

MODULE 2

HIV Clinical Staging and Case Reporting

PARTICIPANT MANUAL



World Health
Organization

Regional Office for South-East Asia

2007

Module 2

HIV Clinical Staging and Case Reporting

Participant Manual

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**World Health
Organization**

Regional Office for South-East Asia

Other HIV surveillance training modules of this series

Module 1 - Overview of the HIV/AIDS epidemic with an introduction to public health surveillance: participant manual

Module 3 - HIV serosurveillance: participant manual

Module 4 - Surveillance for sexually transmitted infections: participant manual

Module 5 - Surveillance of HIV risk behaviours: participant manual

Module 6 - Surveillance of populations at high risk for HIV transmission

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Introduction

How to Study this Module

What you should know before the course

This module contains six units. The information provided is designed for both 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 in which they are presented. In addition, there are several appendices at the end of the module. The last three appendices guide surveillance officers through the process of developing an action plan and operations manual for establishing and maintaining an HIV case-based surveillance system. Throughout the module, small group discussion questions are designed to assist in the development of the action plan and operations manual. The expected outcome from this module is an enhanced understanding of HIV case-based surveillance as well as a completed (or nearly complete) action plan and operations manual

This module can also 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 just be a guess. Answer the questions as best you can.

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

Appendix F, Developing a Draft Operations Manual

Appendix G, Operational Manual Checklist

*Same Appendix A, B and C used for Modules 1, 2, 3 and 4.

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 reporting AIDS cases and the purpose and importance of HIV case reporting. It explains:

- the history of HIV and AIDS case surveillance and how changes in HIV treatment have affected surveillance recommendations and practices
- the natural history of HIV disease and the points in the course of the disease that are important to monitor for surveillance purposes
- the purpose of reporting HIV cases
- how other types of HIV programmes can provide data for surveillance purposes.

Warm-up questions

1. What are the key differences between HIV sero-surveillance and HIV case reporting?
2. True or false? HIV testing of women coming in for antenatal care is a component of HIV case reporting.
True False
3. Which of the following is NOT a purpose of advanced HIV infection (disease) case reporting?
 - a. To determine the burden of disease attributable to advanced HIV disease in the region
 - b. To assess trends in advanced HIV disease cases
 - c. To provide information on the opportunistic infections associated with advanced HIV disease
 - d. To measure HIV incidence.
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 surveillance and how changes in HIV treatments have affected surveillance recommendations and practices
- 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-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 AIDS epidemic in 1981, many industrialized countries moved toward reporting AIDS cases, either by name or anonymously. In the past, in developed countries, AIDS case reporting, combined with active case-finding, allowed AIDS notification and AIDS-specific mortality to be monitored. As the epidemic evolved (and given the limitation of AIDS case surveillance in assessing current transmission patterns), the focus of surveillance shifted from AIDS as an end-stage disease to HIV infection. This led to many developed countries making HIV infection reportable. Today, many of the developed countries are reporting HIV infection cases confidentially, either by name or by codes. It is generally agreed in developed countries that HIV cases should be reported, but there is still a debate regarding whether HIV cases should be reported confidentially by name or by code.

The situation is quite different in developing countries. Although AIDS case reporting was introduced in most countries in the 1980s and early 1990s (depending on the detection of the first case in the country), reporting of AIDS cases for surveillance has occurred primarily via systems that rely on passively receiving reports. This has generated incomplete and inaccurate data, because of under diagnosis, under notification and delay, hampering the utility of case reporting. The HIV case reporting system has not been introduced in most developing countries.

In South-East Asia, Thailand was the first country to introduce AIDS case reporting in 1984. In Thailand, the completeness of AIDS case reporting is estimated about 80%. Reported AIDS cases have, so far, provided useful information on trends in the incidence of the disease.

In all other South-East Asian countries, under-reporting of AIDS cases, exacerbated by a weak health infrastructure and lack of diagnostic capacity, has produced unreliable data of little use for monitoring trends or planning HIV prevention, care and treatment services. It has been difficult to estimate the level of under reporting except for some countries. Thus, most countries have relied on HIV sero-surveillance in selected populations at sentinel sites to monitor HIV trends. Additionally, the second generation surveillance system, which integrates AIDS case reporting, HIV sero-surveillance, STI surveillance and risk-behaviour surveillance, has facilitated the production of estimated numbers of people living with HIV, using epidemiological models.

Impact of ART on AIDS case reporting

The increased availability of timely and appropriate ART (Antiretroviral therapy) delivery may prevent or delay the development of AIDS as it was previously defined and reverse symptoms and CD4 count levels. The advances of ART mean, therefore, that public health surveillance of AIDS 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 populations needing prevention and treatment services. Therefore, the scope of surveillance must move from AIDS case reporting to reporting a wider spectrum of HIV infection.

HIV case reporting refers to the methods used to capture individual-level information on persons with HIV infection. This means that each person with HIV infection is reported using a single case report form containing information that pertains only to that person.

This type of reporting occurs at the facility level and is forwarded to the local level as individual case reports. The local-level surveillance officers aggregate the data and forward that to the national surveillance programme.

In this module, we present updated methods for reporting of persons with HIV disease. Specifically, this module provides guidance for South-East Asian countries to replace the reporting of AIDS cases (clinical stage 4) with the reporting of advanced HIV infection (disease), reporting that corresponds with the new clinical stages 3 and 4. In addition, countries may also conduct HIV infection reporting. Because HIV infection reporting (all clinical stages) identifies information on HIV-infected persons at any stage of HIV disease, it also includes persons with advanced HIV disease (which includes persons with AIDS).

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 (all clinical stages)' and to the reporting of advanced HIV (clinical stages 3 and 4 only) as 'advanced HIV (infection or disease) reporting.' Advanced HIV reporting includes AIDS.

The Relationship Between the Natural History of HIV and Surveillance

Natural history of HIV and target points for surveillance

HIV infection results in a chronic condition. Shortly after becoming infected, an individual may experience signs and symptoms of this initial infection (called *primary HIV infection*). These signs and symptoms may include fever, muscle aches and swollen glands. Often these symptoms go unnoticed by the infected person, and some people do not experience any symptoms or signs of primary HIV disease.

Following primary infection, most HIV-infected persons are without symptoms or have only mild symptoms for several years. Over time, the immune systems of infected persons weaken, resulting in the development of HIV-related illnesses. These illnesses become increasingly severe as the degree of immune weakness progresses. The clinical assessment and classification of *clinical stages* provides a standardized approach to describing the points in the course of the disease that correspond to increasing degrees of immune deficiency. Without specific treatment, HIV-infected persons deteriorate clinically over time. The median time of HIV progression to death, in absence of ART, has been estimated to be 11 years, although there is some evidence that serotype E may have faster progression. The end-stage of disease is called AIDS. AIDS is defined by the presence of a specific group of illnesses (called *opportunistic illnesses*) that are associated with late-stage HIV disease, but they are generally uncommon in persons whose immune systems are functioning normally.

