diagnosis of severe HIV infection among HIV–sero-positive and HIV-exposed children

Clinical criteria for a *presumptive clinical diagnosis* of severe HIV infection among infants and children under 18 months in situations where virological testing is not available.

A *presumptive clinical diagnosis* of severe HIV infection should be made if:

- The infant is confirmed as being HIV–antibody-positive

AND

- Diagnosis of any AIDS-indicator conditions can be made

OR

- The infant is symptomatic with two or more of the following:
  - Oral thrush
  - Severe pneumonia
  - Severe sepsis.

Other factors that support the diagnosis of severe HIV infection in an HIV–sero-positive infant include:

- Recent HIV-related maternal death or advanced HIV infection in the mother
- CD4 cell count of <20%.

Note: confirmation of the diagnosis of HIV-infection should be sought as soon as possible.

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 to discuss these questions:

1. Which AIDS case definition has been used in your country? (Tick the appropriate answer)

Bangui definition	☐Yes ☐ No ☐ Not sure
WHO expanded case definition	☐Yes ☐ No ☐ Not sure
CDC case definition	☐Yes ☐ No ☐ Not sure
Some other definition	☐Yes ☐ No If yes, specify:

2. Have there been any changes made to the case definitions used in your country in the past? If so, when and why?

3. Describe and develop a figure to represent the data flow from the reporting facility up to the national surveillance programme.

4. Although there is no standard case definition for primary HIV infection, what can be learned from reports of these persons?

Apply what you've learned/ case study

Work on this case study independently.

1. As an HIV surveillance officer for the Republic of Melabia, you are charged with standardising the country's HIV reporting practises. What processes would you implement to ensure that HIV case surveillance is standardised?

2. The Republic of Melabia recently began providing free antiretroviral therapy to HIV-infected individuals. Republic of Melabia uses the WHO antiretroviral treatment recommendations to determine the best time to begin antiretroviral therapy.

    a. CD4 testing is available in the northern district of Melabia. What are the WHO recommendations for adults and adolescents to begin ART?

    b. CD4 testing is not available in the western district of Melabia. What are the WHO recommendations for adults and adolescents to begin ART?

Unit 2 Summary

- The increased use of ART resulted in the need for WHO to update its HIV clinical staging criteria, linking them to recommendations for initiation of ART.

- The 2006 WHO clinical staging criteria harmonise the adult and paediatric clinical staging criteria into four stages and provide for inclusive immunologic criteria.

- The 2006 WHO clinical staging criteria are used in the surveillance case definitions.

- WHO recommends that countries standardise their surveillance practises and case definitions.

- The 2006 WHO surveillance case definitions include:
  - HIV infection (stages 1-4)
  - Advanced HIV infection (clinical stages 3 and 4 and/or CD4 count <350)
  - AIDS (clinical stage 4 and/or CD4 count <200).

- The WHO recommends that ART be initiated for persons with clinical stage 4 or CD4 count <200 and for persons with clinical stage 3 if CD4 count is <350. Linking the treatment recommendations to clinical staging and surveillance case definitions should help in HIV surveillance.

Notes

Unit 3

HIV Case Reporting

Overview

What this unit is about

This unit provides an overview of the purpose and importance of HIV case reporting. It explains:

- The purpose of HIV case reporting
- Methods of conducting HIV reporting
- Sources for HIV reporting.

Warm-up questions

1. Which of the following is NOT a purpose of advanced HIV infection case surveillance?

   a. To assess trends in advanced HIV infection cases
   b. To provide information on the opportunistic infections associated with advanced HIV infection
   c. To measure HIV incidence
   d. To determine the burden of infection attributable to advanced HIV infection in the region.

2. Which of the following describes case-based HIV reporting?
   a. All HIV cases reported in a given time period are summarised into a single case report form.
   b. A method to estimate the HIV prevalence among women attending antenatal clinics.
   c. Case surveillance in which each person diagnosed with HIV has a case report form that includes information specific to that person.
   d. A system that measures the rate of HIV transmission in selected risk groups.

3. Which of the following variables is not necessary on a HIV case report form?
   a. Clinical stage of HIV at the time of HIV diagnosis
   b. History of sexually transmitted diseases
   c. Name of facility completing the case report form
   d. Mode of transmission (probable risk category).

Warm-up questions, continued

4. List three potential sources for HIV case reports.
   1.

   2.

   3.

5. List three qualities that are necessary to have in a case identifier.

   1.

   2.

   3.

Introduction

What you will learn

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

- List reportable events in HIV case surveillance systems
- Describe the differences between aggregate and case-based HIV reporting
- List potential HIV reporting sources
- List key variables to include on a HIV case report form
- Describe the purpose of including a patient identifier on HIV case reports.

Defining Reportable Events for HIV Case Reporting Systems

Functions of HIV case surveillance programme

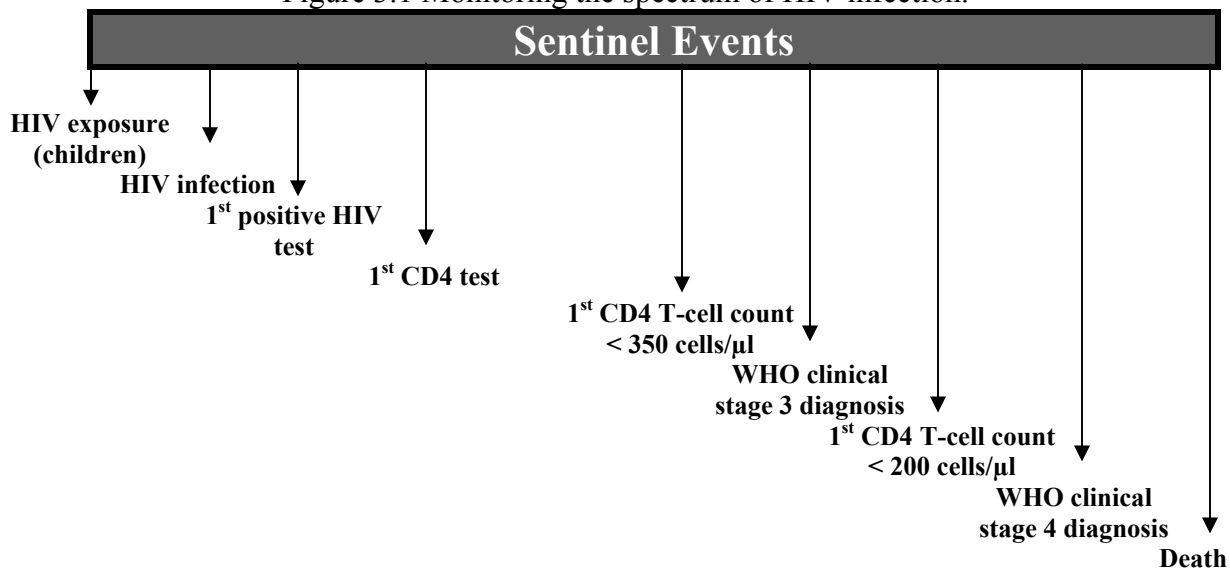
The primary functions of HIV *case reporting surveillance* programmes are to:

- Monitor the HIV epidemic over time by providing information on persons with HIV infection (all *HIV clinical stages*) and *advanced HIV infection*
- Identify the number of persons currently in need of treatment
- Estimate the number of persons who will need treatment in the future
- Monitor the impact of *ART* on trends in HIV *prevalence*
- Provide data for developing and monitoring HIV prevention programmes.

Case reporting activities can be designed to monitor the course and characteristics of HIV. The ability of the *surveillance* programme to monitor the course of HIV infection depends on the extent of clinical care that is routinely provided to persons with HIV infection. Figure 3.1, on the next page, shows events that you may wish to monitor to plan prevention programmes and care and treatment programmes.

Functions of HIV case surveillance programme, continued

Figure 3.1 Monitoring the spectrum of HIV infection.



Countries should standardise HIV *case surveillance definitions* for reporting purposes. All persons meeting the *case definition* should be reported to the sub-national/national *surveillance* programme. To understand the epidemic and to plan effectively for providing *antiretroviral therapy* (ART) and *prophylaxis*, it is important to include information on the *HIV* clinical stage of the patient at the time of diagnosis and CD4 test results, if available. Reporting persons with all stages of HIV infection will provide the most comprehensive picture of the epidemic.

Terminology

This unit discusses the options and methods for case reporting. WHO refers to:

- The reporting of all stages of HIV as "HIV infection" reporting
- The reporting advanced HIV (clinical stages 3 and 4 only) as "advanced HIV (infection or disease)" reporting. This includes AIDS (clinical stage 4).

HIV infection case reporting

In *HIV infection case reporting*, all persons, regardless of their clinical stage at diagnosis and report, should be reported to the *surveillance* programme. This includes:

- Anyone who is newly diagnosed with HIV at any clinical stage
- Anyone who was previously diagnosed with HIV but not previously reported to the *surveillance* unit
- Anyone who was previously diagnosed and reported with clinical stage 1 or 2 who has progressed to clinical stage 3 or 4 (i.e. these individuals are reported again as having *advanced HIV infection*).

HIV *case reporting* includes reporting persons with *advanced HIV infection*, meaning that people who are first diagnosed with HIV at clinical stage 3 or 4 (or CD4 count <350 cells/mm^3) will be reported once. If a person is initially diagnosed with HIV infection at stage 1 or 2, the person will be reported as having HIV infection. If this person progresses to clinical stage 3 (or CD4 count <350 cells/mm^3), he or she will be reported again as having *advanced HIV infection*. All case reports of persons with HIV infection should include the patient's clinical stage at the time of diagnosis.

Reporting all HIV infection cases, regardless of clinical stage, will be challenging in developing countries because of limitations in the infrastructure. In the long term, however, countries should begin moving toward this goal. It is important to gain experience through small-scale pilot projects that eventually can become national in scale.

Advanced HIV infection reporting (including AIDS)

With *advanced HIV infection case surveillance*, all persons with a documented HIV-positive test and a diagnosis of clinical stage 3 or 4 or a CD4 count of <350 cells/mm^3 should be reported to the *surveillance* unit. Persons with clinical stages 1 or 2 or CD4 counts ≥350 cells/mm^3 will not be reported until they reach clinical stage 3 or 4 or have a decline in their CD4 count to 350 cells/mm^3. AIDS cases need not be reported separately because they are already reported as *advanced HIV infection*.

AIDS case reporting

AIDS *case reporting* was recommended as part of *Integrated Disease Surveillance* (IDS), in which a single form is used for all reportable diseases in *aggregate*. However, reporting has been incomplete. Countries should report HIV infection (see *HIV clinical stages*) or *advanced HIV infection* (infection) rather than AIDS cases.

Planning for HIV case surveillance

Although *WHO* has developed new *case definitions* for HIV *surveillance*, these will need to be adopted. Countries should:

- Identify dedicated staff at the national and sub-national levels who will establish and monitor the HIV case *reporting surveillance* system
- Adopt standardised *case definitions*
- Conduct rapid assessment/evaluation to determine the current status of the *case reporting* system
- Work with appropriate staff to incorporate the elements of the *case definitions* into the country's notifiable disease list
- Determine who is responsible for reporting (such as healthcare providers, counsellors at *voluntary counselling and testing* (VCT) sites and laboratories)
- Determine reportable laboratory and clinical events (such as positive HIV *enzyme-linked assay* (EIA), *Western blots*, or CD4 tests)
- Determine if only newly diagnosed persons should be reported or if all persons with HIV infection are to be reported (meaning *prospective* or *retrospective* case reporting)
- Adopt a case report form that is either case-based or designed for aggregate reporting
- Develop an operations manual for case reporting that can be modified at the sub-national level.

Data Collection

Identifying reporting sources

Surveillance programmes should establish or be aware of any laws that require reporting and state who should report cases. Using this information, *surveillance* programmes should identify reporting sources where HIV diagnosis, care and treatment occur. The following are examples of reporting sources:

- Healthcare clinics (health centres)
- *ART* treatment clinics
- *Tuberculosis* (TB) clinics
- HIV *VCT* sites
- Hospices (for *advanced HIV infection*)
- Hospitals
- *Prevention of mother-to-child transmission* (PMTCT) programmes
- Laboratories
- *Vital statistics* registries (for persons diagnosed with HIV only at death. But registries also can be used for information on the trends and numbers in HIV-related deaths).

These reporting sources are useful for identifying cases, but some can yield more cases than others. In general, sites at which ongoing care of HIV-infected persons is provided will be the most useful. This is because these programmes can identify HIV cases, provide information on the clinical stage of infection, and provide the information needed to complete a case report form.

Surveillance officers should contact individuals within these programmes or facilities to discuss *case reporting*, provide case report forms and promote timely and complete reporting from staff at these sites. It is recommended to conduct these activities step by step.

Identifying reporting sources, continued

Table 3.1. Potential reporting sources.

Site	Key features
VCT sites	▪ Provide HIV diagnosis to persons at early and late stages of infection ▪ Source of reports for HIV case reporting (all stages) ▪ Do not provide clinical care, thus stage of infection cannot be included in the case report. Efforts should be made to follow-up the patient once in care
Healthcare providers	▪ Physicians and other healthcare providers will care for patients at any stage of infection, although most are likely to be in advanced stages ▪ Medical records at physicians' offices may contain most of the information needed for the case report form ▪ Information missing from the medical records can be obtained by the physician when the patient returns for care
ART treatment programme	▪ Patients receiving *ART* are most likely to be at clinical stages 3 and 4 and should be reported as having advanced HIV infection ▪ *ART* monitoring data can identify reportable cases ▪ Follow-up data is generally available ▪ May be possible to track deaths
TB clinics/programmes	▪ HIV-infected persons with pulmonary *TB* have clinical stage 3 HIV infection and should receive *ART* (they will often be seen in ART clinics/programmes) if their CD4 count is <350 cells/mm^3 ▪ HIV-infected *TB* patients should be reported as having *advanced HIV infection*
Hospitals	▪ At hospitals, HIV patients are likely to be in more advanced stages of infection ▪ Information for case report forms should be available

Ways to identify cases; passive and active case reporting

New cases of HIV infection are found mainly by *passive surveillance*. In a passive system, healthcare providers identify patients and report those who meet the *case surveillance definitions*. The data are then forwarded to the next level in the system. The success of a passive reporting system depends on how many HIV-infected individuals have access to HIV testing, get tested, obtain care at a health facility, and get reported. In other words, the completeness of reporting (that is, the *sensitivity* of the *surveillance* system) depends on individual behaviour of seeking testing and care and the extent to which healthcare providers complete and forward case reports. *Active surveillance* refers to surveillance staff going to health care facilities and/or other HIV reporting sources to identify cases and complete the case report form.

Case Reporting Methods

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, in which 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 where the data are aggregated (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, and so on. Such an approach is called *aggregate case reporting* and is often simpler than *case-based reporting*. However, it is not as flexible because it does not allow data to be analysed in ways that are not predetermined.

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 specifically to that patient 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.

Case Identifiers

Why case reporting requires unique case identifiers

HIV *case-based reporting* is unique among infectious disease *surveillance* systems because of the following factors:

- An individual can only acquire HIV once
- For reporting purposes, an HIV-infected person is diagnosed and reported with *advanced HIV infection* only once.

Note that for clinical purposes, someone may be at clinical stage 3 but responds to treatment and later meet the criteria for clinical stage 2. However, regardless of improvements in clinical status, case reports should be submitted only for:

- Initial diagnosis of stage 1 or 2 infection
- Initial diagnosis of stage 3 or 4 infection.

Surveillance programmes need an accurate count of persons with HIV infection and *advanced HIV infection*. Since patients may receive care at multiple facilities, they may be reported more than once. To have an accurate count of cases, *surveillance* programmes need a way to identify duplicate cases and remove the most recently reported duplicates from the record. The reason to remove the later report is to maintain the earliest date of diagnosis.

If feasible, programmes may wish to establish *longitudinal surveillance* databases, which can:

- Follow reported cases over time
- Identify when a patient progresses from HIV clinical stages 1 and 2 to advanced HIV infection
- Permit updating a patient record when additional data are obtained.

In countries that have patient monitoring systems, a *longitudinal case-based surveillance* system can be developed using information from the patient monitoring system.

Selecting a case identifier

Implementing a *case-based surveillance* system requires that countries determine the method by which cases will be identified. They must decide whether such systems should employ names or unique identifiers (codes). The *UNAIDS* guidelines for public health and HIV surveillance ask surveillance programmes to consider the following questions:

- Who will be required to report? What clinical information and personal identifiers will they report? To whom will they report?
- How will the proposed system contribute to a more accurate characterisation of the HIV epidemic?
- What is known about the completeness of reporting for other notifiable conditions, including those that bear some stigma? How can such experience be used to anticipate the willingness to cooperate on the part of those who will be required to report?

Surveillance programmes must determine the most effective method of reporting cases that will allow identifying duplicate case reports and permit longitudinal databases (if these are used).

Surveillance programmes should carefully consider the type of identifier used for *case reporting*. The case identifier must:

- Be unique to the individual
- Not change over time (for example, date of birth) or be able to readily determine when a change has occurred (for example, change of name with marriage or divorce)
- Be easy to identify from a clinical record
- Be something that is, or is derived from, information that is routinely collected.

The most effective method that allows all these factors is the use of patient names for HIV case reporting. Many countries have concerns that use of patient names will discourage *at-risk* persons from HIV testing and HIV-infected persons from obtaining care. For this reason, *surveillance* programmes must use methods that keep this information confidential and secure.

Selecting a case identifier, continued

Although patient names are the best method to identify and report cases, countries may choose to develop a code. They should take into account the code's ability to:

- Distinguish duplicate reports for the same person
- Distinguish cases with the same code who are different persons
- Allow follow-up information from the *surveillance* programme and healthcare provider
- Be available without interviewing the patient (that is, should not be created by the patient)
- Be evaluated
- Allow evaluation of the *surveillance* system (that is, permit the determination of the completeness and timeliness of reporting and the validity of the data submitted on case report forms).

Educating providers

Surveillance officers and their staff should educate providers regarding:

- The importance of HIV case reporting
- Reporting requirements, laws and regulations
- *Case definitions*
- How to complete and forward a case report form
- The timeframe in which to report cases (newly diagnosed only, or previously diagnosed and newly diagnosed).

At each of the reporting sites, you should identify a liaison. This is the contact person for the programme who will be responsible for *case reporting*.

The *surveillance* programme should provide the reporting sites with the following:

- Case report forms
- Instructions for completing the forms
- Information on how to contact the surveillance officer if questions arise.

Laboratory-initiated reporting

Laboratory-initiated reporting is a method by which the laboratories notify *surveillance* programmes of patients who should be reported. It is not currently practised in many developing countries but is an important part of HIV reporting.

Laboratory-initiated reporting differs from *provider-initiated reporting*. Laboratories do not diagnose patients and generally do not have enough information to report individual cases, but they are an important source of information for *surveillance* programmes. The feasibility of setting up a laboratory-initiated system in the private sector can be explored to increase the *completeness of reporting*. When laboratories notify programmes of persons who are likely to have HIV infection, information must be included so that the *surveillance* programme can follow-up with the healthcare provider and report the case.

The laboratory should provide the following information to the *surveillance* programme so it can follow-up:

- Patient's name or code
- Sex
- Date of birth
- Laboratory identifier
- Date of test
- Test result
- Requester/provider name and telephone number.

When to report cases

If you have an HIV *case reporting system* (option A), report a case when:

- The person is diagnosed with HIV infection, regardless of clinical status
- A person previously diagnosed and reported with HIV clinical stage 1 or 2 progresses to *advanced HIV infection*
- An HIV-infected person dies.

If you have an advanced HIV *case reporting system* (option B), a case should be reported when:

- An HIV patient is diagnosed with clinical stage 3 or 4 or CD4 count <350 cells/mm^3 (consider CD4 percentage in children <18 months)
- An HIV-infected person dies.

Surveillance staff should work with healthcare providers and others who will be responsible for completing case reports forms to ensure that case

When to report cases, continued

reports are submitted at appropriate times. Look at Table 3.2 below.

Table 3.2. Clinical stages and immunologic criteria for HIV case reporting options.

HIV case reporting options	**Clinical stage and immunologic criteria**		
	1 or 2 or CD4 count ≥350 cells/mm^3	3 or 4 or CD4 count <350 cells/mm^3	4 or CD4 count <200 cells/mm^3
HIV case reporting	Submit case report form	Submit case report form	Submit case report form
Advanced HIV infection reporting		Submit case report form	Submit case report form

Note that a single patient who is initially diagnosed with HIV clinical stages 1 or 2 and who progresses to clinical stage 3 or 4 should be reported again as a case of *advanced HIV infection*.

Mandatory variables for counting cases

A minimum amount of information must be available at the *surveillance* office to count a patient as an HIV case. This information is submitted using the case report form. Only cases that meet the *WHO* HIV or *advanced HIV infection case definitions* should be reported.

The mandatory variables required on the case report form for the *surveillance* programme to count a case are:

- Case identifier (name or code)
- Sex
- Date of birth
- Date of diagnosis by laboratory or healthcare provider (use the earliest date)
- Clinical stage and/or CD4 test result, if available
- Date of death (or number of deaths if using aggregate reporting).