- Prior to *antiretroviral therapy (ART)* (that is, drugs used to fight infection by retroviruses), the average time from HIV infection to onset of clinical AIDS in North American patients was 11 years and from AIDS to death was about 2.7 years.
- There is no significant difference between HIV infection and onset of AIDS in developing countries and developed countries.

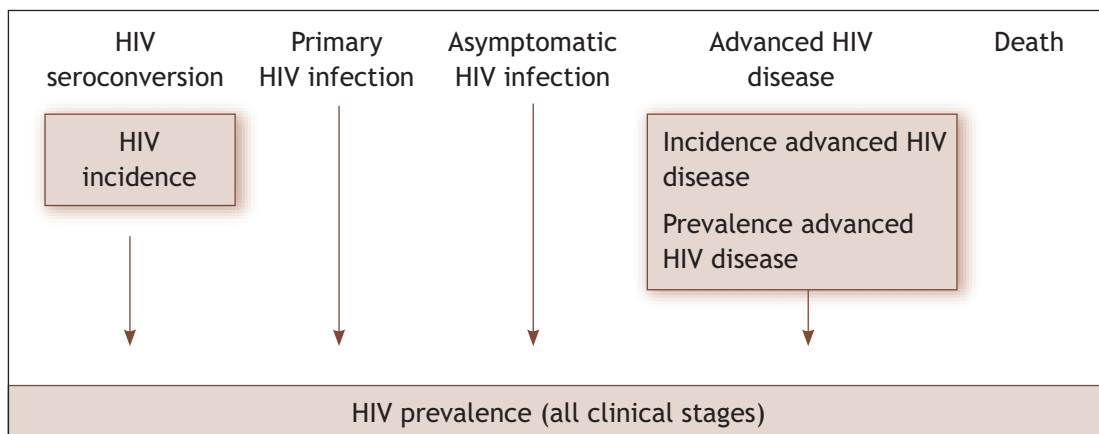
The advent of effective ART has considerably reduced the time and rate of progression to AIDS and death from AIDS in areas where these drugs are available. It has also been associated with the development of fewer HIV opportunistic infections.

In order to fully understand the HIV epidemic, several key stages in the development of the disease should be counted. These are depicted in figure 1.1 and include:

- 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 disease
- The prevalence of advanced HIV disease
- Deaths from advanced HIV disease.

Figure 1.1

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



Measuring each of these points in the course of HIV disease provides for a complete *HIV surveillance* system and can be used for determining the need for prevention or medical interventions, and as measures of the success of such programmes. However, in resource-constrained settings, it is often difficult to include all of these target points in the surveillance system. In areas where not all of these points can be counted, efforts should be made to obtain information on as many points as possible. HIV case surveillance can provide information on some of these points.

Measurement of new HIV infections

In order to know the direction of the HIV epidemic, it is important to have information on the HIV incidence, or the number or rate of new HIV infections occurring. Effective HIV prevention programmes should result in a decrease in the number of new infections. Although only a few methods exist for measuring new HIV infections and these methods are far from perfect, there are some tests that can be done to estimate the number and rate of new HIV infections. There are several assays that have been developed to identify new HIV infections. However, some work for certain sub types only, while others have proven to overestimate results of HIV incidence.

Another, more widely used method of measuring the rate of new HIV infections has been to monitor the trends in HIV prevalence among the youngest group (15-19 or 15-24 years) of women attending antenatal clinics. This use of *sentinel HIV sero-surveillance* has been the most common way of estimating HIV incidence in developing countries. Though difficult to measure accurately, this method of estimating the number and rate of new HIV infections is valuable and is likely to become an increasingly important component of HIV surveillance. Moreover, HIV prevalence among 15-24 years old is an indicator for the Millennium Development Goals.

Measurement of HIV prevalence

HIV prevalence is the number of persons living with HIV infection. This includes persons with any stage of HIV disease (newly acquired infections, long-standing asymptomatic infections and late-stage disease, including AIDS). Prevalence includes HIV-infected persons who may not be aware of their infection. Prevalence does not include HIV-infected persons who have died. It is difficult to have a complete and accurate count of all persons infected with HIV. As a result, prevalence is often estimated. HIV prevalence estimates can be done using a variety of data sources, including HIV/AIDS case reports and results from surveys and special studies. In developing countries, sentinel sero-surveys of women attending antenatal clinics have been the most frequently used data for prevalence estimates.

Measurement of advanced HIV disease

Obtaining an accurate and complete count of persons with advanced HIV disease is important as a way to anticipate need for medical care and other support services, as well as to obtain a measure of the success of treatment of HIV infection at earlier stages of the disease. In countries where ART is now increasingly available, the number of persons with advanced HIV disease and mortality should decline, even in the face of ongoing HIV transmission. You can count the number of persons with advanced HIV disease through case reporting. Persons with advanced HIV disease are symptomatic and, if they seek care, can be reported from healthcare facilities.

Measurement of HIV/AIDS mortality

Deaths from advanced HIV disease/AIDS have dropped dramatically in countries where antiretroviral treatment has been widely used. Thus, tracking deaths from advanced HIV disease 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 are important measures to understand the magnitude of the problem. However, in order to accurately count and track trends in HIV-related deaths, countries must have well-functioning vital statistics registries. In developing countries, reporting of AIDS deaths is highly incomplete due to the stigma associated with the disease and very weak vital reporting systems. The use of alternative methods for mortality surveillance needs to be examined in countries where vital statistics registries are not in place or are incomplete.

Purpose of HIV Case Surveillance

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 disease;
- determine the characteristics and risk factors (transmission categories) of persons with HIV infection;
- determine the burden of disease attributable to HIV in the region;
- know the distribution by age, sex and geographic location;
- assess trends in HIV incidence and prevalence, if reporting is nearly complete (>80%);
- use data from HIV surveillance for the purposes of:
 - advocacy
 - resource mobilization
 - programme planning
 - targeting
 - monitoring and evaluation.

Surveillance terminology

Surveillance is a broadly used term that refers to many types of activities employed in the systematic collection of information on the state of the HIV epidemic. As previously mentioned, South-East Asian countries have relied primarily on blinded HIV seroprevalence 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

| | |
|--|---|
| <i>HIV sero-prevalence or HIV sero-surveillance</i> (means the same thing) | <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • reports all persons newly diagnosed with HIV, regardless of clinical stage or immunologic status. |
| Advanced HIV infection (disease) reporting | <ul style="list-style-type: none"> • reports the number of patients with clinical stages 3 and 4 or CD4 count <350. |
| AIDS case reporting | <ul style="list-style-type: none"> • reports the number of patients with clinical stage 4 or CD4 count <200. |

Discussing the table

Looking at Table 1.1, answer the following questions:

- How are HIV sero-surveys and HIV case reporting different?
- Are serological survey methods used in HIV case reporting?