Updating and un-duplicating cases

Countries that adopt case-based reporting systems will have *longitudinal databases* that will permit:

- The addition of new information into the existing case record
- The ability to capture the time at which the patient was diagnosed and reported with stage 1 or 2 and when HIV infection progresses to *advanced HIV infection*
- Inclusion of information on date of death (and possibly cause of death)
- Adding start dates for care, *ART* and *prophylaxis*.

For countries that adopt a *case-based reporting* system, HIV cases may be reported more than once because individuals may get tested at more than one clinic or healthcare facility or may change the place that they receive healthcare. When that happens, the original and the new healthcare provider will report that patient.

The *surveillance* programme should be able to correctly distinguish newly reported from persons previously reported. Problems related to inaccurate linking include the following:

- Over-counting cases if cases were not properly linked (that is, two reports that are submitted for the same person are thought to represent two different people and are counted as two cases rather than one)
- Under-counting cases if cases were incorrectly linked. (that is, two reports from two different people are thought to be two reports for the same person and are counted as only one case).

To avoid an inaccurate count of cases, the *surveillance* programmes that maintain case-level data should routinely un-duplicate their cases. The simplest way is to determine the case variables that will be used to un-duplicate the cases. At a minimum, these should include the patient identifier (name or code) and the date of birth. Additional information that is likely to be unique to that individual (for example, address) also can be included as variables for un-duplicating cases.

Updating and un-duplicating cases, continued

As individual cases are reported, the *surveillance* staff should compare the name/code and date of birth and any other unique variables with previously reported cases. In general, if there is a correct match on the name and date of birth, it is highly likely to represent a duplicate case report. Un-duplicating cases when a code rather than a name is used is more problematic, unless the code includes at least some parts of the patient's name. At a minimum, *surveillance* programmes should standardise the methods used so that staff responsible for un-duplicating case records do so using the same methods.

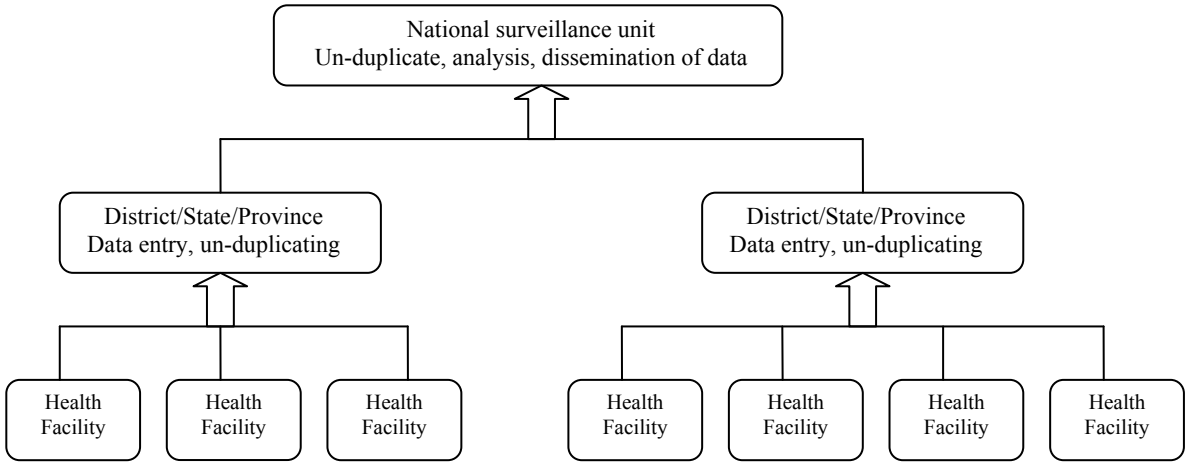
Although un-duplicating cases is important for gathering an accurate case count, sometimes the information necessary to un-duplicate cases is not available or two or more case reports from the same individual are not properly matched. This situation results in over-counting cases and occurs more frequently in settings where cases are identified with codes rather than names.

Forwarding case reports

Each country must determine the reporting chain for HIV case reports. For example, reports may go from healthcare providers to people at the sub-national level. Ultimately, however, HIV case reports should be sent to the national *surveillance* unit where a complete database should be housed. An example of a three-tier reporting structure is given in Figure 3.2 on the next page.

Forwarding case reports, continued

Figure 3.2: Three-tiered HIV reporting system



Roles and responsibilities

For *case reporting* to be successful, a clear understanding of the roles and responsibilities of national and sub-national *surveillance* programmes should be described to everyone involved.

Responsibilities of the national HIV *surveillance* programme are to:

- Develop operational guidelines on HIV *case reporting*
- Train and assist *surveillance* programmes at the sub-national level
- Maintain a complete and accurate HIV case database that is secure and has access limited to authorised personnel only
- Analyse, interpret and disseminate HIV *case reporting* data
- Critically assess the performance of the *surveillance* programmes through ongoing monitoring of *surveillance* activity
- Provide overall guidance and training for sub-national un-duplicate cases programmes.

Roles and responsibilities, continued

Responsibilities of the sub-national HIV *surveillance* programme are to:

- Solicit, receive, review and file HIV case reports in a timely manner
- Ensure that case reports are filled out completely, accurately and clearly
- Evaluate each case report to determine if it meets the criteria for HIV diagnosis
- Evaluate each case report to determine of it contains enough information to determine *HIV clinical stage* (that is, documentation of the clinical stage, clinical information that can be used to determine clinical stage or immunological information such as CD4 count/percentage)
- Ensure that minimum data elements are documented (that is, demographic characteristics, geographic region, risk information, diagnosis date and report date)
- Conduct follow-up investigations on cases of epidemiologic importance
- Maintain a complete and accurate HIV *surveillance* database that is secure and has access limited to authorised personnel
- Identify reporting sources, provide an active liaison with physicians and institutions that report cases, abstract medical records to generate case reports when necessary, and supply routine feedback to un-duplicate case providers in cases reported.

Responsibilities of healthcare providers are to:

- Complete HIV reporting forms for each person newly diagnosed with HIV infection
- Complete HIV reporting forms for persons with a change in clinical status (for example, clinical diagnosis of *advanced HIV infection* or AIDS, CD4 count <350)
- Complete HIV reporting forms upon the death of HIV-infected persons (to include cause of death, if available)
- Submit forms to the sub-national– or national-level *surveillance* unit, as per the reporting chain for the country, maintaining *confidentiality*
- Record each instance of *case reporting* on a patient's clinical record to the *surveillance* programme.

Case Report Form

Purpose of an HIV case report form

The purpose of the case report form is to standardise the collection of information that is obtained on all reported HIV cases.

An HIV case report form is designed to:

- Collect information that promotes understanding of HIV infection, morbidity, and mortality
- Facilitate reporting an HIV case (person diagnosed with HIV)
- Standardise the collection of variables.

Elements of a case report form

A comprehensive case report form should include:

- Administrative information
  - Name and address of facility where the report is submitted from (reporting source)
  - Date form completed
  - Report status (new or update)
- Demographic information
  - Patient identifier (name or code)
  - Date of birth
  - Sex
  - Current status (alive, dead, unknown)
  - Country of residence
- Information on the patient's HIV-related *risk behaviour*
  - Sex with male
  - Sex with female
  - Injected non-prescription drugs
  - *Perinatal/MTCT*
  - Blood transmission-related variables
  - Occupational exposure
- Diagnosis information
  - Date of HIV diagnosis
  - Facility of diagnosis
- *HIV clinical stage*
  - Date of first clinical stage
  - Clinical stage
  - Date of first clinical stage 3 diagnosis
  - Date of first clinical stage 4 diagnosis

Elements of a case report form, continued

- Immunologic status
  - Date of first CD4 test
  - Result of first CD4 test (count and/or percentage)
  - Date of first CD4 count <350 cells/mm^3
  - Date of first CD4 count <200 cells/mm^3
- Care and treatment
  - Use of *ART*
  - Date first used *ART*
  - Use of *prophylaxis* against *Pneumocystis jirovecii* pneumonia
- Vital status
  - Date of death
  - Cause of death.

Countries should carefully consider which elements to include in the case report form. It should include only information that is readily available to the person completing the form and that can be collected from most of the reporting facilities. It should not be a burden to people who complete it.

Surveillance programmes should determine the types of staff responsible for completing the case report form. Issues of patient *confidentiality* should be considered carefully. For example, physicians may report cases but whether clerical staff at *VCT* sites are allowed to report must be considered carefully. Everyone involved in reporting persons with HIV infection should be given information about protecting patients' privacy.

Modifying and piloting the case report form

A generic HIV case report form is shown in Annex 3.1 below. This form can be modified to address country-specific issues and to ensure that the terminology is easy to understand. Providing education on how to complete the reporting form is essential to achieve accurate and standardised case reporting. Prior to adopting a new case report form, it should be pilot-tested at a selected number of reporting sites and modified based on the results.

Monitoring Mortality in HIV Surveillance

Why monitor HIV deaths

Monitoring mortality is an integral part of an effective HIV *case surveillance* system. Information on HIV-related deaths is a useful method of:

- Measuring the impact of HIV-related care and treatment
- Assisting countries in estimating the need for future care of HIV-infected patients
- Estimating the size of the workforce
- Demonstrating the relative impact of HIV-related mortality compared to other causes of death
- Estimating the number of years of productive life lost
- Measuring the number of orphans resulting from HIV deaths in parents.

Interpreting trends in HIV deaths

As the number of HIV-infected persons receiving *ART* increases, the number of deaths attributable to HIV should decline. This can provide a good marker for the impact of treatment on HIV-related mortality. If the vital statistics programme collects causes of death, analysis of the death registry data alone can be used to determine the magnitude of HIV-related deaths relative to other causes.

As HIV-related deaths decline, the number of persons living with HIV infection (that is, the *prevalence* of HIV) will increase. It is important not to mistake this increase in *prevalence* as an indication that the epidemic is worsening. Use of HIV *sero-prevalence surveys* among women attending *antenatal clinics* (ANCs) should be monitored, with special attention to trends in the HIV *prevalence* among the youngest women as an estimate of trends in HIV *incidence*. In addition, if additional methods to estimate HIV *incidence* are used, the results from these activities should be reviewed to determine whether an increase in *prevalence* may reflect an increase in new HIV infections.

ART monitoring programmes often collect ongoing information on patients. Annual data on persons previously reported with HIV can be used to determine if the patient is still alive. At times, a death will be known to the *ART* monitoring staff. This information also can be provided annually to the *surveillance* programme, where it can be used to update the case record. If the data are reasonably complete, they can be used in the same manner as death data obtained from *vital records*.

Identifying patient-level deaths

Patient-level data on deaths can be obtained in three ways:

- Through matching case-based HIV reports with vital statistics programmes
- Through periodic follow-up reviews of patient records in ART-monitoring programmes
- Through HIV case report forms submitted when an HIV-infected person dies (regardless of the cause of death).

Some countries have well-functioning vital statistics programmes. If these countries conduct name-based HIV *case reporting*, matching the two registries can provide case-level information on HIV cases that have died, regardless of the cause of death. If HIV testing rates are high, so that most HIV-infected persons are diagnosed, and HIV *case reporting* and death registries are complete, then adding the date of death into the HIV case registry allows a reasonably good estimate of the number of persons living with HIV. This information can be used to estimate the number of persons who are currently or soon to be in need of care and treatment.

Additional methods of monitoring HIV deaths

In developing counties where vital statistics registries are not comprehensive, alternative methods have been used to determine the number and causes of deaths. Two examples of methods to obtain the number of deaths are:

- The Sample Registration System
- Demographic *sentinel surveillance*.

Both of these systems involve sampling a section of the population and monitoring this sample for vital events, including births, deaths and relocations out of the area.

Although these systems are not as complete as well-functioning vital statistics systems, they are useful methods of determining estimates of vital events.

To find the causes of deaths in these sampled populations, *verbal autopsies* can be used, which are a way of assigning cause of death to persons who have died outside of hospitals, where causes of deaths are usually recorded. Once a death has occurred, a health worker interviews a relative of the deceased.

Additional methods of monitoring HIV deaths, continued

The interview uses a standardised form to:

- Gather information on the signs and symptoms the decedent experienced shortly prior to death
- Collect additional information about each of these deaths that can be used to determine the probable causes of deaths.

The information obtained from the interview is reviewed by a physician, who assigns a probable cause of death using the International Statistical Classification of Diseases and Related Health Problems.

Notes

Annex 3.1 HIV case report form for adults and adolescents

Date form completed: Day ☐☐/Mo. ☐☐/Year ☐☐☐☐	**Name of diagnosis facility:**
Patient name (first, last)**:**	**Address of diagnosis facility:**
Maiden name (if applicable)**:**	
Patient code:	
Patient medical record number:	**Diagnosis facility type:** ☐ ANC/PMTCT CLINIC ☐ PUBLIC HEALTH CLINIC ☐ BLOOD BANK ☐ STI CLINIC ☐ HOSPITAL ☐ TUBERCULOSIS CLINIC ☐ LABORATORY ☐ VCT SITE ☐ PRIVATE HEALTH CLINIC ☐ OTHER, SPECIFY
Reporting source code: ☐☐☐	
Name of person reporting the case:	
Address of person reporting the case:	**Telephone number of person reporting the case:**
	E-mail address of person reporting the case:

PATIENT INFORMATION		
Birth date: Day ☐☐/Mo. ☐☐/Year ☐☐☐☐	**Sex:** ☐ MALE ☐ FEMALE	**Occupation** (mark all that apply): ☐ ☐ ☐ ☐ ☐ ☐
City/town of residence:	**Country of residence:**	**Nationality:**
Is this patient currently pregnant (females only): ☐ YES ☐ NO ☐ UNKNOWN		
Current Status: ☐ ALIVE ☐ DEAD ☐ UNKNOWN	**Date of death:** Day ☐☐/Mo. ☐☐/Year ☐☐☐☐	**Cause of death:** ☐ HIV-RELATED ☐ OTHER/UNKNOWN
Has the patient left the country to reside elsewhere: ☐ YES ☐ NO ☐ UNKNOWN	**Date of departure:** Day ☐☐/Mo. ☐☐/Year ☐☐☐☐	

RISK FACTORS			
Preceding the first positive HIV test, this patient had (respond to all categories):	YES	NO	UNKNOWN
SEX WITH MALE(S)	☐	☐	☐
SEX WITH FEMALE(S)	☐	☐	☐
SEX WITH PERSON(S) OF KNOWN HIV-POSITIVE STATUS	☐	☐	☐
SEX WITH SEX WORKER(S)	☐	☐	☐
INJECTED NONPRESCRIPTION DRUGS	☐	☐	☐
PERINATAL EXPOSURE TO HIV	☐	☐	☐
RECEIVED TRANSFUSION(S) OF BLOOD, BLOOD PRODUCTS OR CLOTTING FACTORS	☐	☐	☐
RECEIVED A TRANSPLANT OF TISSUE OR ORGAN OR ARTIFICIAL INSEMINATION	☐	☐	☐
OCCUPATIONAL EXPOSURE WHILE WORKING IN A HEALTHCARE SETTING OR LABORATORY OR PROVIDING SAFETY OR EMERGENCY SERVICES	☐	☐	☐

LABORATORY RESULTS

Date specimen was obtained from patient: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐

HIV antibody tests performed (respond to all categories)**:**	Positive	Negative	Not performed	**Test result date** Day Mo. Year
SCREENING:				
HIV-EIA	☐	☐	☐	☐☐/☐☐/☐☐☐☐
HIV RAPID TEST	☐	☐	☐	☐☐/☐☐/☐☐☐☐
OTHER (SPECIFY):	☐	☐	☐	☐☐/☐☐/☐☐☐☐
CONFIRMATORY:				
HIV-EIA	☐	☐	☐	☐☐/☐☐/☐☐☐☐
HIV RAPID TEST	☐	☐	☐	☐☐/☐☐/☐☐☐☐
HIV- 1WESTERN BLOT/IFA	☐	☐	☐	☐☐/☐☐/☐☐☐☐
OTHER (SPECIFY):	☐	☐	☐	☐☐/☐☐/☐☐☐☐

Date of HIV diagnosis by healthcare provider: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐

Date of last documented negative HIV test: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐

CLINICAL/ IMMUNOLOGIC INFORMATION

First WHO clinical stage 1 or 2 diagnosis: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐	**First CD4 test:** (at or closest to diagnosis) **Day Mo. Year** ☐☐/☐☐/☐☐☐☐	Count: ☐☐☐☐ Percent: ☐☐
First WHO clinical stage 3 diagnosis: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐	**Date of first CD4 count <350:** **Day Mo. Year** ☐☐/☐☐/☐☐☐☐	Count: ☐☐☐ Percent: ☐☐
First WHO clinical stage 4 diagnosis: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐	**Date of first CD4 count <200:** **Day Mo. Year** ☐☐/☐☐/☐☐☐☐	Count: ☐☐☐ Percent: ☐☐
Date of first viral load test: Day ☐☐/ Mo. ☐☐/ Year ☐☐☐☐	**First viral load value:** ☐,☐☐☐,☐☐☐	

WHO CLINICAL INDICATOR CONDITIONS	**Date diagnosed** Day Mo. Year
WHO clinical indicator conditions for HIV stage 1 (check all that apply):	
☐ ASYMPTOMATIC	☐☐/☐☐/☐☐☐☐
☐ PERSISTENT GENERALISED LYMPHADENOPATHY	☐☐/☐☐/☐☐☐☐
WHO clinical indicator conditions for HIV stage 2 (check all that apply):	
☐ UNEXPLAINED MODERATE WEIGHT LOSS (<10% of presumed or measured body weight)	☐☐/☐☐/☐☐☐☐
☐ RECURRENT RESPIRATORY TRACT INFECTIONS (sinusitis, tonsillitis, otitis media, pharyngitis)	☐☐/☐☐/☐☐☐☐
☐ HERPES ZOSTER	☐☐/☐☐/☐☐☐☐
☐ ANGULAR CHEILITIS	☐☐/☐☐/☐☐☐☐
☐ RECURRENT ORAL ULCERATIONS	☐☐/☐☐/☐☐☐☐
☐ PAPULAR PRURITIC ERUPTIONS	☐☐/☐☐/☐☐☐☐
☐ SEBORRHOEIC DERMITITIS	☐☐/☐☐/☐☐☐☐
☐ FUNGAL NAIL INFECTIONS	☐☐/☐☐/☐☐☐☐
WHO clinical indicator conditions for HIV stage 3 (check all that apply):	
☐ UNEXPLAINED SEVERE WEIGHT LOSS (>10% of presumed or measured body weight)	☐☐/☐☐/☐☐☐☐
☐ UNEXPLAINED CHRONIC DIARRHOEA FOR LONGER THAN ONE MONTH	☐☐/☐☐/☐☐☐☐
☐ UNEXPLAINED PERSISTENT FEVER (above 37.5ºC intermittent or constant, for longer than one month)	☐☐/☐☐/☐☐☐☐
☐ PERSISTENT ORAL CANDIDIASIS	☐☐/☐☐/☐☐☐☐
☐ ORAL HAIRY LEUKOPLAKIA	☐☐/☐☐/☐☐☐☐
☐ PULMONARY TUBERCULOSIS	☐☐/☐☐/☐☐☐☐
☐ SEVERE BACTERIAL INFECTIONS (such as, pneumonia, empyema, pyomyositis bone or joint infection, meningitis or bacteraemia)	☐☐/☐☐/☐☐☐☐
☐ ACUTE NECROTIZING ULCERATIVE STOMATITIS, GINGIVITIS, OR PERIODONTITIS	☐☐/☐☐/☐☐☐☐
☐ UNEXPLAINED ANAEMIA (<8 g/dl), NEUTROPAENIA (<0.5 x 10^9 per litre) AND/OR CHRONIC THROMBOCYTOPAENIA (<50 x 10^9 per litre)	☐☐/☐☐/☐☐☐☐
WHO clinical indicator conditions for HIV stage 4 (check all that apply):	
☐ HIV WASTING SYNDROME	☐☐/☐☐/☐☐☐☐
☐ PNEUMOCYSTIS PNEUMONIA	☐☐/☐☐/☐☐☐☐
☐ RECURRENT SEVERE BACTERIAL PUEUMONIA	☐☐/☐☐/☐☐☐☐
☐ CHRONIC HERPES SIMPLEX INFECTION (orolabial, genital or anorectal of more than one month's duration or visceral at any site)	☐☐/☐☐/☐☐☐☐
☐ OESOPHAGEAL CANDIDIASIS (or candidiasis of the trachea or bronchi or lungs)	☐☐/☐☐/☐☐☐☐
☐ EXTRAPULMONARY TUBERCULOSIS	☐☐/☐☐/☐☐☐☐
☐ KAPOSI'S SARCOMA	☐☐/☐☐/☐☐☐☐
☐ CYTOMEGALOVIRUS INFECTION (retinitis or infection of other organs)	☐☐/☐☐/☐☐☐☐
☐ CENTRAL NERVOUS SYSTEM TOXOPLASMOSIS	☐☐/☐☐/☐☐☐☐
☐ HIV ENCEPHALOPHATHY	☐☐/☐☐/☐☐☐☐
☐ EXTRAPULMONARY CRYPTOCOCCOSIS INCLUDING MENINGITIS	☐☐/☐☐/☐☐☐☐
☐ DISSEMINATED NON-TUBERCULOSIS MYCOBACTERIAL INFECTION	☐☐/☐☐/☐☐☐☐
☐ PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY	☐☐/☐☐/☐☐☐☐
☐ CHRONIC CRYPTOSPORIDIOSIS	☐☐/☐☐/☐☐☐☐
☐ CHRONIC ISISPORIASIS	☐☐/☐☐/☐☐☐☐
☐ DISSEMINATED MYCOSIS (extrapulmonary histoplasmosis or coccidiomycosis)	☐☐/☐☐/☐☐☐☐
☐ RECURRENT SPETICAEMIA (including non-typhoidal *Salmonella*)	☐☐/☐☐/☐☐☐☐
☐ LYMPHOMA (cerebral or B-cell non-Hodgkin)	☐☐/☐☐/☐☐☐☐
☐ INVASIVE CERVICAL CARCINOMA	☐☐/☐☐/☐☐☐☐
☐ ATYPICAL DISSEMINATED LEISHMANIASIS	☐☐/☐☐/☐☐☐☐
☐ SYMPTOMATIC HIV-ASSOCIATED NEPHROPATHY OR SYMPTOMATIC HIV-ASSOCIATED CARDIOMYOPATHY	☐☐/☐☐/☐☐☐☐

TREATMENT AND CARE

Has the patient been informed of his/her HIV status? ☐ YES ☐ NO ☐ UNKNOWN

Does patient receive HIV medical care? ☐YES ☐NO ☐UNKNOWN

Date started care: Day Mo. Year ☐☐/☐☐/☐☐☐☐

Is patient on antiretroviral treatment? ☐YES ☐NO ☐ UNKNOWN

Date started treatment: Day Mo. Year ☐☐/☐☐/☐☐☐☐

Does patient receive prophylaxis for opportunistic infections? ☐YES ☐NO ☐UNKNOWN

Date started prophylaxis: Day Mo. Year ☐☐/☐☐/☐☐☐☐

Reason for HIV test:

☐ EMPLOYMENT/WORK PERMIT/SCHOLARSHIP
☐ KNOWN RISK ENCOUNTER
☐ IMMIGRATION
☐ INSURANCE
☐ POSSIBLE EXPOSURE, THOUGHT TO BE AT RISK
☐ PROVIDER INITIATED TESTING
☐ SYMPTOMS
☐ TO OBTAIN HIV MEDICAL CARE OR TREATMENT

Has the patient been previously diagnosed with HIV? ☐ YES ☐ NO ☐ UNKNOWN

Date of previous HIV diagnosis: Day Mo. Year ☐☐/☐☐/☐☐☐☐

Place of previous diagnosis (city, country):

THIS SECTION TO BE COMPLETED BY NATIONAL SURVEILLANCE UNIT

Date received by national surveillance unit: Day Mo. Year ☐☐/☐☐/☐☐☐☐

Type of report: ☐ NEW ☐ UPDATE

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 to discuss these questions.

1. Which of the following are notifiable in your country?

HIV infection	☐Yes ☐ No
Advanced HIV infection	☐Yes ☐ No
AIDS	☐Yes ☐ No
HIV/AIDS	☐Yes ☐ No
HIV antibody test	☐Yes ☐ No
CD4 counts	☐Yes ☐ No
If Yes, what level/count is reportable?	☐ All ☐ <200 ☐ <350
Viral load	☐Yes ☐ No
Other, specify:	

2. If your country conducts case-based HIV/AIDS reporting, what sort of information is recorded on the form that could be useful for determining the clinical stage of infection?
   - ☐ Clinical presentation (HIV/AIDS indicator conditions)
   - ☐ CD4 counts
   - ☐ No information is recorded that can be used for clinical staging
   - ☐ Viral load.

   Comment:

Small group discussion, continued

3. With the WHO revisions presented earlier, will the surveillance case definitions for HIV infection have to be changed in your country?

   ☐Yes ☐ No

   If Yes: Specify what aspects will have to be changed, and explain what changes will be needed to the following:
   ☐ Notifiable diseases list:
   ☐ Case definitions:
   ☐ Case reporting forms:
   ☐ Detailed case investigation forms:
   ☐ Reporting sources:
   ☐ Data flow
   ☐ Other:

4. Describe the form that is used to report cases with HIV infection in your country. Is it specific to HIV and/or AIDS or is it used for reporting all cases of notifiable diseases (such as the forms used with Integrated Disease Surveillance [IDS])?

5. Is there a separate form for investigation of HIV or AIDS cases? List the forms and describe their use.

6. Review your country's HIV case report form (or AIDS case report form if HIV reporting is not currently done in your country). Does this form include the minimum variables necessary to report a case? If not, what variables are missing?

7. If your country conducts case-based reporting at any level, complete the table below.

Reporting levels	**Patient's Name**	**Coded Identifier**	**Not Applicable**
Public health facility to sub-national level	☐	☐	☐
Public health facility to national level	☐	☐	☐
Laboratory to care providers	☐	☐	☐
Laboratory to national level	☐	☐	☐
Other, specify:	☐	☐	☐

Apply what you've learned/ case study

Work on this case study independently.

You are the district surveillance office for an urban district in the Republic of Melabia, a mid-sized, resource-constrained country with a concentrated HIV epidemic. In the Republic of Melabia, AIDS case reporting has been conducted for many years, but is incomplete. Melabia has opted to conduct reporting of advanced HIV infection and has implemented a case-based reporting system from health facilities to the sub-national level. From the sub-national level to the national level, cases are reported in aggregate.

1. List the responsibilities of the surveillance officer at the sub-national and national levels.

2. Identify the methods used and key issues to consider when un-duplicating cases.

Unit 3 Summary

- HIV case reporting is used to provide information on the number and characteristics of persons with HIV infection and advanced HIV infection. It is used to determine the current and future need for ART and prevention programmes and to assess their impact.

- HIV case reporting includes reporting persons newly diagnosed with HIV, persons previously diagnosed but not reported and persons previously reported with clinical stages 1 and 2 who have progressed to advanced HIV infection (clinical stages 3 and 4).

- Advanced HIV infection reporting includes reporting of persons with clinical stages 3 and/or 4 and persons with CD4 counts <350, regardless of their clinical stage.

- AIDS case reporting includes reporting of persons with clinical stage 4 and persons with CD4 counts <200, regardless of their clinical stage. AIDS case reporting is not necessary if countries are reporting persons with advanced HIV infection.

- Countries should begin HIV case reporting by identifying staff and resources, adopting the surveillance case definition, determining who will be responsible for case reporting, adopting a case report form (using a case-based or aggregate form), and developing an operations manual.

- Surveillance officers should identify likely sources for cases, such as laboratories, healthcare facilities, HIV and tuberculosis treatment programmes, and HIV counselling and testing sites.

- Surveillance officers should work closely with key staff at these sites to integrate surveillance into their programmes.

- HIV case reporting can be conducted using active surveillance methods (in which surveillance officers identify and report cases directly) or through passive surveillance (in which providers report cases to the surveillance programmes).

- Surveillance programmes that use a case-based reporting system must determine a unique case-identifier with which to report cases. Options for case identifiers include codes and names.

- Surveillance programmes should balance the benefits of name-based reporting systems (in terms of un-duplicating and following up on reported cases) with the possible negative impact that reporting names might have on testing and care patterns in at-risk and infected persons.

Unit 3 Summary, continued

- Countries should adopt either a case-based surveillance system (in which each individual will be reported using one case report form per case) or an aggregate surveillance system (in which sub-national surveillance programmes submit one surveillance form that includes the total number of cases and demographic characteristics in aggregate form). Case-based reporting provides the greatest flexibility for data analysis, but may be burdensome for healthcare providers and surveillance programmes.

- Monitoring HIV-related deaths can provide useful information, but it can be difficult in countries with weak vital statistics systems. Alternative methods of monitoring deaths can involve identifying HIV-related deaths from ART treatment programmes or ART cohorts. In some countries, selected areas use Sample Registration Systems or conduct demographic sentinel surveillance, which captures vital events in the selected areas. Causes of deaths that are identified in these areas can be determined using verbal autopsy methods.

Notes

Unit 4
Monitoring Data Quality for HIV Case Reporting Systems

Overview

What this unit is about

The periodic evaluation of case reporting systems is needed to maintain:

- A responsive and relevant system of monitoring disease trends
- Effective interventions for control and management of disease.

Close monitoring of a newly established case reporting system is needed to identify and fix incorrect reporting practises.

This unit discusses how to:

- Monitor the establishment of the HIV case reporting system
- Conduct an effective evaluation, with emphasis on evaluating the completeness, timeliness and validity (or accuracy) of the data collected in the case reporting system.

Warm-up questions

1. List three aspects of a disease under surveillance that an effective case reporting system should monitor.

2. List two methods to measure completeness of case reporting.

3. List two methods to report the timeliness of case reporting.

Introduction

What you will learn

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

- Describe how to monitor the establishment of the HIV case reporting system
- Describe three elements of a disease under surveillance that a reporting system should monitor
- Describe methods to measure the completeness, timeliness, and accuracy of your reporting system.

Purpose of public health surveillance

Public health *surveillance* is conducted to describe the extent and trends of a disease that is determined to be of public health importance and to guide public health interventions, such as prevention, treatment and control.

Why evaluate?

Once you have set up an HIV/AIDS case reporting system, you will want to make sure that it remains effective as the epidemic shifts over time. If your system does not accurately capture information, the *surveillance* and other public health programmes:

- Will not have the right information to control HIV
- Cannot plan appropriately for treatment and prevention
- Will not effectively monitor the impact of treatment and prevention efforts.

Ensuring accurate collection of surveillance data

A number of factors contribute to the accuracy and completeness of information collected on persons diagnosed with HIV. These include:

- The clarity of *surveillance* forms
- The quality of training and supervision of persons who complete the forms
- The care exercised in data management.

Evaluating Surveillance Systems

Purpose of evaluation

Comprehensive guidelines have been developed to address the methods used to evaluate *surveillance* systems[1]. The purpose of such evaluation is to ensure that problems of public health importance are monitored efficiently and effectively. *Surveillance* systems should be evaluated periodically and include recommendations for improving quality, efficiency and usefulness. Evaluation focuses on how well the system meets its objectives and provides information to improve services and delivery. Specific objectives of ongoing evaluations of a *surveillance* system may include the following:

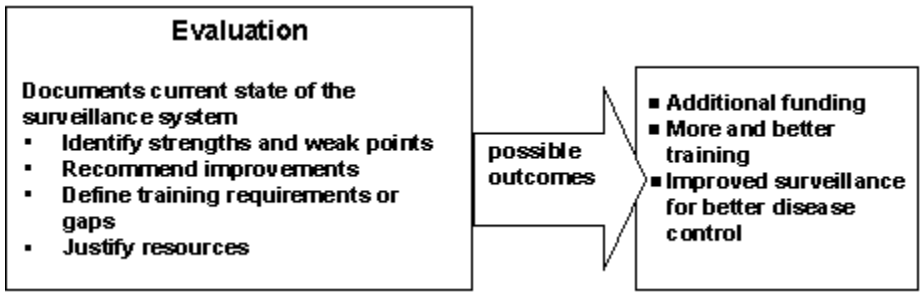
- Evaluating the disease events to be kept under *surveillance*
- Assessing how the system can detect and report these diseases
- Evaluating the quality of the epidemiologic information produced
- Assessing how the system can respond to these diseases
- Assessing how *surveillance* results affect disease control and policy
- Identifying the elements of the system that can be enhanced to improve the quality of information.

The direction and process of the evaluation must be focused to ensure that time and resources are used efficiently. Focusing the evaluation design for a public health *surveillance* system involves:

- Determining the specific purpose of the evaluation (for example, to assess training needs)
- Identifying *stakeholders* who will receive the findings and recommendations of the evaluation (that is, the intended users)
- Considering what will be done with the information generated from the evaluation (that is, the intended uses)
- Specifying the questions that will be answered by the evaluation
- Determining the standards for assessing the performance of the system.

Purpose of evaluation, continued

Figure 4.1. Elements of a well-focused evaluation.



Monitoring and evaluating your HIV *case reporting* system can help determine:

- If reporting sources are providing case report forms as soon as cases are identified
- The completeness of the variables included on the case report forms
- The number and proportion of facilities reporting cases
- Facilities that are not reporting cases.

The methods described below pertain to case reporting programmes that use a *case-based* system. The ability to evaluate a *surveillance* system is another benefit of using a *case-based reporting* system.

Different attributes of a *surveillance* system can be monitored;for example:

- Is the system flexible?
- Is the information accurate?
- Is the system simple?
- Is the system acceptable?
- Are the data complete?

Three attributes of the *case reporting* system should be reported at least annually. These are:

- Completeness
- Timeliness
- Validity (accuracy) of data reported.

Measuring Completeness of Reporting

Measuring the true frequency of HIV infection/disease

Completeness of reporting measures the proportion of all true cases that are reported to the *surveillance* system. This definition should not be confused with measuring the completeness of information that is collected on a case report form. *Surveillance* programmes should strive to report as completely as possible. As *surveillance* systems improve, completeness should increase.

One aspect that will improve *completeness of reporting* is to periodically evaluate the number of facilities that report cases. *Surveillance* programmes should identify the specific healthcare facilities that should report and determine the number of cases reported from these sites.

Methods to measure completeness

Completeness of reporting should be evaluated for a specified time period, such as one year. Measuring completeness can be done by:

- Expanding *surveillance* activities to find (and report) any missed cases
- Estimating the proportion of all cases that was reported in a specified time period using *capture-recapture methods*.

Expanding case finding

Expanding case finding has the benefit of measuring the *completeness of reporting* and of identifying missed cases that can be reported. Expanding case finding can be done by:

- Increasing active *surveillance* activities
- Identifying a secondary database to examine for missed cases.

Some examples of increasing active *surveillance* activities include:

- Visiting health care facilities from which *passive reports* have been received and reviewing the clinic records for missed cases
- Reviewing laboratory records at a facility to identify tests done that are likely to indicate HIV/AIDS, such as CD4 tests, HIV antibody or viral load tests, and tests for *Pneumocystis jirovecii.*

Expanding case finding, continued

Identifying a secondary database against which to match previously reported cases can be challenging in certain settings. It requires that:

- Reported cases be maintained in an electronic database that lists each case separately and includes a name or unique identifier
- The secondary database includes persons with HIV and lists each individual separately by the same identifier as the HIV case registry
- The secondary database has sufficient information to identify a person as having HIV.

Examples of secondary databases that have been used for identifying missed cases and measuring the *completeness of reporting* include:

- Vital statistics registries of deaths in which the cause of death is listed (and would include HIV)
- A registry of patients receiving HIV-related medications.

Capture-recapture methods

Capture-recapture is a method that estimates the *completeness of reporting* but does not identify missed cases to report. This system can be used in areas in which reports from multiple sources that concern a single individual with HIV are received at the *surveillance* programme. For example, consider reports that pertain to one person received from:

- Laboratory reporting
- *Case reporting* from a clinic
- *Case reporting* from a hospital.

The *capture-recapture* methodology assumes that if all of the reports are collected, it represents the true universe of cases. To help understand how this method works, consider the following example in which HIV *case reporting* is done using a unique code and in which case reports come from several sources.

A database is developed into which all reports concerning all HIV cases are recorded. The first column represents five distinct individuals reported with HIV. The next two columns are facilities from which reports are received. One might be a clinic, another might be a laboratory, and so on. A “1” means that a report on this person was received from this site. A “0” means that a report was not received from this facility.

Capture-recapture methods, continued

Table 4.1. Example of case reports from two facilities.

Case number	Facility A	Facility B
X239	1	0
H750	0	0
S000	1	1
W298	0	1
T298	0	1

Use this information to develop a 2x2 table as follows:

	Facility A	
Facility B	a	b
	C	x

In this table, ”a” represents the cases reported from both sources, ”b” are the cases reported only from facility B, “c” are the cases reported only from facility A, and ”x” represents missed cases.

The *capture-recapture* method can be used when alternative sources for case finding are not available. However, a number of statistical adjustments must be made for this method to provide a reasonable estimate of the *completeness of reporting*. For example, a determination must be made regarding the interdependence of reporting sources. In other words, are the reporting sources completely independent? This is generally not the case. A hospital-based laboratory, for example, is not independent from the hospital, meaning that the likelihood of receiving reports from both the laboratory and the hospital are not independent. A number of statistical tests can be used to determine the interaction between reporting sites and to develop appropriate adjustments to the analysis. A number of references regarding use of *capture-recapture* methods for estimating *completeness of reporting* are listed at the end of this unit.

Measuring Timeliness of Reporting

Measuring timeliness

Timeliness of reporting refers to how soon after diagnosis the case was reported to the authorities, such as national *surveillance* officers or Ministries of Health. Timeliness is measured at each level; for example, *surveillance* officers will determine the *timeliness of reporting* from the health facilities to the sub-national level. To implement effective prevention and control measures and to plan care and treatment for infected persons, health officials must know about diseases quickly.

Timeliness can be measured as one of the following:

- Median time between diagnosis of HIV and receipt of the case report form
- The proportion of cases that are received within a specified time period, from diagnosis to receipt of report (for example, within three, six or 12 months of diagnosis).

Standard for timeliness

Countries should adopt realistic and useful standards for the *timeliness of case reporting* in their countries; the following are appropriate goals

- 66% of cases should be reported within six months of diagnosis
- 85% of cases should be reported within a year of diagnosis.

How to measure timeliness

Two variables are needed to measure timeliness:

- The date the case was diagnosed
- The date the case was reported.

Table 4.2, on the next page, demonstrates a four-step process for determining the *timeliness of case reporting*.

How to measure timeliness, continued

Table 4.2. Determine the timeliness of case reporting.

Step	Action
1	Calculate *completeness of reporting* at 12 months after the diagnosis. If completeness is ≥85%, then go to Step 2. (A high rate of completeness is necessary, because when reporting is not 100%, timeliness will be overestimated.)
2	Calculate time (number of months) from diagnosis to report: (report date) - (diagnosis date) OR [(year of report)*12) + month] - [((year of diagnosis)*12) + month] For example, the report date is May 2004 and the diagnosis date is November 2003. The time interval (in months) is: [(2004*12) + 5] - [(2003*12) + 11] = 6 months
3	Determine the number of cases with a time to report ≤6 months.
4	Calculate *timeliness of case reporting*: $\frac{\text{Number of cases diagnosed within a year and reported within six months of diagnosis}}{\text{Number of cases diagnosed and reported for that diagnosis year}}$

Laboratory reporting timeliness

Laboratory-initiated reporting of HIV infection differs from *case reporting* from health care facilities. In general, laboratory reporting provides notification to public health authorities of a person with HIV infection, but it does not contain the detailed information collected in a case report form. It is an important element of HIV *case reporting*, however, and its timeliness should be determined separately from the timeliness of receipt of the case report form.

When you are assessing *timeliness of reporting* from a specific source, such as mandated laboratory reporting, *completeness of reporting* is not taken into account. Here is the calculation:

$$\frac{\text{Number of (reportable HIV-related) tests received within three days of test date during specified time period}}{\text{All tests reported during same period}}$$

Measuring Validity

Measuring validity

Validity measures the extent to which the information on the case report form matches information in the patient record at the health facility. Validity can be considered a measure of the "truth," assuming that the patient's record at the healthcare facility is correct.

You can measure the *validity* of information collected in the case report forms by re-abstracting data on previously reported cases and comparing the information contained in the original and re-abstracted forms. Table 4.3, below, gives steps for re-abstraction.

Table 4.3. Re-abstraction steps for validating case reporting data.

Step	Action
1	Choose a person not previously involved with the data or site to do the re-abstraction check. This person should work for the national *surveillance* programme and should be familiar with the case report forms and methods for reviewing clinic records, abstracting data and completing the case report form.
2	Randomly choose a sample of cases at a site.
3	At the site, go back to patient records (using the unique identification number) for persons chosen as the sample.
4	Compare the information (variables) in the record with Ministry of Health (MOH) records.
5	Record the accuracy of the variables on your national form.

Scheduling re-abstraction studies

For re-abstraction studies, you will need to match *case reporting* information to medical record information. The timeframe for re-abstracting should be one day to six months after the initial case report. The timeframe chosen will vary depending on the nature of a country's recordkeeping. Because of the difficulty in retrieving medical records using a code-based system, re-abstraction of records reported in code-based systems should be performed soon after the original report is received at the *surveillance* programme.

Sampling may also be based on an earlier report year, but it may be difficult to obtain medical records for cases diagnosed several years earlier.

Avoid re-abstracting on the same day as the original abstraction, because bias may be introduced if staff members know re-abstracting is immediately to follow. Because archived data may not be available in the future, re-abstracting should be done in a timely manner.

Once a re-abstraction programme is established, all programmes should routinely re-abstract demographic, risk factor, laboratory and clinical data from a representative sample of records once a year to assess the quality and validity of *case reporting* information.

Sampling strategy

You should use a *simple* or *stratified random sample*. You may use stratification if re-abstraction is to occur at several distinct facilities. Ideally, you will include in the sample all health facilities from which case reports were submitted.

Sample size is calculated once before the beginning of the re-abstraction study, using the prior year's reported case count as a proxy for the expected reported case count. Sampling of cases may occur throughout the year to accommodate the intended sampling frame and to stay within the re-abstracting period of one to six months after original abstraction. The size of the sample should take into consideration the number of case report forms to re-review, as well as time and resource constraints. While a sample of 5% to 10% is usually adequate, in countries with fewer than 100 cases, it is recommended to include all cases.