The need for replacing AIDS case reporting

ART has dramatically altered the natural history of HIV disease. ART delays progression from early HIV disease to the advanced stages of HIV, including AIDS, and reduces HIV-related mortality. In fact, one measure of the success of ART programmes is an increase in HIV prevalence and a decrease in AIDS incidence and HIV/AIDS-related deaths.

The current WHO recommendation is to provide ART to all persons with clinical stage 4, and to consider providing ART to persons with clinical stage 3. In addition, ART should be offered to persons with earlier stages of disease if CD4 counts are low (<200). These changes in treatment have important implications for HIV advanced disease reporting. Providing ART to persons prior to the development of AIDS will result in fewer persons progressing to AIDS. Consequently, AIDS case reporting can no longer 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 of persons with advanced HIV infection (disease)
- reporting of persons with all clinical stages of HIV (this requires including information on the clinical stage of HIV at diagnosis).

As HIV testing in South-East Asian countries becomes more widespread, it provides the opportunity to monitor HIV infections that may occur prior to the development of AIDS. In other words, asymptomatic HIV-infected persons can also be counted. Expansion of AIDS case surveillance to include persons with HIV infection who have not yet developed late-stage HIV disease (advanced HIV disease/AIDS) may provide a more complete picture of the epidemic.

Incorporating Data Collected from HIV Programmes into Case Reporting

Programmes with information for reporting

Though HIV case reporting is a newly recommended surveillance practice, AIDS case reporting has been recommended for many years. In South-East Asia, AIDS case reporting has occurred primarily through passive reporting by healthcare providers. An additional method of collecting case reports is for surveillance officers and staff to work closely with programmes that provide care to persons with HIV infection. In this way, surveillance officers can assist more directly with the reporting process and improve the completeness of case reporting. Programmes that are likely to be good sources of HIV cases include:

- HIV care and antiretroviral treatment 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 identify persons who die with HIV disease).

How to use programme data for case surveillance

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

- programme data can be analysed and used to supplement HIV case reporting data and data collected from HIV sentinel sero-surveillance
- programme data can be used to identify HIV-infected persons who should be reported to the surveillance programme.

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

- programmes collect and retain patient-level information
- methods are in place or developed to record cases that have been reported
- programme staff are trained on how to report cases and provided with case report forms
- surveillance officers provide guidance and technical assistance in completing case report forms.

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

- meet programme managers to discuss the importance of case surveillance, provide case report forms and training
- adequately assure the security and confidentiality of case data (particularly if cases are reported using patient names)
- provide regular feedback to the healthcare workers/providers regarding the results from case surveillance.

In order to ensure efficient use of time and resources, those programmes that serve the largest number of HIV-infected persons should be targeted for assistance with case reporting.

Unit 1 Exercises

Warm-up review

Take a few minutes now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

Small group discussion

Get into small groups to discuss the following 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.

Table 1.2

HIV case reporting in your country

| Surveillance activities | Is this 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 case reporting | Yes / No | | | |
| Case reporting for advanced HIV infection [disease] | Yes / No | | | |
| Case surveillance for AIDS | Yes / No | | | |
| Case surveillance of AIDS deaths | Yes / No | | | |
| TB surveillance: case reporting of diagnosed TB cases | Yes / No | | | |
| Surveillance of death registration | Yes / No | | | |

If you answered 'yes' to more than one of the above questions on case reporting for HIV or AIDS, please answer the following:

Is the surveillance system able to link case reports on one individual reported multiple times or from multiple sources? If so, explain how this is done and at what level (district, national) the linking occurs.

Table 1.3

HIV sero-prevalence surveys in your country

| Surveillance activities | 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 disseminated, and to whom? |
|----------------------------------|-----------------------------------|--------------------|--|--|---|
| Antenatal clinic attendees (ANC) | Yes / No | | | | |
| Prisoners | Yes / No | | | | |
| Men who have sex with men | Yes / No | | | | |
| Injection drug users | Yes / No | | | | |
| Commercial sex workers | Yes / No | | | | |
| Other populations Specify: | Yes / No | | | | |

Please indicate in the table 1.3 which HIV sero-prevalence surveys are being conducted or have been conducted in your country.

Please indicate in the table 1.4 which of the following prevention/control programmes are conducted in your country.

Table 1.4

Prevention and control programmes in your country

| Surveillance activities | Does this programme exist in your country? | When did the programme begin? (Year) | Who monitors the programme? | How often are indicators reported? | How are data disseminated, and to whom? |
|--|--|--------------------------------------|-----------------------------|------------------------------------|---|
| Prevention of mother-to-child transmission (PMTCT) | Yes / No | | | | |
| HIV care | Yes / No | | | | |
| HIV treatment | Yes / No | | | | |
| Tuberculosis control and prevention | Yes / No | | | | |
| Orphans and vulnerable children | Yes / No | | | | |
| STI prevention and control Specify: | Yes / No | | | | |
| Other populations Specify: | Yes / No | | | | |

Additional questions regarding TB control programmes:

- i. Are TB patients routinely tested for HIV?
- ii. If so, describe the mechanism used to report these cases to the surveillance unit.

Please indicate in table 1.5 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/care survey | Yes / No | | | | |
| Service availability mapping survey | Yes / No | | | | |
| 'PLACE' survey | Yes / No | | | | |
| Other: (Specify) | Yes / No | | | | |
| Mortality surveys looking at HIV-related deaths | Yes / No | | | | |
| Behavioural surveys (with or without biomarkers, please indicate) | Yes / No | | | | |
| Population-based surveys (DHS, AIS) | Yes / No | | | | |

Acronyms:

- AIS - AIDS Indicator Survey
- DHS - Demographic Health Survey
- PLACE - Priorities for Local AIDS Control Efforts
- TB - Tuberculosis

Apply what you've learned/case study

Work on this case study independently.

1. You are the district surveillance officer for Serosia in South-East Asia. Serosia 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.

2. The national surveillance officer has indicated that there is an interest in using data collected from HIV and other care programmes for reporting of persons with advanced HIV disease. Review the worksheet you completed in your small group discussion and use this to determine the necessary steps to expand current surveillance activities. List these activities.

Unit 1 Summary

- For a full understanding of the HIV epidemic, you should monitor five key stages in the course of HIV disease: HIV incidence, HIV prevalence, incidence of advanced HIV disease, prevalence of advanced HIV disease, and deaths due to advanced HIV infection.
- HIV case reporting is conducted to obtain accurate and timely information on the burden of disease. This is necessary in order 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 infection (clinical stages 3 and 4). Countries may opt to report all persons with HIV infection, regardless of their clinical stage.
- Information collected as part of HIV-related programmes (tuberculosis control programmes, HIV care and antiretroviral treatment monitoring programmes, etc.) can be a source of identifying and reporting HIV-infected persons.