Data collection

The re-abstracted data are collected on hard copy or electronic case report forms that indicate the data elements to be abstracted. Re-abstracted forms must be clearly marked as *duplicates.* Staff conducting the re-abstraction:

- Should be aware of the case records that need to be abstracted, but should not review the original case report form
- Should work backward from the date when the initial case report form was completed and re-abstract the data
- Should make certain that the case identifier (name or code) is included in the form used for the re-abstraction.

In some situations, the person who is re-abstracting data may come across new information to add to the case report form. Generally, this would be something new in the patient's clinic record. For example, the patient may have started *antiretroviral therapy* (ART) since the initial case report form was completed. The new information can and should be collected and added into the document-based *surveillance* database. To keep the new information separate from the evaluation of the *validity* of reporting, collect the new information on a separate case report form, which must include the patient's name or unique code.

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. Has there been a formal evaluation of the HIV case reporting (or AIDS, if only AIDS case reporting has been conducted so far) surveillance system in your country? If so, which parts of the case reporting system were evaluated?

2. What was the result of the evaluation? What problems were identified?

3. How were the results shared with district/provincial surveillance staff and clinics?

4. How was the case reporting system modified as a result of the evaluation?

Apply what you've learned/ case study

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

The Republic of Melabia implemented HIV case reporting two years ago. Balasu is a large province in the coastal area of Melabia and has the country's major port city. The surveillance officers of Melabia and Balasu have met to discuss developing an evaluation of HIV case reporting in Balasu.

a. What should the surveillance officers focus their evaluation on?

b. What criteria should be used to assess the performance of the system?

c. How should the information obtained in the evaluation be used?

Unit 4 Summary

- The accuracy of case reporting data depends on the clarity of case report forms, the quality of training and supervision of those who complete the forms, and the quality of data management.

- Monitoring reporting systems can help you determine whether reporting is complete, timely and accurate.

- You can measure the completeness of reporting (that is, whether all of the diagnosed cases are reported to surveillance) by expanding case finding or through capture-recapture methods.

- The timeliness of reporting refers to how soon a diagnosed case is reported to the surveillance programme, and can be expressed as the median reporting delay or as the proportion of cases reported in a set time period (such as six months).

- The validity of case reporting data measures the accuracy of the information collected on the report forms. Validity can be measured by re-abstracting information for a sample of reported cases and comparing the originally reported information to the information collected upon re-abstraction. Re-abstraction is used to determine the number and types of errors and to correct errors.

Unit 5
Confidentiality and Ethical Issues

Overview

What this unit is about

Persons with HIV infection and those at risk are vulnerable to a number of social, legal and physical harms. All programmes in HIV case reporting must address these unique ethical issues. This unit discusses those issues and guides you in methods to keep patients' information confidential.

Warm-up questions

1. True or false? Because of the urgent need to treat and prevent HIV infection, the issue of confidentiality does not need to be addressed.

   True False

2. List one reason why case reports from case-based reporting must include patient identification.

3. Fill in the blank with the most appropriate word.

   If _____ about HIV infection is violated, subjects may suffer discrimination and stigmatisation. They may even be subject to criminal charges.
   a. privacy
   b. informed consent
   c. confidentiality
   d. beneficence

4. True or false? Because healthcare providers are responsible for submitting case reports, they do not need to receive information regarding patient confidentiality or surveillance data from the surveillance officer.

   True False

Introduction

What you will learn

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

- Identify potential harms caused by the release of information regarding persons with HIV
- Describe issues of confidentiality and how they relate to HIV case reporting.

Addressing Ethical Issues

Ethical considerations

People and groups at increased risk for HIV infection are vulnerable to a number of social, legal and physical harms. Because of this vulnerability and the *stigma* attached to the disease, the *surveillance* system must address a unique set of ethical issues. Infected persons in the general population and in *high-risk groups* have a legitimate fear of societal discrimination and how it may affect them.

Groups at increased risk may include:

- *Sex workers*
- *Injection drug users*
- *Prisoners*
- Mobile populations (such as persons who leave home for work for extended periods of time)
- *Men who have sex with men (MSM)*
- Sex partners of *high-risk* persons, including those with known HIV infection.

If people fear that information about their behaviour or their HIV status will be used against them, they may avoid HIV testing or provide inaccurate personal information. Successful *surveillance* in marginalised populations depends on assuring *at-risk* and infected communities that information about them will be *confidential* and used only for designated *surveillance* purposes.

Ethical considerations, continued

An effective *surveillance* system requires that *at-risk populations* and populations with known elevated *incidence* or *prevalence* of HIV are identified and accessible for:

- HIV testing
- Ascertainment and monitoring of behaviour
- Care, treatment, and social and prevention services
- Reporting to the HIV *surveillance* programme.

In *concentrated epidemics*, HIV-related public health efforts focus on identification of high-risk and infected persons. In *generalised epidemics*, public health efforts should focus both on these populations and on the broader population.

Experience has shown that the general public may respond to information about HIV infection in *high-risk* populations by calling for restrictive and prohibitive measures. Such measures simply drive risk behaviour further underground, making HIV testing, prevention and care programmes more difficult and also encouraging the spread of the virus.

Confidentiality and data security

HIV *surveillance* is the joint responsibility of many participants in the healthcare system. Participants include the following:

- National and sub-national *surveillance* programmes
- Public and private institutions providing clinical, counselling and laboratory services
- Individual healthcare providers
- Persons at risk for HIV infection
- HIV-infected persons.

The ability of *surveillance* programmes to collect, store, use and transmit sensitive HIV case information in a secure and *confidential* manner is central to the programme's acceptability and success.

The dynamic nature of information technology is important to consider in developing security policies and procedures that will be used to meet the requirements and standards described here. Ministries of Health should routinely assess the changing world of technology and adjust security policies and procedures to protect against potential new risks.

Confidentiality and Security Considerations

Confidentiality and data security guidelines

Case-based surveillance data (that is, data at the individual patient-level), whether they contain a name or a code, represent *confidential* information. Programmes should carefully review their practises to ensure that data are held securely so that patient *confidentiality* is protected. Sub-national and national-level *surveillance* programmes should develop written policies that address security and *confidentiality* of reportable data. The following are areas that should be considered in the development of such policies and procedures:

- *Surveillance* data must be maintained in a physically secure environment. Consider the following:
  - Make certain that data are in a secure building that cannot easily be entered by non-authorised staff
  - Consider how to store both paper and electronic data
  - Restrict access to authorised staff
  - Develop a data-release policy
  - Ensure that any off-site storage (such as a backup system) is secure.
- Data must be transferred in a secure manner.
  - This includes submitting reports from healthcare facilities to the sub-national level to the national level.
  - Specific methods of transmitting *surveillance* data should consider that data might be transmitted by any or each of the following methods:
    - Telephone
    - Facsimile
    - Email
    - Postal service
    - Computer file
    - Courier service.
- Computers that hold *surveillance* data must be secure.
  - Surveillance programmes must consider the security of:
    - Desktop computers
    - Laptop computers
    - Servers/local area networks.
- *Surveillance* staff should receive training regarding the security and *confidentiality* policies and procedures at time of hire and periodically thereafter, such as annually.
- A breach in security or *confidentiality* should be thoroughly investigated to determine the source. Corrective measures, including additional staff training, to prevent recurrence.

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.

1. Think about the staff you work with. How well do you believe that these staff members can maintain patient confidentiality, particularly for patients with HIV infection?

2. What are your concerns in determining a case identifier?

3. What do think are the current gaps in protecting patient confidentiality in your surveillance programme? You may discuss gaps in the healthcare system in general as well.

4. Are other communicable diseases in your country reported using a case-based system? How are these cases identified? (For example, are they reported using a code or name?)

5. What do you think are the existing barriers to implementing HIV case-based reporting in which cases are reported by name?

6. Does your country have existing laws that protect public health information?

Apply what you've learned/ case study

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

You are the health officer in charge of HIV case reporting for Tehama Province in the Republic of Melabia. A prominent newspaper in this province recently published a list of names of persons in the province who have been diagnosed with HIV. What steps would you take to investigate this situation?

In the course of your investigation, you learn that a newspaper reporter thought that publishing the list of HIV-infected persons would make an interesting article and bring him fame and promotion. To obtain this list, he called the clerk for the *prevention of mother-to-child transmission* (PMTCT) programme and simply asked for the list. The clerk was not aware of any problems that might arise by providing the reporter with this list. What corrective action would you recommend?

Unit 5 Summary

- Persons who have HIV or who are at risk for infection may be stigmatised and vulnerable to social, legal and physical abuse.
- Fears of stigmatisation and harm may result in persons avoiding HIV testing or care.
- Surveillance programmes must develop, maintain, and communicate their policies and procedures for ensuring the privacy of reported persons.
- Surveillance programmes should follow established guidelines for protecting patient privacy.
- Surveillance programmes should be aware of ethical principles for the conduct of surveillance and ensure that data collected are maintained securely so that confidentiality of reported persons is not breached.
- Published guidelines for security and confidentiality of surveillance data should be reviewed and adopted as needed for in-country use.

Notes

Unit 6
Analysis, Interpretation and Dissemination of HIV Case Reporting Data

Overview

What this unit is about

This unit describes how HIV reporting data can be analysed, summarised, interpreted and disseminated. It describes the different analyses that can be performed from HIV case reporting data and the types of reports that should be generated and disseminated. It also outlines the elements of an HIV annual case reporting report.

Warm-up questions

1. List three elements of an HIV case reporting report.

   a.

   b.

   c.

2. True or false? The conclusion section of an HIV case reporting annual report is an optional element.

   True False

3. True or false? Changes in reporting practises may result in a false increase or decrease in incidence of advanced HIV infection.

   True False

4. When describing the HIV epidemic, why is it preferable to perform analysis based on date of diagnosis versus date of report?

Warm-up questions, continued

5. True or false? Increases in the number of persons receiving ART can result in a decrease in the incidence of advanced HIV infection (new diagnoses of HIV clinical stage 3 and/or 4 infection) regardless of the number of new HIV infections occurring.

   True False

6. Which of the following are potential target audiences for HIV case reporting annual reports?

   a. General public
   b. Healthcare workers
   c. Public health officials at the district, provincial, national and international levels
   d. All of the above

Introduction

What you will learn

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

- Summarise data obtained from HIV case reporting activities
- Interpret HIV case reporting data
- Describe the basic elements of an annual HIV case reporting report.

Value of case reporting data

Decisions regarding public health are dependent on quality data. Accurate HIV case reporting data are central to:

- The effective monitoring of trends in HIV infection
- Characterisation of the populations affected
- Identifying the number of persons eligible for *antiretroviral treatment* (ART)
- Determining the number of persons receiving *ART*
- The successful development and evaluation of HIV intervention and prevention programmes.

It is also important that *case reporting* data are presented in a manner that aids their use for public health action. Therefore, it is essential that these data meet certain criteria for quality before being analysed and disseminated.

Analysing HIV Case Reporting Data

Newly established HIV case reporting

Interpretation of HIV *case reporting* data should begin only after it has been in place long enough for previously diagnosed cases to have been reported. This may take several years, but it is necessary to be sure that the data, especially trend data, are not misinterpreted. As reporting begins, there may be a *bias* in case reports, particularly if only selected geographic areas or facilities are reporting. Countries should continue to use data from HIV *sero-prevalence surveys* to estimate the overall *prevalence* of infection until HIV *case reporting* is determined to be sufficiently complete and can provide a reasonably accurate estimate of the HIV *prevalence*.

HIV infection is usually asymptomatic for many years and persons may not be diagnosed until they seek care for symptoms. As HIV testing becomes more widely available and *stigma* decreases, persons who are at risk for HIV may be tested prior to developing symptoms of infection. This will lead to a more complete count of HIV-infected persons. If HIV testing is not occurring frequently in *high-risk groups*, HIV *case reporting* is unlikely to provide a complete count of infected persons. If your country's HIV case report forms include information on the *clinical stage* of infection, you will be able to determine whether persons in early stages of infection are being tested and reported.

Many countries have not had complete AIDS *case reporting*. In those countries, initiating reporting of all *HIV clinical stages* along with reporting of *advanced HIV infection* should not affect the interpretation of data because previous AIDS *case reporting* was not likely to be complete enough to use in a meaningful way.

There are special studies and serologic tests that can be done to estimate HIV *incidence*. For trends in HIV *incidence*, countries have traditionally relied on examination of trends in HIV *prevalence* in the youngest group of women tested as part of the blinded *sero-prevalence surveys* among women attending *antenatal clinics* (ANCs). These data sources, rather than HIV *case reporting* data, should be used to estimate HIV *incidence* level and trends.

Analyses using HIV surveillance Data

The term "HIV" in the context of *case reporting* refers to three categories of cases:

1. New diagnoses of HIV infection only
2. New diagnoses of HIV infection with later diagnoses of *advanced HIV infection*
3. Concurrent diagnoses of HIV infection and *advanced HIV infection*.

HIV and *advanced HIV infection* and case data should be examined to answer the following questions:

- Are new diagnoses of HIV and/or *advanced HIV infection* increasing, decreasing or remaining stable?
- Which geographic areas (for example, urban vs. rural areas) have the greatest number of new diagnoses of HIV and *advanced HIV infection*?
- What are the demographic and risk characteristics of new diagnoses of HIV and/or *advanced HIV infection*, and have these changed over time?
- What proportion of persons with *advanced HIV infection* is receiving *ART*?
- Are there demographic or geographic differences in persons receiving *ART*?
- What are the most frequent HIV-related *opportunistic illnesses* and are these changing over time? This is relevant only for programmes that collect information on specific *opportunistic illnesses*.

Interpreting and using surveillance data

Using HIV *case reporting* data to answer the types of questions outlined above will lead to a better understanding of the HIV epidemic. These data should be used to describe the epidemic in terms of:

- Person
- Place
- Time.

Data should be used to describe characteristics of people who are currently infected and newly infected and to show how these populations differ. Identifying the infected populations directs treatment and prevention efforts to those most in need. For example, if a large proportion of HIV-infected persons are commercial *sex workers*:

- HIV testing programmes can be targeted to commercial *sex workers*
- Linkage programmes to refer infected persons to care and treatment should be made available
- Prevention programmes directed specifically at this population can be implemented
- *Sero-prevalence* and *behavioural surveillance* surveys can be implemented to obtain additional information that cannot be obtained from *case surveillance*.

HIV infection is usually not evenly distributed within a country. Often there are particular areas where the infection is concentrated, such as large urban areas or coastal areas. *Case reporting* data should be used to locate these areas to allow for developing, implementing and evaluating treatment and prevention programmes.

HIV *case reporting* data can provide information on how diagnoses of HIV and/or *advanced HIV infection* change over time. Keep in mind that *case reporting* data reflect diagnoses of HIV, and may not provide any information on the number and rate of new HIV infections.

HIV-related mortality

Most developing countries do not have complete death registries, although it is hoped that they will be implemented over time. If information on the number and causes of death are available, *surveillance* programmes should include the number and trends of HIV-related deaths.

If countries conduct *case-based HIV reporting* that can be linked directly to death registries, the number of persons living with HIV can be determined by subtracting the cases of death from the total number of cases reported. In some countries, collection of mortality data has improved through wider use of demographic census and *verbal autopsies*. If HIV-related mortality data are available, *surveillance* programmes should use these data in their summary reports.

Misinterpreting HIV case reporting data

Increases and decreases in case reports of HIV and/or advanced HIV infection may be due to factors other than a true decrease or increase in the number of infections and deaths occurring. Consider factors that may influence the interpretation of *case reporting* data, such as:

- Increases or decreases in the size of the population will affect both the number of infections and the *incidence* and *prevalence* levels.
- Increases in HIV testing—such as expanded *voluntary counselling and testing* (VCT) sites or changes in HIV testing practises among healthcare providers—may lead to more diagnoses, but do not necessarily reflect changes in the epidemic.
- Adoption of a new *case definition*, particularly one that is broader, will result in an increase in cases.
- *ART* delays the progression of HIV infection thereby reducing to *advanced HIV infection*, thereby reducing the incidence of advanced HIV infection.
- Changes in *case reporting* practises, such as efforts to increase reporting from private providers, should increase the number of reports.
- Increases or decreases in the number of healthcare facilities or other factors that affect the use of healthcare services can impact diagnoses and reports of HIV. For example, implementing or increasing a user fee may result in fewer people seeking care, which may reduce HIV diagnoses and case reports.
- Duplicate case reports (more than one report provided for an individual) may lead to counting one person twice.

Misinterpreting surveillance data, continued

A number of factors may affect the true *incidence* of *advanced HIV infection*, including:

- Past HIV *incidence*. The time it takes to develop *advanced HIV infection* should be kept in mind
- *ART* impact on delaying the progression of HIV to *advanced HIV infection*
- Past HIV *prevalence* (that is, whether the epidemic is mature or new).

Factors that may affect the true *prevalence* of *advanced HIV infection* cases are:

- Changes in HIV-related mortality
- Changes in the *incidence* of HIV, although this is unlikely to impact trends in *advanced HIV infection* until many years later
- Changes in *incidence* of *advanced HIV infection* and AIDS that may occur as people progress from earlier to later *clinical stages* (from 1 and 2 to 3 and 4) and reflect HIV transmission that may have occurred years earlier.

Displaying and Interpreting Surveillance Data

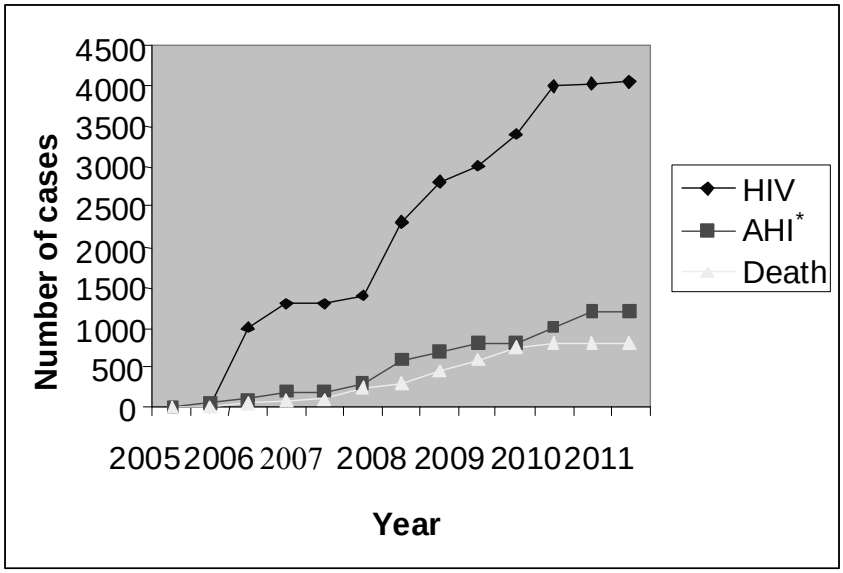
Displaying and interpreting data

Surveillance officers and data analysts should know the purpose of the data and analyse them with this purpose in mind. For example, the data may be used by national AIDS control programmes to assess the direction of the epidemic. In this situation, trends in HIV *case reporting*, along with trends in data obtained from *sero-prevalence surveys*, would be used.

Surveillance data may be used with *ART* monitoring data to measure the proportion of eligible persons who are receiving it. *Trend analysis* allows programmes to monitor how well *ART* is reaching those in need of treatment.

Displaying and interpreting data, continued

Figure 6.1**.** Reported HIV infections and advanced HIV infection cases and deaths, Republic of Melabia, by year of diagnosis/death, 2005 through 2011.



*AHI, advanced HIV infection.

Discussing the figure

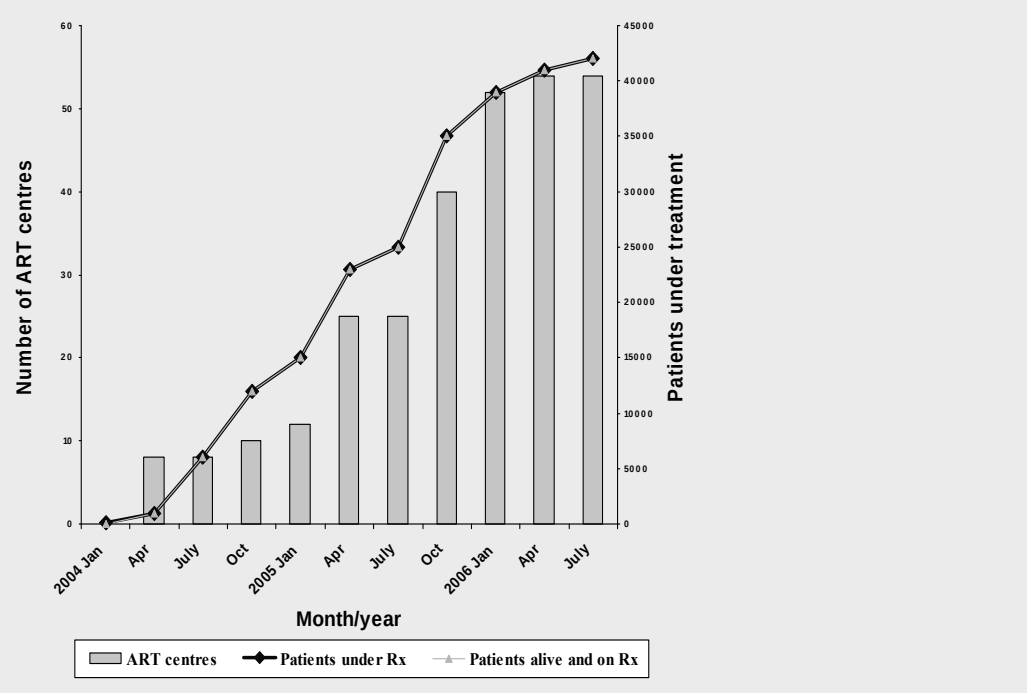
Look at figure 6.1 and answer the following questions:

1. What factors may explain the difference in the trends in HIV infection and *advanced HIV infection* cases between 2005 and 2011 (that is, high numbers of HIV cases, but relatively low number of *advanced HIV infection* cases)?