Notes

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 the following:

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

True False

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

5. 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 disease, and AIDS

- list at least one advantage and one disadvantage of HIV case surveillance, advanced HIV case surveillance, and AIDS case surveillance
- 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 recognizing 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 disease among HIV sero-positive and HIV-exposed children |

History of Clinical Staging and HIV/AIDS Case Surveillance Definitions

Previous clinical staging criteria

Clinical staging criteria for HIV and AIDS were developed to:

- provide uniformity for clinical evaluation of persons with HIV infection
- provide an indicator of prognosis
- guide clinical management of patients
- help study the natural history of HIV infection.

The Walter Reed staging classification system was developed in 1986 for use among United States military personnel. This staging system included both clinical and laboratory manifestations of HIV disease. The inclusion of a laboratory component and the list of AIDS opportunistic illness in the Walter Reed staging classification system worked well in developed countries, but was not suitable for developing countries.

To provide a clinical staging system that could be used worldwide, the WHO convened a panel of experts in 1989 and developed the 1990 staging system for adults. The 1990 staging system was based primarily on clinical criteria. A paediatric staging system was adopted in 2003.

Previous surveillance case definitions

There have been several AIDS surveillance case definitions used throughout the world. The initial WHO AIDS surveillance case definition (Bangui) was developed in 1985 and formalized in 1986 for developing countries. The definition 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. Each of these definitions was modified as laboratory testing became available and as additional information regarding the clinical manifestations of late-stage HIV disease became known. In addition

to modifications of the AIDS surveillance definitions, some regions developed surveillance case definitions for HIV disease not yet meeting the criteria for AIDS. The WHO had not previously developed a surveillance case definition for HIV disease alone (that is, for persons who are HIV-infected, but do not meet the surveillance case definition of AIDS).

The 2006 HIV Clinical Staging System and Surveillance Case Definitions

Updated clinical staging system

The increased availability of ART has resulted in the need for an updated HIV/AIDS clinical staging system that:

- harmonizes the 2002 three-stage paediatric staging system with the 1990 four-stage adult system
- includes stages at which prophylactic and antiretroviral therapy should be considered and recommended
- updates clinical conditions
- harmonizes the clinical staging and surveillance case definitions
- includes immunologic criteria for clinical staging and surveillance case definitions.

Anticipating greater availability of ART, WHO and CDC convened a panel of experts in 2004 to develop updated clinical staging systems for adults and children. Regional consultations were held in all WHO regions in 2004 and 2005. The clinical staging criteria and surveillance case definitions were adopted in 2006. The revisions were intended to identify the treatable nature of HIV infection in the presence of ART. Clinical staging should be done at the time of 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 diagnoses that can be made in the absence of sophisticated laboratory tests
- definitive clinical criteria that require confirmatory laboratory tests.

With expansion of laboratory capacity in developing countries, including those in South-East Asia, the WHO developed an immunological classification system for HIV infection. These criteria are based upon the known decline in CD4 cells with the progression of HIV disease. Listed below are the age-related values and associated degree of immunodeficiency. Note that for children under five years of age, the CD4 percent rather than absolute count should be used.

Table 2.3.

WHO-proposed immunological 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% |

Table 2.4.

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

| |
|--|
| Clinical Stage 1 |
| Asymptomatic Persistent generalized 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) ³ 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) |

¹ Assessment of body weight in a pregnant woman needs to 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 can also be included in regional classifications (for example, American trypanosomiasis reactivation in Americas region).

| Clinical Stage 4 |
|---|
| HIV wasting syndrome |
| Pneumocystis pneumonia |
| Recurrent severe bacterial pneumonia |
| Chronic herpes simplex infection (orolabial, genital or ano-rectal 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 |

Table 2.5.

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

| Clinical Stage 1 |
|---|
| Asymptomatic |
| Persistent generalized 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 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 bronchiectasis
Unexplained anaemia (< 8g/dl), neutropenia (<0.5X 10⁹/L³) or chronic thrombocytopenia (< 50 x 10⁹/L³)

Clinical Stage 4

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 expanded 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 disease (including AIDS).

Table 2.6.

WHO case definition for HIV infection

| |
|---|
| Adults and adolescents and children >18 months |
| HIV infection is diagnosed basing on: <ul style="list-style-type: none"> • a positive HIV antibody testing (rapid or laboratory-based enzyme immunoassay). This is usually confirmed using a second HIV antibody test (rapid or laboratory-based enzyme immunoassay) relying on different antigens or different operating characteristics than the initial test And / or <ul style="list-style-type: none"> • 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 basing on: <ul style="list-style-type: none"> • 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. |

Table 2.7

Criteria for diagnosis of advanced HIV disease (including AIDS) for reporting for 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 4 condition |
| Immunological criteria for diagnosing advanced HIV disease in adults and children five years or older with confirmed HIV infection |
| CD4 count less than 350 per 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 immunological criteria in adults and children with confirmed HIV infection and ≥ 5 years of age; first-ever documented % CD4 count < 200 per mm³ 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 of primary HIV infection

There is no standard case definition of primary HIV infection. However, primary HIV infection is of great importance, both because it represents recently acquired infection and because persons with primary HIV infection are highly contagious. The reporting of persons with primary HIV infection is one method of capturing the leading edge of the epidemic. Currently, in settings where persons with primary HIV infection are not likely to seek medical care (as is likely in much of South-East Asia), reporting of persons with primary HIV infection is probably of limited value and is not recommended. Rather, patients who may be diagnosed with primary HIV infection 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
- meningoencephalitis
- lymphopaenia (including low CD4)
- opportunistic infections.

These clinical conditions should not be confused with 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 surveillance recommendations

In the light of the case definition revisions, WHO recommends that countries standardize their surveillance practices and case definitions to include the reporting of HIV-infected persons not previously reported. A case of HIV disease includes all stages of HIV infection (clinical stages 1-4).

Countries may choose to report all cases diagnosed with HIV (clinical stages 1-4). If this option is implemented, countries will report persons at any clinical stage of infection/disease, as well as reporting all persons with advanced HIV infection/disease (clinical stages 3 and 4). This means that persons who are initially diagnosed with HIV at stages 1 or 2 and later fall into advanced HIV infection/disease 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/disease and will only be reported once.

However, if countries are not able to report all cases of HIV, they may choose to report cases diagnosed with advanced HIV infection/disease. If countries are reporting advanced HIV infection/disease, AIDS case reporting is not required.

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

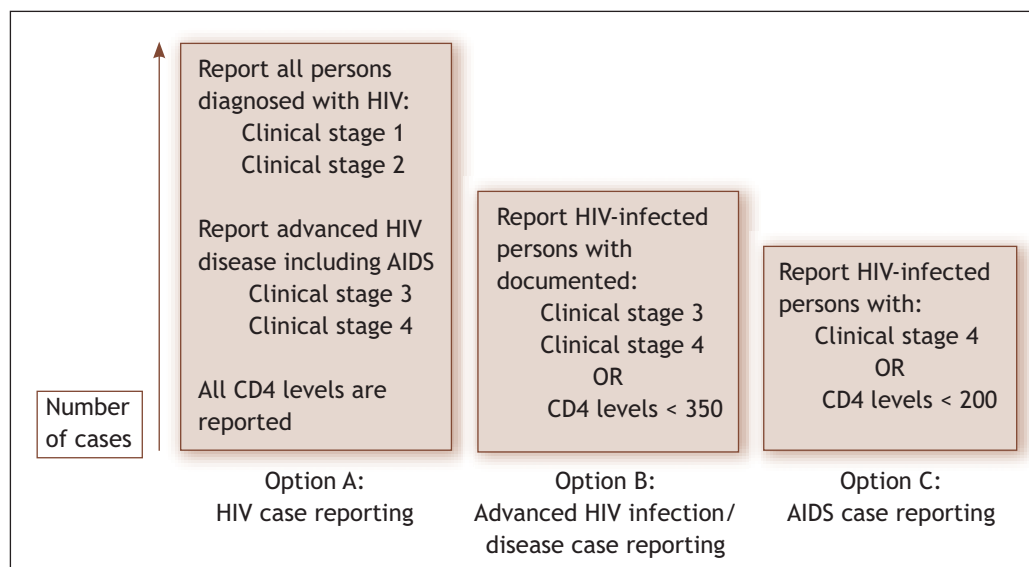
Advantages and disadvantages of case reporting options

WHO recommendations on case reporting:

1. Countries should replace AIDS case reporting (option C) with reporting of HIV advanced infection/disease (option B). While it is no longer necessary for a country to report AIDS cases if advanced HIV infection/disease case reporting has begun, countries may choose to continue to report AIDS cases for monitoring trends, particularly if the completeness of reporting of AIDS cases was 80% or more.
2. Option A is the ultimate goal and as a long-term strategy, countries should plan to report all HIV infection cases to obtain a more complete picture of the epidemic. It is recommended that countries implement pilot projects to gain experience in

Figure 2.1

Levels of case reporting



implementing a system of reporting all HIV infection/disease cases. Based on these experiences, national scale HIV case reporting system can be planned.

Selecting the type of case surveillance to conduct should be based on a thorough understanding of the advantages and disadvantages of the various surveillance options, as well as the availability of resources to collect, analyse and interpret surveillance data. Regardless of the option selected, it is recommended that surveillance programmes conduct surveillance activities in a manner that provides for complete, timely and consistent reporting that can accommodate changes.

Table 2.8

HIV case surveillance, all clinical stages (1-4)

| Advantages |
|--|
| <ul style="list-style-type: none"> • 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, HIV case reporting can estimate the level of and trends in HIV prevalence and provide information on characteristics of persons more recently infected • provides a more complete picture of the HIV-infected population • includes reporting of persons with advanced HIV disease. |
| Disadvantages |
| <ul style="list-style-type: none"> • cannot determine the rate of newly acquired infections (incidence) • requires frequent and widespread HIV testing among at-risk persons if data are to provide complete count of HIV-infected persons • in countries with mature epidemics, the initial HIV case-reporting activities will result in a substantial number of persons reported with more advanced HIV disease (clinical stages 3 and 4) • if clinical stages are not included in the HIV case reporting, it will be difficult to compare trends in countries in which AIDS case reporting has been functioning well. |

Table 2.9

Advanced HIV infection case surveillance (includes AIDS) (clinical stages 3 and 4)

| Advantages |
|---|
| <ul style="list-style-type: none"> • is likely to provide complete picture of persons with advanced HIV disease, because they seek care for symptoms, 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, but not yet receiving, ART (assists with programme planning efforts) • allows for more complete reporting, since persons receiving ART are in care settings where surveillance officers can assist with case reporting and can train clinic staff to report cases • countries with mature epidemics and decreasing incidence, are likely to include a large proportion of the total number of cases. |
| Disadvantages |
| <ul style="list-style-type: none"> • 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, this cannot provide information on populations newly infected and diagnosed. |

Table 2.10

AIDS case surveillance (clinical stage 4)

| Advantages |
|--|
| <ul style="list-style-type: none"> • allows for monitoring trends in countries where AIDS case reporting has been complete (at least 70% complete for at least the previous five years) • 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 |
| <ul style="list-style-type: none"> • does not provide adequate information for planning for ART and prevention services • provides an incomplete picture of the number of persons diagnosed with HIV disease. |

Linking HIV Clinical Staging, ART Use and HIV Surveillance

Initiating ART

The best time to begin antiretroviral treatment can be determined using clinical staging and CD4 counts/percents. Current WHO treatment recommendations are divided into recommendations for use in areas in which CD4 testing is available, and areas in which such testing is not available.

WHO has specified the optimal times to initiate ART based upon clinical staging and CD4 count when available.

Table 2.11

WHO SEARO recommendations for initiating ART based on clinical staging and CD4 testing⁴

| Clinical stage | CD4 available | CD4 not available |
|----------------|-------------------|-------------------|
| I | Treat if CD4 <200 | Do not treat |
| II | Treat if CD4 <200 | Do not treat |
| III | Treat if CD4 <350 | Treat |
| IV | Treat | Treat |

ART is recommended for children and infants with clinical stages 3 and 4, regardless of the 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.

As described above, clinical staging is:

- used to determine the best time to begin treatment for HIV disease
- a key component of the surveillance case definitions.

The link between these is useful for surveillance purposes. HIV surveillance is generally conducted by healthcare providers, usually from hospitals and clinics that provide ART. Thus, patients who are receiving care at these facilities will have their clinical stage determined. This is particularly useful in those countries in which reporting of advanced HIV disease or AIDS is done. In those settings, persons on ART are likely to include those who should be reported to the public health authorities. In addition, ART programmes may use monitoring programmes that can easily identify persons who should be reported to the health authorities. These monitoring systems usually include all the information necessary to report these cases. The new clinical staging system, HIV treatment recommendations, and surveillance case definition and recommendations for reporting should facilitate optimal care of HIV-infected persons and improve reporting.