2. What would you expect to happen to the number of *advanced HIV infection* cases and deaths in the absence of *ART* in 2004?

Discussing the figure, continued

Figure 6.2: Trends in the number of ART centres, number of patients on ART, and survival, January 2004 – July 2006.



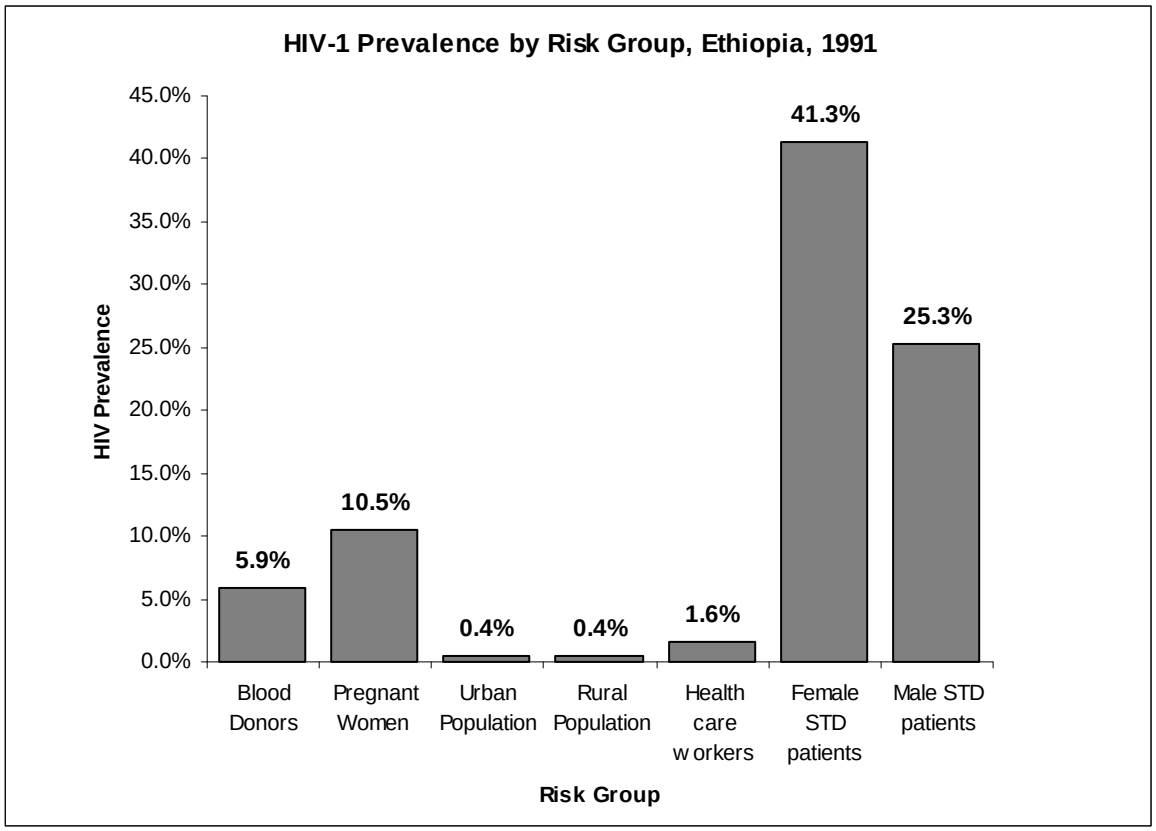
Look at figure 6.2 and answer the following questions:

1. Describe the trends in the number of *ART* centres and how this relates to the number of persons on *ART* and the number of persons alive and on *ART*.

2. Why are the trend lines for the number of patients on *ART* and the number of patients alive and on *ART* the same?

Discussing the figure, continued

Figure 6.3. HIV Prevalence by risk group, Ethiopia, 1991.



Source: Sentjens, R, et al. Prevalence of and risk factors for HIV infection in blood donors and various population subgroups in Ethiopia Epidemiol Infect. 2002;128:221-8.

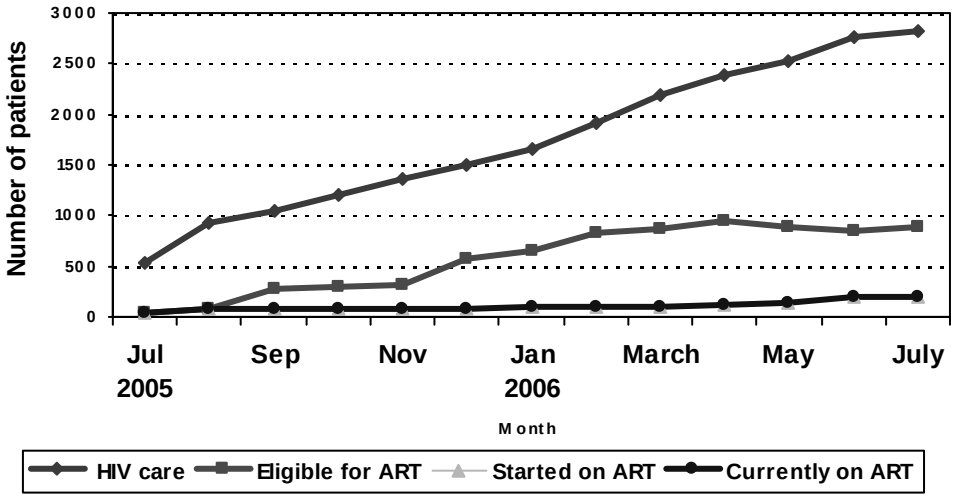
Look at figure 6.3 and answer the following questions:

1. What risk group accounts for the largest number of HIV cases?

2. Do you think this is a reasonable representation of the state of the HIV epidemic in Ethiopia today?

Discussing the figure, continued

Figure 6.4. Trends in patients eligible for ART, July 2005–July 2006.



Look at figure 6.4 and answer the following questions:

1. Describe the trends in the number of patients who are eligible for *ART*. Explain what this means in terms of what the national AIDS control programme should consider when planning for the number of persons who might need *ART* in 2007.

2. What are some possible explanations for why there are more patients in HIV care than receiving *ART*?

3. How would you compare these data to data obtained with the HIV *case reporting* system?

Presenting HIV Case Reporting Data

Target audiences for surveillance reports

Surveillance reports need to be disseminated to the persons responsible for decision making. HIV reports are one of the primary means of communication with colleagues, co-workers, and other *stakeholders* in the HIV epidemic.

Potential target audiences for *surveillance* reports on HIV include:

- Persons who contribute to the collection of the data
- Healthcare workers
- Public health officials at the district, provincial, national and international levels
- Government officials, policy-makers and planners
- Journalists/professional writers
- The general public.

Meeting minimum performance standards

Before analysis, HIV *case reporting* data should meet the minimum quality standards for *timeliness* and *completeness of reporting*. Additionally, any report or presentation of the data should include a discussion of the quality and limitations of the data.

Some countries have had *case reporting* only from selected healthcare facilities that provide care for HIV patients. Reporting from these facilities may be complete, but this does not mean that reporting for the country is complete. Analysis of *case reporting* data should always consider how complete they are. When using incomplete data, it should be mentioned as a limitation. When possible, you should use methods to estimate the proportion of missing cases.

Preserving patient privacy

To reduce the risk of inadvertent identification of individuals, it is essential that data be presented in a way that preserves the *confidentiality* of persons in the HIV database. Countries should establish data-release policies that are described in writing and available for anyone who has access to *case reporting* data. Policies for data release should:

- Be guided by knowledge of the overall population characteristics and distribution of the HIV-infected population
- Maintain *confidentiality*
- Permit use of *case reporting* data for public health purposes
- Specify who can receive *case reporting* data and in what format.

The data-release policy should address reports from the *surveillance* programmes and the release of *case reporting* data for any other purposes.

How data should be presented

Data can be presented in graphical/tabular format and narrative format. There are important considerations for presenting data. Below are some minimum standards for graphical/tabular formats:

All figures must include:

- Clear titles, including time period
- Labelled axis
- Data source
- Footnotes
- Interpretation (including limitations of data).

Additionally, when presenting HIV data, you should follow local *confidentiality* procedures for displaying small cell sizes.

Presenting trend data

To assess trends in HIV cases, deaths or *prevalence*, it is preferable to analyse and present the data by year of diagnosis. Analyses by year of diagnosis will more closely reflect the reality of the HIV trends. Presenting data using the date of the case report inserts an artefact of reporting delays.

Formats for Disseminating Results from HIV Case Reporting

Communicating results

There are a variety of ways to disseminate the results from analysis of HIV *case reporting* data. The format used should be tailored to the audience based on:

- Their familiarity with the terminology and concepts of *case reporting*
- The action they will take based on the information, perhaps determined by their position in the HIV public health structure
- Whether their interest is in specific information or a comprehensive overview
- Their motivation to review the data critically
- Their needs or expectations.

The more organised the report, the more effective it will be in meeting the objectives.

HIV case reporting annual report

The HIV *case reporting* report should focus on the analysis and interpretation of the data. This type of report is usually limited to descriptive statistics, though more sophisticated analyses may be included. The report should include observed trends of the HIV epidemic, observed risk patterns, transmission categories, age, sex and geographic distributions.

Annual epidemiological report

The purpose of the annual epidemiological report is to use the strategic information available in the country to inform about the HIV epidemic. The report provides data from all HIV and *sexually transmitted infection* (STI) *surveillance* activities (for example, HIV *case reporting*, HIV *sentinel site reports*, HIV *sero-prevalence surveys*, STI syndromic/aetiology surveillance) as well as other related programme areas (such as *tuberculosis* [TB] control programmes, *prevention of mother-to-child transmission* (PMTCT) programmes, and care and treatment programmes). Ideally, this report can summarise the state of the HIV epidemic.

Fact sheets

Fact sheets are brief descriptions written in simple language and formatted to convey basic information on a single topic or subject area. In areas where multiple languages are spoken, some fact sheets may need to be translated into other languages. Fact sheets often will include contact information for follow-up when more in-depth information is desired. They also can be tailored to address specific populations, including division by:

- Special interest (*sex worker*, homeless, *migrant* populations)
- Sex
- Risk category
- Age (paediatric, adolescents, 50+).

Recommended analyses include:

- Annual number of cases, percentages
- Case rates per 100,000 population.

Slide sets and presentations

Visual presentations of *surveillance* data are useful for conveying information to the Ministry of Health (MOH) staff, the National AIDS Programme staff, *community-based organisations* (CBO), community-planning groups, the general public, international donors and policy-makers. Graphic presentations can add interest and impact to numeric data, such as comparisons and trends. Slides prepared in Microsoft PowerPoint (or similar programmes) can be used for electronic presentations, embedded with text in printed reports or printed as posters/displays. Slide sets can address topics similar to the fact sheets and should be updated annually. Examples of information included in these slides are:

- Summary data
- Geographic distribution
- Trends (five or 10 years)
- Proportions by demographic factors (race/ethnicity, sex, risk).

Recommended analyses include:

- Annual number of cases, percentages (5-10 years)
- Annual case rates per 100,000 population over time (5-10 years).

HIV Case Reporting and Annual Report

The HIV case reporting annual report presents descriptive statistics to people who report the data, to other units of the Ministry of Health and national AIDS programmes that use the data for HIV prevention and patient care, and to the public.

In addition to the annual report, areas of medium and high *morbidity* should also consider publishing summary data on a quarterly or semi-annual basis. Producing and distributing a routine report will decrease the number of individual requests for data. The report can be developed including the following components:

Title or cover page
A title or cover page announces what is to follow. It extends an invitation to the reader:

- The title should describe the content of the report, including the time period covered.
- The title page should also include information on where the data come from (for instance, HIV case reporting for the Republic of Melabia, the staff who contributed to the report, and so on).

Executive summary
An executive summary abstracts the entire report in approximately one page. This is useful for busy officials who may not have time to read the whole report. Include the salient points, especially any recommendations.

Introduction
The introduction includes the title of the report, dates and contents of previous reports and statement of objectives and purpose of the report.

Body of the report
The body of the report includes how the data were collected and managed as well as the results. It includes:

- Definitions of terms used in the report
- Discussion of the quality and limitations of the data (such as *timeliness* and *completeness of reporting*)
- Narrative interpretation of the data presented
- A presentation of the data in a logical sequence, beginning with the summary or general data and progressing to a specific display of data
- Data presented separately for HIV cases and *advanced HIV infection*, or as combined HIV/advanced HIV.

Body of the report, continued

The following analyses should be included in the report for HIV and advanced infection. The title of each table or figure should clearly describe the type of data displayed and the time period covered:

- HIV and *advanced HIV infection* cases diagnosed in most recent calendar years
- Number and percentage of HIV and *advanced HIV infection* cases diagnosed in the most recent calendar year, presented by:
  - Age group and sex
  - Transmission category and sex
  - Transmission category for each race/ethnicity/sex group (may not be applicable for all areas, depending on morbidity).
- Information on trends in new diagnoses of HIV and *advanced HIV infection*, stratified by age and sex and mode of transmission.

In those areas where *case-based reports* can be linked to death registries, calculation of living cases can and should be conducted. These include:

- The number and percentage of persons living with HIV (including all *clinical stages* and CD4 counts):
  - Sex
  - Age groups and sex
  - Mode of transmission/risk factor by sex.

- The number and percentage of persons living with *advanced HIV infection* (clinical stage 3 or 4 or CD4 cell count <350, including AIDS):
  - Sex
  - Age groups and sex
  - Race/ethnicity/sex (if applicable)
  - Mode of transmission/risk factors by sex.

Discussion

The discussion section interprets the data and explains the epidemic and how it has changed from previous years. It should also address any biases or limitations to the data. In particular, it should be noted if the data presented are not complete.

Conclusion

The conclusion re-emphasises pertinent findings and integrates them into a comprehensive section on the state of the epidemic.

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 to discuss these questions.

1. Who is responsible for data analysis and reporting at each level, and what kinds of reports are generated?

2. Describe the types of reports that are routinely produced using surveillance data in your country.

3. What do you think will be the effect of HIV case reporting on the existing trends for your country?

Apply what you've learned/ case study

Work on this case study independently.

You work in the surveillance unit of the Republic of Melabia and are responsible for developing the HIV case reporting annual report. You have data from HIV case reporting nationwide. Use this information to answer the following questions.

1. What data will you include in your report? Describe some of the ways you might display the data according to the source of the data.

2. The following table shows the advanced HIV infection case incidence rates over seven years. The rates are per 1,000 population. Use this information to develop a figure that will represent what you think are the most important aspects of these data.

Apply what you've learned/case study, continued

Table: Incidence of advanced HIV infection (per 1 000), 1999-2005, Republic of Melabia.

	Age group (years)		
Year	**15-19**	**20-24**	**≥25**
1999	60	150	103
2000	75	160	118
2001	20	29	18
2002	90	155	120
2003	60	162	125
2004	50	140	120
2005	30	88	100

3. What would you write in your report about these data? (That is, what is your interpretation of these data?)

4. HIV case reporting has only been conducted for one year. In what way will this information affect your report and is this something that will be mentioned in the report. Will you use the data in a report?

Unit 6 Summary

- Data from HIV case reporting should be analysed and disseminated so that they can be used for public health action.
- Reported data should be evaluated prior to analysis and dissemination to be sure that reporting is complete. In particular, programmes that have recently adopted HIV (or advanced HIV infection) case reporting should wait until the reporting of cases that were diagnosed in the past is complete.
- When interpreting case reporting data, it is important to consider factors that may falsely indicate increases or decreases in prevalence, such as changes in the size of the population, reporting practises or case definitions.
- Reports that summarise surveillance data should be disseminated to the people who contributed to collecting the data, including healthcare workers, public health officials, government officials and policy makers, and the general public.
- Before analysing and disseminating case reporting data, the reporting system should be evaluated to make sure that it meets the minimum standards for completeness, timeliness, and accuracy.
- Programmes must take care to ensure that any reports using surveillance data in a way protects confidentiality.
- Data from HIV case reporting can be presented in tables and figures and may have text that explains and interprets the data alongside the tables and figures.
- It is important to present trend data using the date of diagnosis rather than the date of report in order to accurately describe the epidemic without bias from reporting practises.
- HIV case reporting data may be presented as periodic, at least annual, reports, annual epidemiologic reports that include case reporting data as well as additional strategic information, fact sheets, and presentations to specific audiences, such as the staff in the Ministry of Health.

Notes

Unit 7

Operational Aspects of HIV Case Reporting System

Overview

What this unit is about

This unit provides guidelines for developing an HIV case reporting operational manual and for preparing an action plan to implement an HIV case reporting system in a country.

Warm-up questions

1. List the key sections of an operational manual.

2. Which of the following are elements in an implementation plan to initiate reporting of HIV or advanced HIV infection?
   a. Timeline
   b. Key activities
   c. Responsible person
   d. All of the above

3. True or false? Case definitions for reporting HIV cases should be applicable nationally.

   True False

Introduction

What you will learn

At the end of this unit, you will be able to:

- Design an operational manual for HIV *case reporting* in your country
- Develop an action plan for implementing an HIV case reporting system in your country.

To begin operationalising the HIV case reporting system in your country, you will need to:

- Develop a country-specific operational manual for HIV case reporting (or modify an existing operational manual used in AIDS case reporting)
- Develop country-specific implementation work plans
- Outline the steps necessary for implementing case reporting in your country and how this fits within guidelines and operations for regional case reporting.

Operational Manual

What is an operations manual?

An operational or *operations manual* is a written document that spells out the national policy and procedures on various aspects of HIV infection and case reporting, including *case definitions*, sources of data, reporting procedures, data *confidentiality* and dissemination. An *operations manual* should serve the needs of the national AIDS programme and must be consistent with international guidelines on HIV *case reporting*.

Additionally, an *operations manual* can serve other purposes, such as being:

- A reference tool for healthcare workers and *surveillance* staff
- A training tool to conduct initial and refresher training on *case reporting*
- A tool for monitoring the quality of the *case reporting* system.

In general, guidelines for *surveillance* are applicable nationally. Hence, a central agency, such as the *surveillance* programme in the national AIDS programme, should be responsible for preparing and distributing the operations manual.

Key sections of an operational manual

Key sections of an operational manual are briefly described below.

1. Purpose of the HIV case reporting system

This section should detail the expected purpose that the system will serve and how the information generated will contribute to HIV prevention and control activities in the country.

As an example:
The national HIV case reporting system will be used to plan for the treatment and care needs of HIV-infected persons; in particular, these data will help in planning for procurement of drugs for prophylaxis and treatment of opportunistic infections, and for antiretroviral therapy. Data on demographic and risk behaviours of HIV-infected individuals will assist in characterising transmission patterns in communities and help in targeting prevention efforts to vulnerable population sub-groups. In areas where completeness of data is adequate, HIV case reporting will assist in assessing and monitoring trends in HIV incidence and prevalence and in ascertaining the burden of disease attributable to HIV in the region. HIV case reporting data will also be used for advocacy and resource mobilisation. Finally, HIV case reporting will add to our understanding of the progression of HIV infection and the impact of ART, and in refining epidemiologic assumptions for estimating and projecting the impact of the HIV epidemic.

Key sections of an operational manual, continued

2. Reportable events and case definitions

This section of the operations manual lists selected events in the spectrum of HIV infection that should be captured in the HIV *case reporting* system. The *case definitions* of these reportable events will also be provided in this section.

Each country should decide on the reportable events that will be captured. In countries where *completeness of reporting* is very low, AIDS *case reporting* does not serve much purpose. It is recommended that all such countries implement a new system to start reporting cases of *advanced HIV infection*, a term which includes AIDS.

In addition, it is recommended that countries consider reporting all HIV infection cases (*clinical stages* 1-4). This would include cases that have not yet progressed to *clinical stage* 3 or 4. From the perspective of HIV prevention and care, it is undoubtedly of utmost importance to identify HIV infection cases early to prevent further spread of infection. Early identification also would provide the required care, counselling and psychosocial support to the infected individuals. From a *surveillance* perspective, a comprehensive system that captures HIV infection early is more useful because it provides a more complete picture of HIV infection and of the epidemic, particularly if HIV testing rates are high. Ultimately, all countries should aim to move toward the goal of capturing all HIV infections. Currently, *case reporting* systems are very weak in most countries because of limitations in the overall public health infrastructure. Hence, countries should use a step-by-step approach to reach the ultimate goal of reporting all HIV infections. It is recommended that each country assess the feasibility of implementing a comprehensive HIV infection *case reporting* system by undertaking pilot studies in few geographical areas. Based on this experience, further strategies can be considered.

Key sections of an operational manual, continued

3. Reporting sources

This section of the manual describes the types of facilities that will be included in the HIV *case reporting* system. The scope of reporting may include the public sector, *non-governmental organisations* (NGOs) and private-sector facilities. Reporting *advanced HIV infection* requires *clinical staging* and CD4 testing, so it should be done from a facility where physicians are available. Examples of reporting sources in the public sector include health facilities where HIV care and treatment are provided (such as primary health centres, district hospitals, *prevention of mother-to-child transmission* [PMTCT] centres, *tuberculosis* [TB] clinics, medical colleges, and hospitals,). A complete list of such facilities should be created for every geographical area.

4. Variables and data collection forms

The national *surveillance* programme should identify a minimal set of variables that each reporting unit will be required to report. Standard data collection forms should be developed and provided to all reporting facilities, including provincial/district-level *surveillance* programmes. Ensure that each variable that is collected serves a purpose and will be used for generating information to contribute to HIV prevention and control efforts. Filling out data forms takes the time of health workers at the expense of another programme activity; therefore, *case-reporting* forms should be carefully designed to avoid collecting nonessential information. The *case-reporting* forms may be designed either as individual forms (one for each individual) or in the line-list register format, with one row dedicated to each HIV case.

This section of the manual should also provide instructions on how to complete the *case-reporting* form, as well as definitions of the variables.

Key sections of an operational manual, continued

5. Data transmission and reporting procedures

This section of the manual outlines how to report, who should report, to whom they should report, when they should report and the levels through which data should flow from collection through dissemination.

In a large country, for example, a four-tier system may be used for data transmission. In this system, data are collected at the first level in a community health centre (a health facility for a population of 100,000). Data are then forward to the second level—the provincial/district surveillance programme—and then to the national/regional surveillance programme, where data are entered in a computerised database. After data entry and removal of duplicate records, the electronic files are sent to the fourth level, which is the national/regional *surveillance* programme.

In a small country, however, where few HIV cases are reported each year, HIV *case reporting* forms may be directly faxed to the national *surveillance* programme. As much as possible, data transmission should follow and build on the existing data transmission systems for HIV and other diseases. Protocols for transmission of case data that includes personally identifying data should be done in a manner that protects patient *confidentiality* and privacy.

The flow of data should be schematically presented and should describe how the *case reporting* forms will be forwarded from the healthcare providers to the *surveillance* programme at the district/regional level to the national level and back (called the dissemination feedback loop).

6. Data management and analyses

This section should describe how data will be managed at different levels of the system. At the source of data collection, a country may collect data on a paper form. Then, at some level, data will get computerised. Systems for paper-based and computerised data management should be described clearly, including the hardware, networks and software used at different levels. This section also should contain information on who is responsible for entering, maintaining, cleaning and analysing the *case reporting* data.

7. Data security and confidentiality procedures

This section details the data security and *confidentiality* procedures that support the HIV *case-reporting* system. It describes how case information should be reported, transported and stored. It also describes the actions taken if there is a breach in *confidentiality*.

Key sections of an operational manual, continued

8. Roles and responsibilities for programmes and personnel involved in HIV case reporting

This section details the roles and responsibilities for all persons involved with HIV *case reporting*. This includes roles for reporting sources (such as healthcare providers) and sub-national and national *surveillance* staff. The roles and responsibilities should complement the data flow diagram and data reporting procedures.

9. Training staff in data collection, management and analyses

This section outlines a training plan for implementing the HIV *case reporting* system. A training plan should include who will be trained, in what topics and for how many days, and when the training will occur.

To prepare a training plan, list all staff that are likely to be involved in the HIV *case reporting* system. List the tasks each staff member is required to accomplish. Based on a task analysis, create a list of competencies that each staff must have to fulfil his/her role in the HIV *case reporting* system. Using this list, prepare a teaching curriculum and teaching materials, including handouts/training manuals. The training curriculum should differ for staff working at different levels. For example, at the source of reporting, healthcare providers need to know how to fill out reporting forms correctly, what constitutes a reportable event, how to report (case report form), and what to report (the variables on the case report form). Take care that providers understand all the variables on the case report form. Obtaining risk information is always challenging; developing posters or other instructional materials that are easy to review can assist providers in accurately collecting this critical information.

Staff must understand how to enter the data, how to identify duplicate records and how to clean the data. The national *surveillance* staff must be trained in data analysis, interpretation and report writing. Additionally, all personnel involved in HIV *case reporting* (Ministries of Health and reporting sources/healthcare providers) must attend annual *confidentiality* training.

Key sections of an operational manual, continued

9. Training of staff in data collection, management and analyses, continued

The training materials should be of high quality and preferably pilot-tested and revised if necessary. The approach to training may differ based on the size of the country. In a large country, a cascade training approach may be required—that is, master trainers should be trained in each province. These trainers will, in turn, train other staff in the region, who in turn will train healthcare providers at the district level.

A single training session is not necessarily adequate and training needs should be reviewed annually. As you monitor the data submitted from reporting sources, you may discover a need to train staff more often if you find that the case reports are incomplete or not filled out correctly. Ministries of Health staff outside of the *surveillance* programme should also be apprised of the changes in the *case reporting* system.

10. Data dissemination

This section of the operations manual details all the external and internal HIV reports and publications the *surveillance* unit produces and when these should be available. The purpose of collecting HIV *case reporting* data is to use it for programme planning. The *surveillance* programme should work with stakeholders, including other programmes in the Ministries of Health, national AIDS programmes, and national AIDS committees, to determine their data needs and incorporate them into the reports. You should also consider the following information:

- The type of statistical software programmes that should be used
- Which analyses should be conducted monthly, quarterly and/or annually.

11. Standards and monitoring

This section of the manual explains how the *case reporting* system will be monitored in your country. There are general monitoring principles that should be adapted to your setting, such as *completeness of reporting*, *timeliness of reporting*, and accuracy of data.

Apply what you've learned

Work with your country's team members to discuss each of the following sections of the *operations manual* for your country.

1. Articulate the purpose of HIV *case reporting* system.
2. Identify reportable events.
3. Specify the minimum variables required to report a case.
4. Identify sources of data collection.
5. List variables to be collected.
6. Schematically present data flow (flow chart).
7. Identify training approach.
8. List key elements of data confidentiality.

Purpose of an action plan

A well-developed action plan allows you to:

- Establish clear objectives and outputs
- Present your ideas to achieve consensus among all persons involved
- Establish a realistic budget
- Ensure that the appropriate staff in each facility are trained in case reporting methods
- Determine activities
- Determine responsible persons
- Establish a timeline for completion of activities.

National Action Plan Worksheet

List of activities

- Identify stakeholders; debrief Ministries of Health (MOH) and National AIDS Control Programme (NAP).
- Finalise operational procedures manual.
- Finalise and pilot-test the forms.
- Conduct staff training at reporting units (go through case report forms, data flow, roles and responsibilities within one month of finalising forms and operational manual).
- Adapt district/regional/national database to match the data collection forms.
- Train data-entry persons.

You will want to consider other important areas, and may add any of these activities to your action plan:

- Determining budget
- Determining final training dates
- Selecting the appropriate audience for training
- Adapting the training curriculum from existing materials
- Organising the training(s) (facility, audiovisual equipment, supplies, etc.)
- Evaluating the training
- Informing participants about follow-up activities, such as visits, review of completed *case report* forms, and contact information for technical assistance.

Timeline

Adding a timeline to an action plan helps you establish a realistic schedule. The sequence of events in planning a timeline is as follows:

- List your activities.
- Put the activities in the order you (or your team) will do them.
- Add timeline to the action plan.

Why establish a timeline?

Having deadlines:

- Provides the overall picture for planning your programme
- Helps keep your project on schedule
- Avoids assigning too many things to one person
- Helps you to meet your programme goals and objectives
- Helps you to remember critical steps so nothing is forgotten in the planning process.

How to choose a timeline

When you are developing due dates, think about:

- The order of activities
- Which activities are dependent on earlier activities
- The overall timeframe for completing the entire activity
- What factors might cause someone to miss a deadline, such as existing schedules, commitments, holidays, vacation schedules or any other sources of delay.

It is important to remember to include the people who will be involved and who will be responsible for meeting the deadlines. If the team is involved in the decision-making process about key issues like deadlines, they will be more likely to meet those deadlines. Everyone involved should receive a copy of the agreed-upon action plan.

Apply what you've learned

Work with your country team members and, using the template provided on the next page, prepare an action plan for implementing a HIV case *reporting* system in your country. You may modify the template as you wish. You may change the order of the activities or add additional activities. Check your calendar to assign realistic deadlines for each activity. Some suggested timeframes have been added to the activities. You may change those if you wish.

Apply what you've learned, continued

WORKSHEET FOR DEVELOPING ACTION PLAN (WORKSHEET 1)	
1. What is the name of your country?	
2. Who are the stakeholders who will review your plan? Please provide names, if possible.	Ministries of Health: Non-governmental organisations: International agencies/donors: Other:
3. List key persons who will be working to complete the actions in the action plan and their position. Develop a contact list with the name, address, phone number, fax number, email address and role of each person.	▪ Finalise operational procedures manual: ▪ Finalise case-report forms: ▪ Co-ordinate training (logistics, materials): ▪ Instructors:
4. List facilities involved with case reporting.	
5. List staff in need of training at each facility (community health nurses, family welfare educators, data managers, data-entry clerks, etc.)	
6. What is the estimated number of people in need of training? (Multiply the number of facilities by the estimated number of persons at each facility in need of training).	

Worksheet for Developing Action Plan, continued

7. What are the best dates to conduct trainings? List conflicting meetings/holidays during which the trainings cannot be held.	
8. Are you aware of any sites where training can be conducted? If yes, please list the name and type of facility and how many people it can accommodate at one time.	
9. Challenges in implementing your action plans can include: ▪ Few or no designated trainers ▪ Lack of or conflicting policies ▪ Lack of necessary materials ▪ Scheduling conflicts ▪ Lack of money ▪ Turnover/attrition of staff List your possible challenges in the column to the right.	
10. List resources that you may be missing.	
11. How can partner organisations help you to implement your plan?	

Notes

National Action Plan: (Your Country and Title of the Plan)
(Worksheet 2)

Activities	Responsible Person	Resources Needed	Challenges/ Solutions	Target Due Date	Actual Completion Date
1. Debrief MOH (within 1 month).					
2. Conduct rapid assessment of current reporting system.					
3. Finalise operational procedures manual (within 2 months)					
4. Finalise test forms (within 2 months).					
5. Conduct training of providers and labs (within 1 month of finalising forms and operational manual).					
6. Talk with central statistics office to obtain death records (within 2 months).					
7. Develop and check national database to make sure it is set up appropriately.					

National Action Plan, continued

8. Train data-entry persons and back-up staff.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					

Summary

- HIV case reporting is a key method of monitoring the HIV epidemic. It involves reporting each person diagnosed with HIV infection to the health authorities.

- HIV case reporting provides information about:
  - The number and characteristics of persons diagnosed with HIV and advanced HIV infection
  - The number and characteristics of persons living with HIV
  - The number of deaths among HIV-infected persons.

- HIV case reporting can be used to:
  - Determine the number of persons in need of ART
  - Measure the impact of ART on HIV-related mortality
  - Plan for and target HIV prevention programmes.

- The WHO revised the HIV clinical staging and surveillance case definitions in 2006 to include:
  - Recommendations to report all persons with HIV infection, regardless of their clinical stage at diagnosis.
  - Countries that do not adopt HIV infection reporting may report persons with advanced HIV infection. In this situation, AIDS cases are no longer reported.

- Countries must plan for HIV case reporting by:
  - Identifying dedicated staff at the national level (and sub-national if applicable) who will establish and monitor the HIV case reporting system
  - Adopting standardised HIV surveillance case definitions (this is likely to be the WHO surveillance case definitions)
  - Conducting surveillance assessment/evaluation to determine the current status of the disease surveillance system (for instance, communicable disease surveillance)
  - Working with appropriate staff to incorporate the elements of the case definitions into the country's notifiable disease list
  - Determining who is responsible for reporting (for example, healthcare providers, counsellors at voluntary counselling and testing sites, laboratories)
  - Determining reportable laboratory and clinical events (such as positive HIV EIA, Western blots, and viral load or CD4 tests)
  - Determining whether only newly diagnosed persons (that is, newly diagnosed HIV infection and newly diagnosed advanced HIV infection) or all persons with HIV infection are to be reported (that is, prospective and retrospective case reporting of HIV in all clinical stages)

S**ummary**, continued

- Adopting a case report form that is either case-based or designed for aggregate reporting
- Develop a model operations manual for case reporting that can be modified at the sub-national level.

- Case identification can employ both active and passive surveillance methods and should be conducted from all places where persons with HIV infection are diagnosed or cared for. Sources of HIV cases include:
  - Laboratories
  - Healthcare clinics (health centres)
  - ART treatment clinics
  - Tuberculosis (TB) clinics
  - Voluntary HIV counselling and testing (VCT) sites
  - Hospices (for advanced HIV infection)
  - Hospitals
  - Blood banks
  - Prevention of mother-to-child transmission (PMTCT) programmes
  - Vital statistics registries (for persons diagnosed with HIV only at death, but they can also be used to provide information on the number of and trends in HIV-related deaths).

- In countries with an HIV case reporting system, report a case when:
  - The person is diagnosed with HIV infection, regardless of clinical status
  - When a person previously diagnosed and reported with HIV clinical stage 1 or 2 progresses to advanced HIV infection
  - An HIV-infected person dies.

- In countries with an advanced HIV infection surveillance case reporting system, a case should be reported when:
  - An HIV patient is diagnosed with clinical stage 3 or 4 or CD4 count < 350 cells/mm^3 (note the need to consider CD4% in children < 18 months)
  - An HIV-infected person dies.

- In countries where AIDS case reporting has been highly complete, AIDS cases may continue to be reported. If AIDS case reporting continues, reporting of HIV clinical stage 3 should also be conducted so that analysis of advanced HIV infection can be performed (this allows comparison with other countries in which only advanced HIV infection reporting occurs. In this situation, an AIDS case should be reporting when:
  - An HIV patient is diagnosed with clinical stage 4 or CD4 count < 200 cells/mm^3 (note the need to consider CD4% in children < five years)
  - A person with AIDS dies.

Summary, continued

- Countries should delineate and communicate the roles and responsibilities of all persons involved with HIV case reporting, including those in the national and sub-national surveillance programmes, healthcare providers, HIV test counsellors and laboratories.

- HIV case reporting programmes must be evaluated periodically to ensure that the information they provide can be used to monitor the HIV epidemic.

- At a minimum, HIV case reporting programmes should measure the completeness, timeliness, and validity of the data they collect.

- Problems identified in the evaluation of the case reporting programmes should be used to improve the programmes.

- All persons who handle information concerning HIV-infected persons must be mindful of the need for patient confidentiality and data security. All HIV programmes must develop detailed methods of ensuring the confidentiality and security of their data.

- Information on persons with HIV infection must be properly protected to prevent breaches of security that can result in disclosure of HIV status. All policies developed and all surveillance activities conducted should take into account the five guiding principles of data security. Countries should work toward achieving the requirements described with regards to policies, training, physical security, data security, and security breaches.

- Analysis and dissemination of HIV surveillance data should be conducted routinely to public health officials at the district, regional, national, and international levels for effective programme planning and evaluation.

- Dissemination of case reporting data can be performed using a variety of formats. Formats should be tailored to the target audience. Examples include:
  - HIV case reporting reports
  - HIV epidemiologic reports
  - Fact sheets
  - Slide sets and presentations.

Summary, continued

- Countries should develop an operations manual that clearly identifies the case reporting practises for the countries. The operations manual should include:
    - The purpose of the HIV case reporting system
    - The reportable events and case definitions
    - All reporting sources
    - The list of variables to be collected and the data collection forms
    - The data transmission and reporting procedures
    - Methods of data management and analyses
    - The data security and confidentiality procedures
    - The roles and responsibilities for programmes and personnel involved in HIV case reporting
    - Methods of training of staff in data collection, management and analyses
    - Methods to disseminate data
    - The surveillance standards and methods of monitoring the quality of the data.

Appendix A, References and Further Reading

CDC Guidelines Working Group. Updated guidelines for evaluating public health surveillance systems. *MMWR*. 2001; 50(RR13): 1-35.

Ghys PD, Diallo MO, Ettiegne-Traore V, Satten GA, Anoma CK, Maurice C, et al. Effect of interventions to control sexually transmitted disease on the incidence of HIV infection in female sex workers. *AIDS*. 2001; 15: 1421-1431.

Global Fund to Fight AIDS, Tuberculosis, and Malaria. *Frontliners, Country Coordinating Mechanisms Newsletter*. Geneva: GFATM. Available at: www.theglobalfund.org/en/about/publications

Johnson AM, Laga M, Levy JA, Phair JP, eds. A year in review. *AIDS* 1998; 12 (suppl A)

Mann J, Tarantola D, eds. *AIDS in the World II*. New York: Oxford University Press; 1996.

UNAIDS. *Prevention of HIV transmission from mother to child: Strategic options*. Geneva: UNAIDS; May 1999.

UNAIDS. *AIDS Epidemic Update: 2004*. Geneva: UNAIDS; December 2004. Available at: www.unaids.org/en/resources/publications/corporate+publications.asp

UNAIDS. *2004 Report on the global AIDS epidemic*. Geneva: UNAIDS; 2004. Available at: www.unaids.org/en/resources/publications/corporate+publications.asp

UNAIDS. *"Three Ones" key principles: coordination of national responses to HIV/AIDS, guiding principles for national authorities and their partners*. Geneva: UNAIDS; 2004. Available at: www.unaids.org/html/pub/una-docs/three-ones_keyprinciples_en_pdf.pdf

United Nations Department of Economic and Social Affairs, Population Division. *World Population Prospects: the 1998 Revision.* New York: United Nations; 1998.

United Nations Department of Economic and Social Affairs. *World Population Profile: the 2000 Revision*. New York: United Nations; 2001.

US Bureau of the Census. *HIV/AIDS in the Developing World, 1999*. Washington: US Government Printing Office; 2000. Report WP/98-2.

US Bureau of the Census. *World Population Profile 2000*. Washington: US Government Printing Office; 2000.

WHO. *A Public Health Approach for Scaling Up Antiretroviral Treatment: A Toolkit for Programme Managers*. Geneva: WHO; October 2003. Available at: www.who.int/3by5/publications/en

WHO. *Human capacity-building plan for scaling up HIV/AIDS treatment*. Geneva: WHO; 2003. Available at: www.who.int/3by5/publications/en

WHO. *Treating 3 Million by 2005: Making it Happen, the WHO Strategy*. Geneva: WHO; 2003. Available at: www.who.int/3by5/publications/en

WHO. *World Health Report, 2003: Shaping the Future*. Geneva: WHO; 2003. Available at: www.who.int/whr/2003/en

WHO. *World Health Report, 2004: Changing History*. Geneva: WHO; 2004. Available at: www.who.int/whr/2004/en

WHO, Department of HIV/AIDS. *Global Health-Sector Strategy for HIV/AIDS, 2003-2007: Providing a Framework for Action*. Geneva: WHO; 2003. Available at: www.who.int/hiv/pub/advocacy/en

WHO/UK Department for International Development. *Provision of antiretroviral therapy in resource-limited settings: a review of the experience up to August 2003*. London: Health Systems Resource Centre; November 2003. Available at: www.who.int/3by5/publications/en

WHO/UNAIDS. *National AIDS programmes: a guide to monitoring and evaluating HIV/AIDS care and support*. Geneva: WHO; 2004. Available at: www.who.int/hiv/pub/epidemiology/en

WHO/UNAIDS. *National Guide to Monitoring and Evaluating Programmes for the Prevention of HIV in Infants and Young Children*. Geneva: WHO; 2004. Available at: www.who.int/hiv/pub/epidemiology/en

WHO/UNAIDS Working Group on Global HIV/AIDS/STI Surveillance. *Guidelines for conducting HIV sentinel serosurveys among pregnant women and other groups*. Geneva: WHO; December 2003. Available at: www.who.int/hiv/pub/epidemiology/en

WHO/UNAIDS Working Group on Global HIV/AIDS/STI Surveillance. *Guidelines for effective use of data from HIV surveillance systems*. Geneva: WHO; 2004. Available at: www.who.int/hiv/pub/epidemiology/en

World Bank. *Education and HIV/AIDS: A Window of Hope*. Washington: World Bank; April 2002.

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.

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

Aetiological: 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.

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 sub-groups. 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 recruitee 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, manipulation, analysing, modelling and display of spatially referenced data for solving planningand 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 informed 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 practises 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 gonnorrhoeae*:** 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.