⁴ WHO SEARO adult and pediatric treatment guidelines

Annex 2.1

Presumptive and definitive criteria for recognizing 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 generalized lymphadenopathy (PGL). | Painless enlarged lymph nodes > 1 cm, in two or more non-contiguous sites (excluding inguinal), in absence of known cause & persisting for \geq 3 months. | Histology. |
| Clinical Stage 2 | | |
| Moderate unexplained weight loss (< 10% of body weight). | Reported unexplained weight loss. In pregnancy, failure to gain weight. | Documented weight loss < 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, and usually respond 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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE 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 (\geq than 10% of body weight). | Reported unexplained 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 malaria areas. | Documented fever $>$ 37.6 °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. |
| 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 lateral borders of the tongue, which do not scrape off. | Clinical diagnosis. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|--|--|--|
| Pulmonary tuberculosis (current). | <p>Chronic symptoms: (lasting ≥ 2-3 weeks) cough, haemoptysis, shortness of breath, chest pain, weight loss, fever, night sweats and no clinical evidence of extrapulmonary disease.</p> <p>Discrete peripheral lymph node M tuberculosis infection (especially cervical) is considered a less severe form of extrapulmonary tuberculosis.</p> | 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 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 (< 8 g/dl), neutropenia ($< 0.5 \times 10^9/L$ or chronic (more than one month) thrombocytopenia ($< 50 \times 10^9/L$). | Not presumptive clinical diagnosis. | <p>Diagnosed on laboratory testing and not explained by other non-HIV conditions.</p> <p>Not responding to standard therapy with haematinics, anti-malarials or anthelmintics as outlined in relevant national treatment guidelines, WHO Integrated Management of Childhood Illness guidelines or other relevant guidelines.</p> |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|--------------------------------|--|---|
| Clinical Stage 4 | | |
| HIV wasting syndrome. | <p>Unexplained weight loss (> 10% body weight), with obvious wasting or body mass index <18.5.</p> <p>PLUS</p> <p>unexplained chronic diarrhoea (loose or watery stools three or more times daily) reported for longer than one month;</p> <p>OR</p> <p>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 malaria areas.</p> | <p>Documented weight loss > 10% of body weight;</p> <p>PLUS</p> <p>two or more unformed stools negative for pathogens;</p> <p>OR</p> <p>documented temperature of > 37.6 °C or more with no other cause of disease, negative blood culture, negative malaria slide and normal or unchanged CXR.</p> |
| <i>Pneumocystis pneumonia.</i> | <p>Dyspnoea on exertion or non-productive cough of recent onset (within the past three months), tachypnoea and fever</p> <p>AND</p> <p>Chest x-ray evidence of diffuse bilateral interstitial infiltrates</p> <p>AND</p> <p>No evidence of a bacterial pneumonia; bilateral crepitations on auscultation with or without reduced air entry.</p> | <p>Cytology or immunofluorescent microscopy of induced sputum or bronchoalveolar lavage, or histology of lung tissue.</p> |
| Recurrent bacterial pneumonia. | <p>Current episode plus one or more previous episodes in last six months; acute onset (< 2 weeks) of symptoms (such as fever, cough, dyspnoea and chest pain)</p> <p>PLUS</p> <p>New consolidation on clinical examination or CXR; response to antibiotics</p> | <p>Positive culture or antigen test of a compatible organism.</p> |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|---|---|--|
| 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. | Positive culture or DNA (by polymerase chain reaction) of herpes simplex virus or compatible cytology/histology. |
| Oesophageal candidiasis. | Visceral herpes simplex virus requires definitive diagnosis. Recent onset of retrosternal pain or difficulty in swallowing (food and fluids) together with Oral <i>Candida</i> . | 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, mediastinum or abdominal. Discrete peripheral <i>Mycobacterium tuberculosis</i> infection (especially cervical) is usually considered a less severe form of extrapulmonary tuberculosis. | <i>M. tuberculosis</i> isolation or compatible histology from appropriate site or radiological evidence of military TB (diffuse, uniformly distributed small military shadows or micronodules on CXR). |
| Kaposi's sarcoma. | Typical appearance in skin or oropharynx of persistent, initially flat, patches with a pink or violaceous 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. | 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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|--|---|---|
| Central nervous system toxoplasmosis. | Recent onset of a focal nervous system abnormality consistent with intracranial disease or reduced level of consciousness AND response within ten 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 <i>Cryptococcus neoformans</i> 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 (PML). | 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 microscopic examination of unformed stool. |
| Chronic isosporiasis. | No presumptive clinical diagnosis. | Identification of <i>Isospora</i> . |
| Disseminated mycosis (coccidiomycosis, histoplasmosis, penicilliosis). | No presumptive clinical diagnosis. | Histology, antigen detection or culture from clinical specimen or blood culture. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|---|------------------------------------|--|
| 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. |
| Visceral leishmaniasis. | No presumptive clinical diagnosis. | Diagnosed by histology (amastigotes visualized) or culture from any appropriate clinical specimen. |
| HIV-associated nephropathy. | No presumptive clinical diagnosis. | Renal biopsy. |
| HIV-associated cardiomyopathy. | No presumptive clinical diagnosis. | Cardiomegaly and evidence of poor left ventricular function confirmed by echocardiography. |

Children (younger than 15 years)

| Clinical Stage 1 | | |
|--|--|---------------------|
| Asymptomatic. | No HIV related symptoms reported and no signs on examination. | Clinical diagnosis. |
| Persistent generalized 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 an obvious cause. | Clinical diagnosis. |
| Papular pruritic eruptions. | Papular pruritic vesicular lesions, scabies and insect bites should be excluded. | 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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE 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. |
| 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 onychomycosis is uncommon without 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 pseudomembrane. | Clinical diagnosis. |
| Unexplained persistent parotid enlargement. | Asymptomatic bilateral swelling that may spontaneously resolve and recur, in absence of other known cause, usually painless. | Clinical diagnosis. |
| Lineal gingival erythema. | Erythematous band that follows the contour of the free gingival line; may be associated with spontaneous bleeding. | Clinical diagnosis. |
| 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 midlines. | Clinical diagnosis. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|--|--|---|
| Recurrent upper respiratory tract infection (URTI). | Current event with at least one episode in past six 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 (laryngeotracheal bronchitis). Persistent or recurrent ear discharge. | Clinical diagnosis. |
| Clinical Stage 3 | | |
| Unexplained moderate malnutrition. | 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 >37.5°C 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 °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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE 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 <i>Mycobacterium</i> . |
| Severe recurrent bacterial pneumonia. | Cough with fast breathing, chest in drawing, nasal flaring, wheezing, and grunting. Crackles or consolidation on auscultation. Responds to course of antibiotics. Current episode plus one or more in previous six 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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|---|--|--|
| Unexplained anaemia (<8g/dl), neutropenia (<0.5X 10 ⁹ /L ³) or chronic thrombocytopenia (<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 anthelmintics 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 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 in breathing, cyanosis, tachypnoea and fever; chest indrawing or stridor. (Severe or very severe pneumonia as in WHO Integrated Management of Childhood Illnesses guidelines. Rapid onset especially in infants younger than 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, 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 six 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. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|---|--|---|
| Oesophageal candidiasis (or candida 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 difficulties/crying when feeding. | Macroscopic appearance at endoscopy, microscopy of specimen from tissue or macroscopic appearance at bronchoscopy or histology. |
| Extrapulmonary/ disseminated tuberculosis | Systemic illness usually with prolonged fever, night sweats, weight loss. Clinical features of organs involved, 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. | Not required but may be confirmed by: <ul style="list-style-type: none"> • typical red-purple lesions seen on bronchoscopy or endoscopy; • dense masses in lymph nodes, viscera or lungs by palpation or radiology; • histology. |
| Cytomegalovirus retinitis or cytomegalovirus infection affecting another organ, with onset at age over one 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. cerebrospinal fluid polymerase chain reaction. |
| Central nervous system toxoplasmosis onset after age over one month. | Fever, headache, focal neurological signs, convulsions. Usually responds within ten days to specific therapy. | Computed tomography scan (or other neuroimaging) showing single/multiple lesions with mass effect/ enhancing with contrast. |
| Extrapulmonary cryptococcosis (including meningitis). | Meningitis: usually sub acute, fever with increasing severe headache, meningism, confusion, behavioural changes that responds to cryptococcal therapy. | Cerebrospinal fluid microscopy (India ink or Gram stain), serum or cerebrospinal fluid cryptococcal antigen test or culture. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|---|---|--|
| 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, gait disturbances. | Neuroimaging demonstrating atrophy and basal ganglia calcification and excluding other causes. |
| Disseminated mycosis (coccidiomycosis, histoplasmosis, penicilliosis) | 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 mycobacteria species from stool, blood, body fluid or other body tissue, excluding lung. |
| Chronic cryptosporidiosis | No presumptive clinical diagnosis. | Cysts identified on modified Ziehl-Nielsen microscopic examination of unformed stool. |
| Chronic <i>Isospora</i> | No presumptive clinical diagnosis. | Identification of <i>Isospora</i> spp. |
| Cerebral or B cell non-Hodgkin lymphoma. | No presumptive clinical diagnosis. | Diagnosed by central nervous system neuroimaging; histology of relevant specimen. |

| CLINICAL EVENT | CLINICAL DIAGNOSIS | DEFINITIVE DIAGNOSIS |
|--|------------------------------------|--|
| 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 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 disease among HIV-sero-positive and HIV-exposed children

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

A presumptive diagnosis of severe HIV disease 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 disease in an HIV-sero-positive infant include:

- Recent HIV-related maternal death or advanced HIV disease in the mother
- CD4 <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 now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

Small group discussion

Get into small groups to discuss the following 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 on 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 persons with primary HIV infection?

Apply what you've learned/case study

Work on this case study independently.

As an HIV surveillance officer for Serosia, you are charged with standardizing the practice of the country's HIV reporting. What processes would you implement to ensure that HIV case surveillance is standardized?

Serosia recently began providing free antiretroviral therapy to HIV-infected individuals. Serosia uses the WHO recommendations for antiretroviral treatment to determine the best time to begin antiretroviral therapy.

- a. CD4 testing is available in the northern district of Serosia. What are the WHO recommendations as to when adults and adolescents should begin ART?
- b. CD4 testing is not available in the western district of Serosia. What are the WHO recommendations as to when adults and adolescents should 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 harmonize the adult and paediatric clinical staging criteria into four stages and provide for inclusive immunological criteria.
- The 2006 WHO clinical staging criteria are used in the surveillance case definitions.
- WHO recommends that countries standardize their surveillance practices and case definitions.
- The 2006 WHO surveillance case definitions include:
 - HIV disease (stages 1-4)
 - advanced HIV infection/disease (clinical stages 3 and 4 and/or CD4 count <350)
 - AIDS (clinical stage 4 and/or CD4 count <200).
- WHO recommends that ART be initiated for persons with clinical stage 4 or CD4 stage 3 and <350 or any stage with CD4 count <200. Linking the treatment recommendations to clinical staging and surveillance case definitions should facilitate HIV surveillance.

Notes

Overview

What this unit is about

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

- the purpose of HIV case surveillance
- methods of conducting HIV surveillance
- reporting sources for HIV surveillance.

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 disease cases
 - b. To provide information on the opportunistic infections associated with advanced HIV disease
 - c. To measure HIV incidence
 - d. To determine the burden of disease attributable to advanced HIV disease in the region.
2. Which of the following describes case-based HIV surveillance?
 - a. All HIV cases reported in a given time period are summarized into a single case report form
 - b. A method to estimate the HIV prevalence among women attending antenatal clinics
 - c. Each person diagnosed with HIV has a care 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 an 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).
4. List three potential sources for HIV case reports.

Introduction

What you will learn

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

- list reportable events in HIV case surveillance system
- 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.

Defining Reportable Events for HIV Case Surveillance Systems

HIV surveillance programme functions

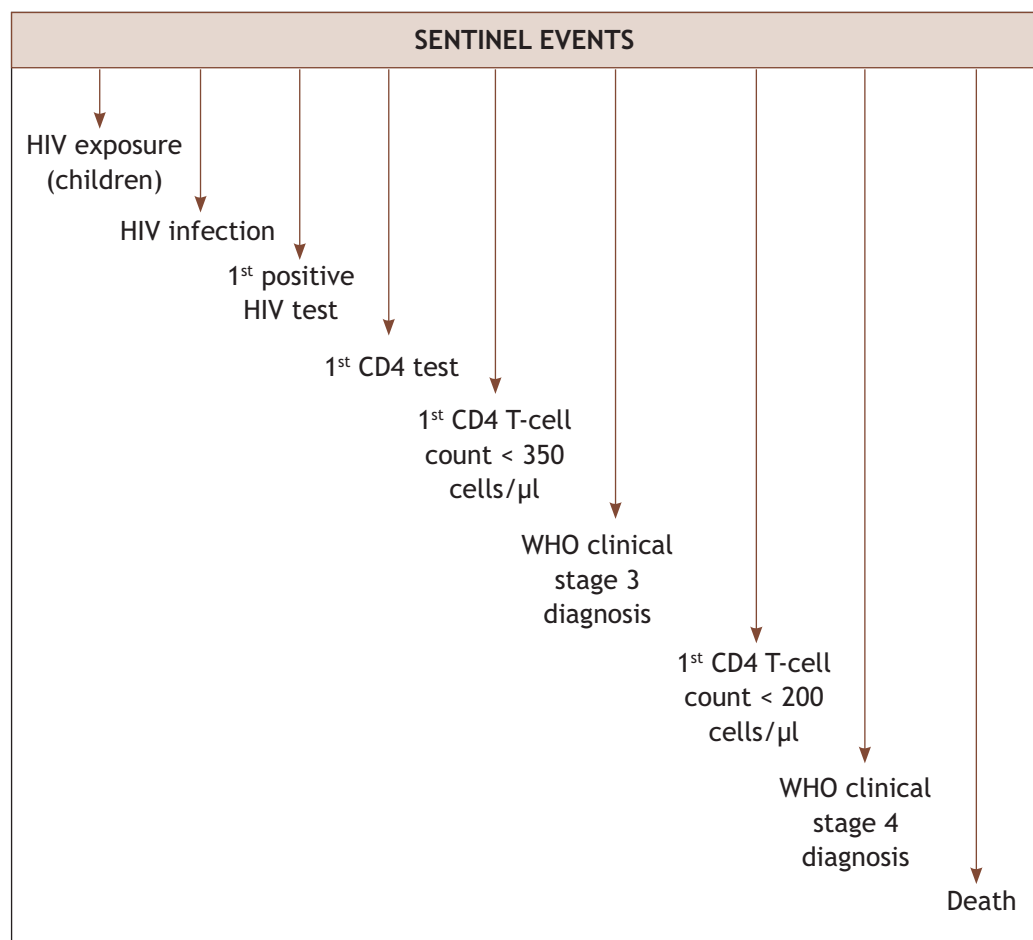
The primary functions of HIV surveillance programmes are to:

- monitor the HIV epidemic by providing information on the characteristics of persons with HIV infection (all clinical stages) and advanced HIV infection over time
- identify the number of persons currently in need of treatment
- estimate the number of persons who will need treatment in the near future
- provide data for developing and monitoring the impact of prevention programmes.