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, Useful 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 Programme was created in 2002 to support the World Bank's efforts to address the HIV/AIDS pandemic from a cross-sectoral perspective. The programme offers global learning and knowledge sharing on approaches and best practices to addressing HIV/AIDS.
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 coordinates 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

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
www.unaids.org/en/resources/epidemiology.asp

Surveillance information on HIV/AIDS from UNAIDS
www.unaids.org/en/in+focus/topic+areas/surveillance+and+reporting.asp

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

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.
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 Programme (CDC)
The Global AIDS Programme (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

Division of AIDS, STD, and TB Laboratory Research (CDC)
The Division of AIDS, STD, and TB Laboratory Research (DASTLR) was established to centralise CDC's laboratory studies on human immunodeficiency virus (HIV), other retroviruses, other sexually transmitted diseases (STDs), hematologic disorders, and mycobacteria, including Mycobacterium tuberculosis.
www.cdc.gov/ncidod/dastlr

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

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 Behaviour Research of the National Institute of Mental Health
The Division of AIDS and Health and Behaviour Research (DAHBR) supports research and research training to: develop and disseminate behavioural 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.
www.nih.gov/od/oar

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

United States Department of Commerce, U.S. Census Bureau's International Programmes Center

The International Programmes 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.
vhaaidsinfo.cio.med.va.gov/aidsinfo/TOC.htm

Notes

Appendix D, Answers to Warm-Up Questions and Case Studies

Answers are provided in italics for each unit's warm-up questions and case studies.

Answers to the questions within the unit are not included. Questions on tables and figures are designed to stimulate small group discussion among participants in the workshop or class.

Unit 1 Answers

Warm-up questions

1. What are the key differences between HIV sero-prevalence surveillance and HIV case reporting?

   HIV sero-prevalence surveillance measures the prevalence of HIV infection using serological survey methods and does not report on individual patients.

   HIV/AIDS case reporting refers to reporting of individual patients with HIV infection, advanced HIV infection (clinical stages 3 and 4) and AIDS (clinical stage 4).

2. True or false? HIV testing of women coming in for antenatal care is a component of HIV case reporting.

   True *False*

   False. Sero-surveys are conducted in a blinded fashion and cases are not reported.

3. Which of the following is NOT a purpose of advanced HIV infection/AIDS case reporting?

   a. To determine the burden of disease attributable to advanced HIV infection in the region
   b. To assess trends in advanced HIV infection cases
   c. To provide information on the opportunistic infections associated with advanced HIV infection
   d. To measure HIV incidence

Warm-up questions, continued

4. List five surveillance target points in the natural history of HIV infection.

   HIV incidence (that is, the number or rate of new HIV infections)
   HIV prevalence (that is, the number or rate of all persons living with HIV, regardless of how long they have been infected or whether or not they are aware of their infection)
   The incidence of advanced HIV infection (or AIDS)
   The prevalence of advanced HIV infection (or AIDS)
   Deaths from advanced HIV infection (or AIDS)

5. List three reasons for conducting HIV case reporting.

   1. *To capture the leading edge of the epidemic*
   2. *To provide a complete count or estimate of the number of persons with HIV infection, because AIDS case reporting does not include asymptomatic HIV-infected persons*
   3. *To measure the effectiveness of treatment programmes and other interventions.*

Case study

Work on this case study independently.

1. You are the district surveillance officer in the Republic of Melabia in a resource-constrained country. The Republic of Melabia has been estimated to have one of the highest prevalence levels of HIV in the region. The national AIDS control programme is interested in expanding and improving its surveillance programme and the national surveillance officer is conducting site visits to various districts to discuss ways of improving surveillance. During your meeting with the national surveillance officer, you are asked to suggest additional surveillance activities in your district that you believe could be implemented successfully. Describe what these activities would be.

   Ideally, surveillance would be able to measure the following:

   - *HIV incidence (or recently acquired HIV infections)*
   - *HIV prevalence*
   - *Advanced HIV infection/AIDS incidence (clinical stages 3 and 4)*
   - *Advanced HIV infection/AIDS prevalence*
   - *HIV/AIDS mortality.*

   Developing methods of measuring each of these points in HIV disease may be very difficult. At a minimum, reporting of advanced HIV infection (clinical stages 3 and 4) should be developed. This would require the development of a standardised case report form, training surveillance staff to use the form, locating clinics where HIV- infected persons receive care, and working closely with the staff at the clinics to ensure that reporting is done properly and completely.

2. The national surveillance officer has indicated that there is interest in using data collected from HIV and other care programmes for reporting persons with advanced HIV infection. What programmes would you suggest using?

   - *Treatment programmes*
   - *Tuberculosis (TB) programmes (especially those that conduct HIV testing among TB patients)*
   - *Voluntary HIV counseling and testing programmes*
   - *Programmes that provide for pregnant women (prevention of mother-to-child transmission [PMTCT] programmes)*
   - *Vital statistics registries.*

Unit 2 Answers

Warm-up questions

1. True or false? In the revised (2006) adult and paediatric WHO HIV clinical staging systems, there are four clinical stages.

   True False

   True. Both the adult and paediatric clinical staging systems include four stages.

2. True or false? The revised (2006) WHO HIV surveillance case definition includes the same clinical stages for adults and infants.

   True *False*

   False. Adults and infants may have different clinical manifestations of AIDS and serologic evidence of immunosuppression differs between adults and infants. These differences are reflected in the two case definitions.

   For adults the AIDS case definition is:
   A positive HIV antibody test
   -AND EITHER-
   Any clinical stage 3 or stage 4 infection
   -OR-
   Where CD4 testing is available, any clinical stage and CD4 count <350 cells/mm^3

   For infant, the AIDS case definition is:
   The presence of HIV infection
   -AND EITHER-
   Any clinical stage 3 or stage 4 infection
   -OR-
   Where CD4 testing is available, any clinical stage with:
   - *CD4 <20% TLC in children aged 12-59 months*
   - *CD4 <25% total lymphocyte count (TLC) in children under 12 months*
   - *CD4 count <350 cells/mm^3 in children aged 5 years and above.*

Warm-up questions, continued

3. List the two options for HIV reporting that WHO recommends.

   a) HIV case reporting (all clinical stages of HIV infection)
   b) Advanced HIV infection reporting (clinical stages 3 and 4)

4. True or false? The clinical criteria included in the revised (2006) WHO HIV surveillance case definition only include definitive diagnosis of clinical events.

   True *False*

   False. Presumptive criteria may also be used. This is to assist areas in which access to laboratories is limited.

5. List four reasons why HIV clinical staging systems were developed.

   a. provide uniformity for clinical evaluation of persons with HIV infection
   b. as an indicator of prognosis
   c. to guide clinical management of patients
   d. to help study the natural history of HIV infection.

6. True or false? Previous surveillance case definitions in developing countries focused only on stage 4 (AIDS).

   True False

   True. Current recommendations for reporting have been expanded to include reporting of advanced HIV infection (clinical stages 3 and 4) as well as reporting of persons with HIV infection at any stage (clinical stages 1-4).

Case study

1. As an HIV Surveillance officer for the Republic of Melabia, you are charged with standardising the country's HIV/AIDS reporting practises. What processes would you implement to insure that HIV/AIDS reporting is standardised?

   A surveillance case definition should be adopted. Once it is adopted, all district and provincial surveillance officers should identify persons who diagnose and care for HIV-infected persons to inform them of reporting requirements. Any of the following surveillance case definitions may be adopted.

   - *All HIV cases (clinical stages 1-4) should be reported.*
   - *All persons with advanced HIV infection should be reported (clinical stages 3 and 4).*
   - *Additionally, all diagnosed HIV cases that have not been previously reported should be reported, using a standard case definition such as the WHO case definition of HIV for reporting.*

Case study, continued

2. The Republic of Melabia recently began providing free antiretroviral therapy to HIV-infected individuals. The Republic of Melabia uses the WHO antiretroviral treatment recommendations to determine the best time to begin antiretroviral therapy.

   a. CD4 testing is available in the northern district of Melabia. What are the WHO recommendations for adults and adolescents to begin ART?

   If CD4 testing is available, WHO ART recommendations for adults and adolescents call for beginning ART for persons at:

   - *WHO clinical stage 4 (AIDS) regardless of their CD4 count*
   - *WHO clinical stage 3 whose CD4 count is <350 cells/mm^3*
   - *WHO clinical stage 1 or 2 whose CD4 count is ≤200 cells/mm^3*.

   b. CD4 testing is not available in the western district of Melabia. What are the WHO recommendations for adults and adolescents to begin ART?

   If CD4 testing is not available, a total lymphocyte count ≤1200 cells/mm^3 can be used as an indication of immunodeficiency that is severe enough to begin ART. In the absence of CD4 testing, WHO antiretroviral treatment recommendations for adults and adolescents call for beginning ART for persons at:

   - *WHO clinical stage 4 (AIDS) regardless of total lymphocyte count*
   - *WHO clinical stage 3 regardless of total lymphocyte count*
   - *WHO clinical stage 2 with a total* lymphocyte count ≤ 1200 cells/mm^3.

Unit 3 Answers

Warm-up questions

1. Which of the following is NOT a purpose of advanced HIV disease case surveillance?

   a. To assess trends in advanced HIV infection cases
   b. To provide information on the opportunistic infections associated with advanced HIV infection
   c. To measure HIV incidence
   d. To determine the burden of infection attributable to advanced HIV infection in the region

2. Which of the following describes case-based HIV reporting?
   a. All HIV cases reported in a given time period are summarised into a single case report form.
   b. A method to estimate the HIV prevalence among women attending antenatal clinics.
   c. *Case surveillance in which each person diagnosed with HIV has a case report form that includes information specific to that person*.
   d. A system that measures the rate of HIV transmission in selected risk groups.

3. Which of the following variables is not necessary on a HIV case report form?
   a. Clinical stage of HIV at the time of HIV diagnosis
   b. History of sexually transmitted diseases
   c. Name of facility completing the case report form
   d. Mode of transmission (probable risk category)

Warm-up questions, continued

4. List three potential sources for HIV case reports.

   Any of the following:
   - *Laboratories*
   - *Healthcare clinics (health centres)*
   - *ART treatment clinics*
   - *Tuberculosis (TB) clinics*
   - *Voluntary HIV counselling and testing (VCT) sites*
   - *Hospices (for advanced HIV infection)*
   - *Hospitals*
   - *Blood banks*
   - *Prevention of mother-to-child transmission programmes*
   - *Vital statistics registries (for persons diagnosed with HIV only at death, but they can also be used to provide information on the number of and trends in HIV-related deaths).*

5. List three qualities that are necessary to have in a case identifier.
   a. It must be unique to the individual.
   b. It must not change over time.
   c. It must be easy to identify from a clinical record.

Case study

Work on this case study independently.

You are the district surveillance office for an urban district in the Republic of Melabia, a mid-sized country in a resource-constrained country with a concentrated HIV epidemic. In the Republic of Melabia, AIDS case reporting has been conducted for many years, but is incomplete. Melabia has opted to conduct reporting of advanced HIV infection and has implemented a case-based reporting system from health facilities to the sub-national level. From the sub-national level to the national level, cases are reported in aggregate.

1. List the responsibilities of the surveillance officer at the sub-national and national levels.

   Responsibilities of the sub-national HIV surveillance programme.

   - *Solicit, receive, review and file HIV case reports on a timely basis*
   - *Ensure that case reports are filled out completely, accurately and clearly*

Case study, continued

- *Evaluate each case report to determine of it meets the criteria for HIV diagnosis*
- *Evaluate each case report to determine if it contains enough information for determination of clinical stage (that is, documentation of the clinical stage, clinical information that can be used to determine clinical stage or immunological information such as CD4 count/percent)*
- *Ensure that minimum data elements are documented (that is, demographic characteristics, geographic region, risk information, diagnosis date and report date)*
- *Conduct follow-up investigations on cases of epidemiologic importance*
- *Maintain a complete and accurate HIV surveillance database that is secure and has limited access by authorised personnel only*
- *Identify reporting sources, provide an active liaison with physicians and institutions who are reporting cases, abstract medical records to generate case reports when necessary, and supply routine feedback to providers in cases reported.*

Responsibilities of the national HIV surveillance programme:

- *Develop operational guidelines on HIV surveillance*
- *Train and assist surveillance programmes at the sub-national level*
- *Maintain a complete and accurate HIV surveillance database that is secure and has limited access by authorised personnel only*
- *Analyze, interpret and disseminate HIV surveillance data*
- *Critically assess the performance of the surveillance programmes through ongoing monitoring of surveillance activity*
- *Provide overall guidance and training of sub-national surveillance programmes.*

2. Identify the methods used and key issues to consider when un-duplicating cases.

Surveillance programmes that collect patient-level data will likely receive case reports for a given individual more than once. This happens because people may test and/or receive medical care at more than one site. Each time that a person tests HIV-positive, or each time that a patient is seen by a new healthcare provider, the case will be reported. This is because the testing site and provider are not likely to know if the person was previously reported or not.

If the surveillance programmes receive multiple case reports on a single person, the programme should determine if the new report is for a new case or for a previously reported case. This means that

Case study, continued

surveillance programmes need a method to link case reports. If case reports are improperly linked, the following may happen:

- *Over-counting cases if cases were not properly linked (that is, two reports that are submitted for the same person are thought to represent two different people and are counted as two cases rather than one).*
- *Under-counting cases if cases were incorrectly linked (that is, two reports from two different people are thought to be two reports for the same person and are counted as only one case).*

To avoid an inaccurate count of cases, the surveillance programmes at which case-level data are maintained should routinely un-duplicate their cases. The simplest way to do this is to determine the case variables that will be used to un-duplicate the cases. At a minimum, these should include the patient identifier (name or code) and the date of birth. Additional information that is likely to be unique to that individual (for example, address) can also be included as the variables used for un-duplicating cases.

Unit 4 Answers

Warm-up questions

1. List three aspects of a disease under surveillance that an effective case reporting system should monitor.

   -*Completeness*
   -*Timeliness*
   -*Validity (accuracy of the data)*

2. List two methods to measure completeness of case reporting.

   -*Capture-recapture method*
   -*Expanded case-finding*

3. List two methods to report the timeliness of case reporting.

   -*The median time between diagnosis of HIV or AIDS and receipt of the case report form*
   -*The proportion of cases that are received within a specified time period from diagnosis to receipt of report (for example, within three, six or twelve months of diagnosis).*

Case study

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

The Republic of Melabia implemented HIV case surveillance two years ago. Balasu is a large province in the coastal area of Melabia and has the country's major port city. The surveillance officers of Melabia and Basu have met to discuss developing an evaluation of HIV case reporting in Balasu.

a. What should the surveillance officers focus their evaluation on?

Completeness, timeliness, and validity. If performance standards are not met, corrective action (such as additional training) should be undertaken.

b. What criteria should be used to assess the performance of the system?

Performance standards should be developed by the national surveillance programme.

Surveillance programmes should strive to have reporting at least 85% complete.

The following are reasonable standards for timeliness:
- *66% of cases should be reported within six months of diagnosis*
- *85% of cases should be reported within a year of diagnosis.*

c. How should the information obtained in the evaluation be used?

Information obtained from the evaluation should be used to correct discrepancies (when errors are found when conducting an evaluation of validity) and to develop corrective action. The evaluation may identify systematic errors, and correcting these should result in marked improvement in the performance of the surveillance system.

Unit 5 Answers

Warm-up questions

1. True or false? Because of the urgent need to treat and prevent HIV infection, the issue of confidentiality does not need to be addressed.

   True *False*

   People and groups with increased risk for HIV infection are vulnerable to a number of social, legal and physical harms, including domestic violence, loss of employment and even arrest. Maintaining confidentiality is very important.

2. List one reason why case reports from case-based reporting must include patient identification.

   Case reports in case-based surveillance must include patient identification so the programmes have an accurate count of persons with HIV infection and advanced HIV infection. Since some patients receive care at multiple facilities, surveillance programmes need a mechanism that can identify duplicate cases.

3. Fill in the blank with the most appropriate word.

   If _____ about HIV infection is violated, subjects may suffer discrimination and stigmatisation. They may even be subject to criminal charges.
   a. Privacy
   b. Informed consent
   c. Confidentiality
   d. Beneficence

4. True or false? Because healthcare providers are responsible for submitting case reports, they do not need to receive information regarding patient confidentiality or surveillance data from the surveillance officer.

   True *False*

   False. Healthcare providers should be kept informed about the policies regarding patient confidentiality, so they can be certain that information regarding their patients is kept secure. Healthcare providers can reassure their patients that surveillance data are secure and private.

Case study

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

You are the health officer in charge of HIV case reporting for Tehama Province in the Republic of Melabia. A prominent newspaper in this province recently published a list of names of persons in that province who have been diagnosed with HIV. What steps would you take to investigate this situation?

A first step is to meet with each of the surveillance staff who have access to the data and could have provided it to the newspaper. If this does not yield any information, it would be reasonable to speak with other surveillance staff to determine what they know about the incident and to follow up with the newspaper reporter. You should discuss this incident with your supervisors, such as the director in the Ministry of Health.

In the course of your investigation you learn that a newspaper reporter thought that publishing the list of HIV-infected persons would make an interesting article and bring him fame and promotion. To obtain this list, he called the clerk for the prevention of mother-to-child transmission (PMTCT) programme and simply asked for the list. The clerk was not aware of any problem that might arise by providing the reporter with this list. What corrective action would you recommend?

This breach occurred outside of the surveillance programme and, as such, is not directly under your jurisdiction. However, incidents such as these may cause great harm not only to the individuals whose privacy was breached, but to the surveillance programme as well. Healthcare providers, infected and at-risk persons and the community at large are likely to lose confidence in the ability of surveillance programme, as well as the HIV care, treatment, and prevention programmes' ability to protect patient confidentiality.

This breach provides an opportunity for the Ministry of Health and directors of all programmes in which the identity of HIV-infected persons is known to review existing security and confidentiality policies and procedures. If there are no policies and procedures regarding confidentiality and security, they must be developed. These policies must include a data-release policy that specifies what data can be released, the format (including restrictions) that the data need to be in for release, to whom data can be released and the circumstances that permit release. An appropriate response to the reporter's request might be to provide the number of women who used PMTCT.

Case study, continued

As part of the process of developing these policies, you should conduct a review of the country's laws regarding release of public health records (particularly those that pertain to HIV), recommendations from other public health programmes in the country, from the US Centers for Disease Control and Prevention, and from the WHO.

1. *Surveillance staff should be trained on all aspects of security and confidentiality, including the data-release policy. Staff should be made aware of relevant laws and punitive actions for breaches of confidentiality and the impact that such breaches may have on the patients involved. If previous training has taken place, staff should be retrained following this incident and receive annual updates in this training. The incident itself should be discussed frankly.*

2. *Healthcare providers should be informed of the surveillance security and confidentiality policies and procedures so they can be confident that information concerning their patients is protected. Also, you may need to address information to the community in order to reassure the public.*

3. *If the release of information happened despite existing policies that forbade such release, disciplinary action should be imposed on the staff person who released the information.*

Unit 6 Answers

Warm-up questions

1. List three elements of an HIV case reporting report.

   The following elements can be included in surveillance reports:

   1. *Title or Cover Page*
   2. *Executive Summary*
   3. *Introduction*
   4. *Body of the Report* –
   5. *The following should be the minimum information included in the report:*
      a. *Number of cases reported during the period (universal reporting)*
      b. *Incidence and prevalence levels (universal reporting)*
      c. *Age and gender of cases (universal reporting)*
      d. *Transmission mode (sentinel AIDS case surveillance only)*
   6. *Discussion*
   7. *Conclusion.*

2. True or false? The conclusion section of an HIV case reporting annual report is an optional element.
   False. The conclusion should be included and should re-emphasise pertinent findings in the report and integrate these findings into a comprehensive statement on the state of the epidemic.

3. True or false? Changes in reporting practises may result in a false increase or decrease in incidence of advanced HIV infection.
   True. Changes in reporting practises can change the number of cases reported, but this change is an artefact of reporting and not an indication of a true change in the epidemic. For this reason, it is important to pay attention to reporting practises and to investigate any change in the number of reported cases that seems unlikely to be true.

4. When describing the HIV epidemic, why is it preferable to perform analysis based on date of diagnosis versus date of report?
   Using the date of diagnosis provides information on what is truly happening with HIV diagnoses trends. Using the date of report inserts a bias associated with reporting practises, such as reporting delays. The date of report should be used to evaluate timeliness of case reporting.

Warm-up questions, continued

5. True or false? Increases in the number of persons receiving ART can result in a decrease in AIDS incidence of advanced HIV infection (new diagnoses of HIV clinical stage 3 and/or stage 4 infection) regardless of the number of new HIV infections occurring.
   True. ART can delay the clinical progression of HIV infection, which means that HIV-infected persons on ART may not develop AIDS, or if they do, it may take longer than it would have if they were not treated.

6. Which of the following are potential target audiences for HIV case reporting annual reports?
   a. General public
   b. Healthcare workers
   c. Public health officials at the district, provincial, national and international levels
   d. All of the above

Apply what you've learned/ case study

Work on this case study independently.

You work in the surveillance unit of the Republic of Melabia and are responsible for developing the HIV case reporting annual report. You have data from AIDS case reporting nationwide. Use this information to answer the following questions.

1. What data will you include in your report? Describe some of the ways you might display the data according to the source of the data.

   The case definitions used will affect the type of data displayed. If HIV case reporting is conducted, there will be reports of all persons with HIV infection, as well as those with advanced HIV infection. It is possible that AIDS case reporting will continue (if AIDS case reporting was relatively complete prior to the change in the WHO surveillance case definitions in 2006).

   The characteristics of all persons with HIV (that is, after combining all reports of persons with HIV and advanced HIV infection) should be used to show the characteristics of reported cases as well as trends. The data can be stratified by geographic region, age, gender, transmission category (mother-to-child, injection drug use, homosexual/bisexual, blood or blood products, heterosexual). These same analyses can be done for HIV cases and for advanced HIV infection separately. In addition, the report can list the type(s) of opportunistic illnesses and the proportion of persons with advanced HIV infection who are using antiretroviral therapy.

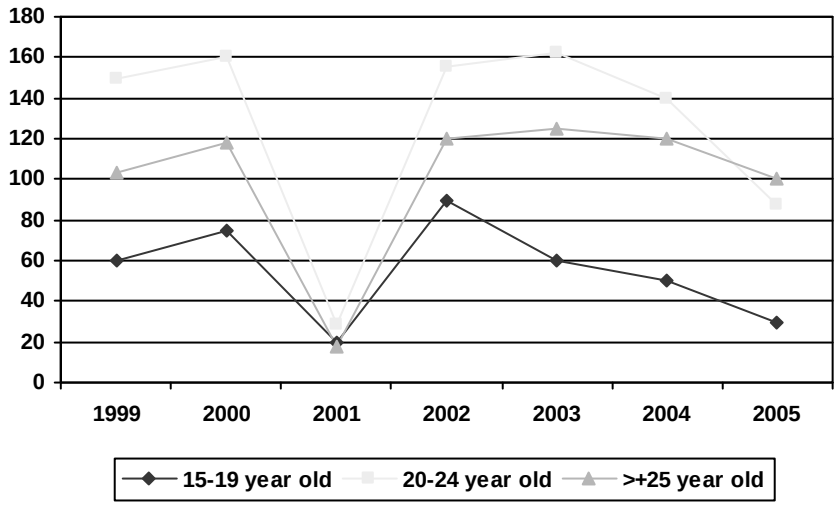
Apply what you've learned/case study, continued

2. The following table shows the advanced HIV infection case incidence rates over seven years. The rates are per 1000 population. Use this information to develop a figure that will represent what you think are the most important aspects of these data.

Table: Incidence of advance HIV infection (per 1000), 1999-2005, Republic of Melabia.

	Age group (years)		
Year	**15-19**	**20-24**	**>=25**
1999	60	150	103
2000	75	160	118
2001	20	29	18
2002	90	155	120
2003	60	162	125
2004	50	140	120
2005	30	88	100

Trends in AIDS incidence by age group by age group, 1999-2005.



Apply what you've learned/case study, continued

3. What would you write in your report about these data? (That is, what is your interpretation of these data)?

   AIDS incidence is lowest in the 15- to-19-year-old group and highest in the oldest group. In 2001, all age groups had markedly lower incidence, suggesting a reporting (or surveillance) artefact. If that year is ignored, it appears that AIDS incidence peaked in 2003 for the two older groups and peaked in 2002 for the 15-to-19-year-olds, and has started to decline in all groups. Depending on when prophylactic and antiretroviral therapies became available, the decline may be due to improved medical care. It is also possible that these declines are due to earlier changes in the HIV epidemic, which may have declined in the earlier years. It is also possible that both of these factors are contributing to these changes.

4. HIV case reporting has only been conducted for one year. In what way will this information affect your report and is this something that will be mentioned in the report. Will you use the data in a report?

   HIV case reporting from only one year will not be able to show trends. Yes, it is worth mentioning. As the surveillance system matures and an increase in reported HIV cases may be the result of improved case reporting as opposed to a growing epidemic.

Unit 7 Answers

Warm-up questions

1. List the key sections of an operational manual.

   An operations manual should describe each of the following:
   - *The purpose of the HIV case reporting system*
   - *The reportable events and case definitions*
   - *All reporting sources*
   - *The list of variables to be collected and the data collection forms*
   - *The data transmission and reporting procedures*
   - *Methods of data management and analyses*
   - *The data security and confidentiality procedures*
   - *The roles and responsibilities for programmes and personnel involved in HIV surveillance*
   - *Methods of training of staff in data collection, management and analyses*
   - *Methods to disseminate data*
   - *The surveillance* s*tandards and methods of monitoring the quality of surveillance data.*

2. Which of the following are elements in an implementation plan to initiate reporting of HIV or advanced HIV infection?
   a. Timeline
   b. Key activities
   c. Responsible person
   d. All of the above

3. True or false? Case definitions for reporting HIV cases should be applicable nationally.

   True False

   True. This allows for summarizing national data and comparing data between geographic areas in the country.

Appendix E. Action Plan for Implementing HIV Case Reporting

Introduction

To begin the process of operationalising HIV case reporting, you will need to:

- Develop country-specific operational guides for HIV/AIDS/STI surveillance
- Develop country-specific implementation work plans
- Organise your country's approach to case reporting.

What is an action plan?

A well-developed action plan allows you to:

- Establish clear goals and objectives
- Present your ideas to achieve consensus among all persons involved
- Establish a realistic budget
- Ensure that the appropriate staff in each facility are trained on surveillance
- Determine activities
- Determine responsible persons
- Establish a timeline for completion of activities.

Instructions

Over the next couple of days, you will be developing a draft action plan and will discuss your action plan with the group. You will use the following resources:

- The Worksheet for Developing an National Plan (Worksheet 1)
- Your country's Action Plan and presentation, 30 minutes.

National Action Plan Worksheet

Instructions

- If you are not doing so already, move now to sit with all the participants from your country.
- As a team, take some time to discuss and fill out the questions on the National Action Plan Worksheet on the next page (facilitator will hand out a clean version of this form). This worksheet will help you determine the activities you need to implement your country surveillance activities. This worksheet will also help us in determining each country's plans and schedules, as we will be providing technical assistance where needed.
- You may not know all the final answers to the questions in the National Action Plan Worksheet. Please fill in the information as completely and accurately as possible.
- If you have questions, facilitators will be available to discuss the worksheet process with you.

Timing

Choose a scribe to keep track of your team's comments on each area of the worksheet.

Spend about 30 minutes on this worksheet.

WORKSHEET FOR DEVELOPING ACTION PLAN (WORKSHEET 1)	
1. What is the name of your country?	
2. Who are the stakeholders who will review your plan? Please provide names, if possible.	MOH: NAP: NGOs: Donors: Other:
3. List key persons who will be working to complete the actions in the Action Plan and their position. 4. Develop a contact list with the name, address, phone number, fax number, e-mail address and role of each person.	▪ Finalise operational procedures manual: ▪ Finalise case-report forms: ▪ Co-ordinate training (logistics, materials): ▪ Instructors:
5. List facilities involved with case reporting.	
6. List staff in need of training at each facility (community health nurses, family welfare educators, data managers, data entry clerks, etc.)	
7. What is the estimated number of people in need of training? (Multiply the number of facilities by the estimated number of persons at each facility in need of training).	

8. What are the best dates to conduct trainings? List conflicting meetings/holidays during which the trainings cannot be held.	
9. Are you aware of any sites where training can be conducted? If yes, please list the name and type of facility and how many people it can accommodate at one time.	
10. Challenges in implementing your action plans can include: ▪ few or no designated trainers ▪ lack of or conflicting policies ▪ lack of necessary materials ▪ scheduling conflicts ▪ lack of money ▪ turnover/attrition of staff List your possible challenges in the column to the right.	
11. List resources that you may be missing.	
12. How can partner organisations help you to implement your plan?	

Discuss your worksheet with a facilitator or go on to the next part of the action-planning process.

Action Plan Development

Now use the information from your national worksheet to develop an action plan. An action plan helps you keep track of all activities and helps you review your progress. We have provided an action plan template for your use.

Instructions

- Remain in your country group.
- Address the key elements listed below.
- Add additional elements if you wish.
- Work together to develop a PowerPoint presentation that goes with your action plan.

Timing

- You will need a calendar for this activity.
- Take 30 minutes for this activity.

Activities

While completing your action plan, please address the key elements listed below (these activities and the general time frame have been added to the action plan template on the next page):

- Identify stakeholders; debrief MOH and NAP (within one month).
- Finalise operational procedures manual (within two months).
- Finalise and pilot case report forms (within two months).
- Conduct training of and labs (go through case report forms, data flow, roles and responsibilities within one month of finalising forms and operational manual).
- Talk with statistics office to obtain death records (within two months).
- Develop national database to make sure it is set up appropriately.
- Train data-entry persons (identify back-up).
- You will want to consider other important areas and may add any of these to your action plan:
    - Determining budget
    - Determining final training dates
    - Selecting the appropriate audience for training
    - Adapting the training curriculum from existing materials

Activities, continued

- Organising the training(s) (facility, audiovisual equipment, supplies)
- Evaluating the training
- Conducting follow-up activities i.e., site visits review case report forms, provide TA.

If you have other details you would like to add, please do so.

Deadlines

Adding deadlines to an action plan helps you establish a realistic schedule. The sequence of events is as follows:

- List your activities.
- Put the activities in the order you (or your team) will do them.
- Add deadlines.

Why establish deadlines?

Having deadlines:

- Provides the overall picture for planning your programme
- Helps keep your project on schedule
- Avoids assigning too many things to one person
- Helps you to meet your programme goals and objectives
- Helps you to remember critical steps so nothing is forgotten in the planning process.

How to choose deadlines

When you are developing due dates, think about:

- The order of activities
- Which activities are dependent on earlier activities
- The overall timeframe for completing the entire activity
- What factors might cause someone to miss a deadline, such as existing schedules, commitments, holidays, vacation schedules or any other sources of delay.

It is important to remember to include the people who will be involved and who will be responsible for meeting the deadlines. If the team is involved in the decision-making process about key issues like deadlines, they will be more likely to meet those deadlines. Everyone involved should receive a copy of the agreed-to action plan.

Action plan template

An action plan template is provided on the next page.

- You may use the template or any other format you desire.
- Use the notes and discussion you had when you filled out your worksheet.
- Change the order of the activities or add additional activities.
- Check your calendar to assign realistic deadlines for each activity. Some 'suggested' timeframes have been added to the activities. You may change those if you wish.

Your presentation

- Develop your presentation as you complete the action plan or after it is done.
- Choose a member of your team to present the action-plan presentation to the group.
- The facilitators have a slide master you may use, or you may use one of your own.

Notes

National Action Plan: (Your Country and Title of the Plan)
(Worksheet 2)

Activities	Responsible Person	Resources Needed	Challenges/ Solutions	Target Due Date	Actual Completion Date
1. Debrief MOH and NAP (within 1 month)					
2. Conduct rapid assessment of current reporting system.					
3. Finalise operational procedures manual (within 2 months)					
4. Finalise case report forms (within 2 months)					
5. Conduct training of providers and labs (within 1 month of finalising forms and operational manual)					
6. Talk with central statistics office to obtain death records (within 2 months)					
7. Develop and check national database to make sure it is set up appropriately					

8. Train data entry persons and back-up staff.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					

Appendix F. Developing a Draft Operational Manual

Approaches to completing your operational manual

Discuss each of the steps in developing the operations manual with your work group and fill in the appropriate sections of the operations manual. Instructions and examples for specific sections of the operations manual are presented in italics. You should delete these instructions and examples after you have completed each of the sections of the operations manual. Note that some parts of the operations manual may require additional investigation to complete. Just leave these sections blank until additional information has been located.

<Your country>

<Add full title of manual>

e.g. 'Draft Operational Manual for HIV Case Reporting'

Add information your stakeholders/reviewers will expect to see on the cover (based on recent documents produced by your Ministry); for example:

Name of your programme
Address or office location
Country map, seal, logos
Date of submission of this draft
Other

Leave this page blank; when you print the manual two-sided, you don't want text on the back of the title or acknowledgments pages

Acknowledgments

Add name, organisation of people who worked on or reviewed the manual.

Follow the lead of other documents developed and released by your Ministry.

Leave this page blank

Table of Contents

Add/generate here. If the Table of Contents is only one page, make the next page blank to make the first page of the manual start on a right-hand page.

Figure 8.2. Make the first page of every section start on a right hand page.

If this is an open book…

Top **This is a left-hand page (even-numbered page); end every section here or leave it blank.** **Bottom**	**Top** **This is a right-hand page (odd-numbered page); start every new section here.** **Bottom**

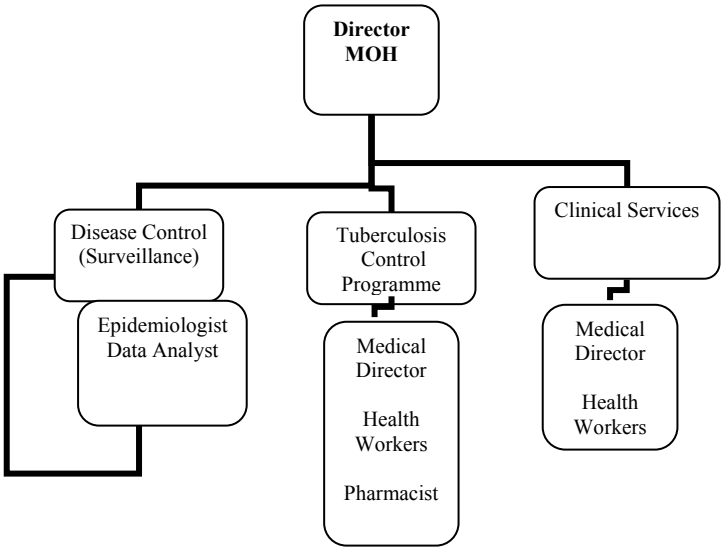
Mission Statement

Use your department's mission statement or a new one based on the SEARO mission statement.

Organisational Chart

This section outlines the organisational structure of the Ministry of Health. It includes the surveillance programme and other programme sections. It's important for surveillance staff to liaise with programme staff, because HIV prevention and control cuts across several programme areas in the Ministry of Health, including TB control, HIV care and treatment, and maternal and child health.

The organisational structure is often easiest to understand if it is presented as a figure.



Description of Geographic Area and Governance

This section details the geographic jurisdiction for which the surveillance programme has responsibility, including both sub-national and national surveillance programmes. The multi-island nations need to outline who has responsibility for soliciting, receiving, reviewing and filing, analysing and disseminating HIV surveillance data for each of the islands. If there are surveillance programmes on these islands, this should also be reflected in the organisational chart.

List of Key Contacts

The section lists all the persons at the surveillance programme(s) who should be contacted at the regional or national level if there are questions about HIV case reporting. Information to be included for each key contact:

- *Name and position of key contact*
- *Areas of expertise*
- *Address*
- *Telephone number*
- *Fax number*
- *Email address.*

List of Reporting Sources

This section details the universe of reporting sources in your geographic area. It is advisable to give each reporting facility a code number that will be recorded on each case reporting form that they submit. Facility/source codes are useful for:

- *Monitoring sources/facilities that are reporting cases versus those that are not*
- *Identifying the sources/facility–written facility/source names can differ on forms submitted by different people; source/facility names can change over time*
- *Identifying the sources/facility on the contact list*
- *Preserving patient confidentiality, especially in areas with small populations where the combination of a patient's name and the facility name may be enough to identify the person definitively.*

Information to be included for each reporting source in this section:

- *Name of clinic/laboratory/provider*
- *Name of primary contact*
- *Name of back-up contact*
- *Address*
- *Telephone number*
- *Fax number*
- *Email address (if available).*

Facility Code	Facility Name	Facility Type	Contact Officer's Position	Name & Address (1) Main Contact (2) Back-Up Contact	Telephone Fax Email Address
			Chief Technologist	Jane Brown-Smith National Public Health Laboratories 1 King Street St. James Republic of Melabia	123-456-6789 (ph) 123-456-7890 (fax) Email: brown-smith@Republic of Melabia.net

Staff Training

This section outlines the training schedule for MOH staff and reporting sources.

MOH staff will need to be trained on the revised reporting system. Persons should be cross-trained to ensure continuity of the programme. There may be special training needs for staff, such as software and database management training. The needs should be reviewed annually and budgeted appropriately.

MOH staff outside of the surveillance programme should also be apprised of the changes in the case reporting system.

Staff at reporting sources should be trained on what constitutes a reportable event, how to report (case report form) and what to report (the variables on the case report form). Pay close attention to ensuring the providers understand all the variables on the case report form. Obtaining risk information is always challenging, developing posters or other instructional material that is easy to review can assist providers to accurately collect this critical piece of information. This should be conducted annually. As you monitor the data submitted from reporting sources, there may be a need to train the staff more often if you find the case reports are incomplete or not filled out correctly.

Additionally, all personnel involved in HIV case reporting (MOH and reporting sources/healthcare providers) must attend an annual confidentiality training (See Unit 7).

Roles and Responsibilities for programmes and personnel involved in HIV case reporting

a. *This section details the roles and responsibilities are for all persons involved with HIV surveillance. This includes roles for reporting sources (such as laboratory personnel and healthcare providers), sub-national surveillance staff (if applicable) and national surveillance staff. The roles and responsibilities should complement the data flow diagram and data reporting procedures.*

b. *Below is a list of the functions that a national surveillance programmes should perform. Identify appropriate staff/positions that will be responsible for each of these functions.*

Functions of the HIV/AIDS case reporting programme:

- *Solicit, receive, review and file HIV case reports on a timely basis*
- *Ensure case reports are filled out completely, accurately and clearly*
- *Evaluate each case report to determine if it meets the HIV case definition and assess clinical staging*
- *Classify HIV cases according to demographic characteristics, geographic region, mode of exposure, and other data collected*
- *Conduct follow-up investigations on cases of epidemiologic importance*
- *maintain a complete and accurate HIV case reporting database that is secure and has limited access by authorised personnel*
- *Identify reporting sources, provide an active liaison with physicians and institutions reporting cases, abstract medical records to generate case reports when necessary, and supply routine feedback to providers in cases reported*
- *Analyse, interpret and disseminate HIV case reporting data*
- *Critically assess the performance of the HIV case reporting programmes through on-going evaluations.*

Description of Hardware/Software

This section describes computers, networks and software that are used in the surveillance system at the national level, sub-national level (if applicable) and reporting source sites (if applicable). Also should list the HIV database administrator and backup administrator for these systems.

Data Security and Confidentiality Procedures

This section details the data security and confidentiality procedures in place for your country. It describes how case information should be reported, transported and stored. It also describes actions taken if there is a breach in confidentiality. A confidentiality oath/agreement should also be in place for all persons working with HIV case data to sign annually. This includes staff at the Ministry Health, laboratories, healthcare providers etc. (See Unit 7). The confidentiality/oath agreement should be included in the Appendix of the Operational Manual (see sample in Unit 7 Annex).

Surveillance Case Definitions for HIV Infection and Reportable Events

This section contains the conditions under surveillance and the surveillance case definitions for the conditions (See Unit 4).

Diagnostic Testing Algorithm

This section details the HIV diagnostic testing algorithm in your country.

Data Reporting Procedures

This section details what persons are required to report, how to report, whom to report to and when to report. This will complement the data flow diagram.

Data Flow Diagram

This section diagrams the data flow (case report forms, laboratory reports) from the laboratories and healthcare providers to the surveillance unit and back (the dissemination feedback loop).

HIV Case Report Form

This section provides instructions on how to complete the case report form, including the variables on the form, definitions of the variables, data sources where this information should be abstracted.

Standards and Monitoring

This section details how the surveillance system will be monitored in your country. There are general monitoring principles that should be adapted to your setting (See Unit 6).

Data Quality

This section contains information on how to monitor data quality adapted for your setting. (Unit 6)

Timeliness

This section contains information on how to monitor timeliness adapted for your setting. (Unit 6)

Data Management and Analysis

This section contains information on who is responsible for entering, maintaining, cleaning and analysing the surveillance data. The section details when each of these activities occurs.

Additional information to consider:

- *Type of statistical software programmes that should be used*
- *Which analyses should be conducted monthly, quarterly and annually*
- *Suppression of small cell sizes in publications (Unit 7 and Unit 8).*

HIV Data Dissemination Plan (Surveillance Reports, Epi Profile, NAP Indicators, etc)

This section details all the external and internal HIV reports and publications the surveillance unit produces, and when these reports/publications should be available. The purpose of collecting HIV surveillance data is to use it for programme planning. The surveillance unit should work with stakeholders, including other programmes in the MOH, national AIDS programmes, and national AIDS committees to determine their data needs, and incorporate them in the reports.

The HIV surveillance data should also be disseminated to the reporting sources and others involved in the surveillance system.

Appendices

- *HIV confidentiality oath/agreement*
- *HIV case report form (including directions on how to fill out the form)*

Appendix G. Operational Manual Checklist

COUNTRY: _____

Manual Section		**Section completed in workshop**	**Source of information**	**Comment**
Mission statement		To be done in-country		
Organisational chart		☐		
Description of geographic area		To be done in-country		
List of reporting sources		☐		
List of key contacts		To be documented in-country		
Staff training		☐		
Responsible officers:	Job descriptions	☐		

	Duties for all staff	☐		
Description of:	hardware	To be done in-country		
	software	☐		
Country/regional legislation and regulations		☐		
Security and confidentiality procedures (less than 5 cases how to present data)		☐		
Diagnostic testing algorithm		To be done in-country		
Data reporting procedures		☐		
Data flow –diagram		☐		
Data analysis (less than 5 cases how to present data)		☐		
Dissemination plan		☐		

(annual reports, epi profile, NAP, indicators, etc.)			
How to fill out case report form – variables, definitions etc	☐		
Standards and monitoring o Data quality o Timeliness	☐		

Notes