HIV case surveillance activities can be designed to monitor the full spectrum of HIV disease. The ability of the surveillance programme to monitor the clinical events during the course of HIV infection depends on the extent of clinical care that is routinely provided to persons with HIV infection. Figure 3.1 shows events that surveillance programmes may wish to monitor. Monitoring each of these events will provide data to assist in planning prevention programmes and care and treatment programmes.

Figure 3.1

Monitoring the spectrum of HIV disease



Countries should standardize HIV case definitions for surveillance purposes. All persons meeting the case definition should be reported to the sub-national/national surveillance programme authority. To understand the epidemic and to effectively plan for providing antiretroviral therapy and prophylaxis, it is important to include information on the clinical stage of the patient at the time of diagnosis. Reporting persons with all stages of HIV disease 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 of advanced HIV (clinical stages 3 and 4 only) as 'advanced HIV (infection or disease)' reporting. This includes AIDS.

HIV infection case reporting

In HIV infection case surveillance, all persons, regardless of their clinical stage, 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 is reported again as having advanced HIV infection/disease.

Thus, all persons who have been diagnosed with HIV disease will be reported and their clinical stages and CD4 counts (if available) at the time of diagnosis or closest to diagnosis should be reported as well.

HIV case reporting includes reporting persons with advanced HIV infection/disease.

This means that HIV-infected persons who are first diagnosed with HIV at clinical stage 3 or 4 (or CD4 count <350 cells/mm³) will be reported once (as advanced HIV infection). 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 deteriorates to clinical stage 3 (or CD4 count <350 cells/mm³), the person will be reported again as having advanced HIV infection. All case reports of persons with HIV infection, including advanced HIV infection, should include the patient's clinical stage at the time of diagnosis (of HIV infection or advanced HIV infection).

Reporting of all HIV infection cases, regardless of the clinical stage, will be challenging to implement and conduct in developing countries because of various infrastructural constraints and weak information systems. However, this is the goal standard, and in the long term, countries should see themselves moving towards this goal. It is important to begin thinking and planning and to gain experience by undertaking small-scale pilot projects that can eventually be taken to national scale.

Advanced HIV infection/disease reporting (including AIDS)

With advanced HIV disease case surveillance, all persons with a documented HIV-positive test and who have a clinical stage 3 or 4 diagnosis or CD4 count <350 cells/mm³ should be reported to the surveillance system. Persons with clinical stages 1 or 2 or CD4 counts ≥350 cells/mm³ will not be reported to the surveillance system until they reach clinical stage 3 or 4 or have a decline in their CD4 count to 350 cells/mm³. AIDS cases do not need to be reported separately, as they are reported as cases of advanced HIV disease.

AIDS case reporting

AIDS case reporting has been in place in South-East Asia for many years. It has been relatively complete in a few countries, but in most others, few of the AIDS cases have been reported.

For countries in which AIDS case reporting has been relatively complete, (80% or more) continuing AIDS case reporting (that is, clinical stage 4) should be considered. The merit in continuing with AIDS case reporting is that it will permit the tracking of trends.

However, in those countries in which few of the AIDS cases have been reported, countries should switch to reporting of advanced HIV infection (disease), as this option already includes AIDS cases (clinical stage 4) and data on AIDS cases can be easily analysed.

Planning for HIV case surveillance

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

- identify dedicated staff at the national level (and sub-national, if applicable) who will establish and monitor the HIV case surveillance system
- adopt standardized HIV surveillance case definitions
- conduct rapid assessment/evaluation to determine the current status of the AIDS 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 sites and laboratories)
- determine reportable laboratory and clinical events (such as positive HIV EIA, rapid tests, western blots, or CD4 tests)
- determine if only newly diagnosed persons (that is, newly diagnosed HIV disease and newly diagnosed advanced HIV disease) should be reported, or if all persons with HIV disease are to be reported (meaning prospective and retrospective case reporting)
- adopt 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
- Start in a small scale, perhaps in major health centers or urban hospitals to roll out the system, before expanding. ART clinics may be a good starting point as these clinics attract HIV-infected individuals.

Data Collection

Identifying reporting sources

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

- healthcare clinics (health centers)
- ART treatment clinics
- tuberculosis (TB) clinics
- voluntary HIV counselling and testing (VCT) sites
- hospice (for advanced HIV disease)
- hospitals
- 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).

These are useful sources for identifying cases because these are places where HIV-infected people can be found. Although all of these sources should be included as places from which cases will be reported, some are more likely to yield a larger number of cases than others. In general, sites at which ongoing care of HIV-infected persons is provided will be the most useful sites to identify cases. This is because these programmes can identify HIV cases, provide information on the clinical stage of disease (and therefore which case definition applies), and provide most, if not all, of 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.

Ways to identify cases

New cases of HIV infection are found mainly by passive surveillance. In a passive surveillance system, healthcare providers identify individuals who seek care at a facility and report those who meet the case surveillance definitions. The data are then forwarded to the next level in the surveillance system. The ability of a passive reporting system to identify and report all individuals who meet the surveillance case definition depends on how many HIV-infected individuals have access to HIV testing, get tested, obtain care at a health facility, and then get reported. In other words, the completeness of reporting (that is, the sensitivity of the surveillance system) depends both on individual behaviour (seeking testing and care) and the extent to which healthcare providers complete and forward case reports. The sensitivity of the surveillance system can be improved by increasing access to testing—providing HIV testing facilities at primary healthcare centers, using rapid tests, providing confidential and high-quality counselling and testing services, taking steps to reduce HIV-associated stigma, and ensuring that health staff are well trained in HIV surveillance.

Table 3.1

Potential reporting sources

| Site | Key features |
|-------------------------|---|
| VCT sites | <ul style="list-style-type: none"> • Provide HIV diagnosis to persons at early and late stages of disease • Source of reports for HIV case reporting (all stages) • Since they do not provide clinical care, stage of disease cannot be included in the case report; efforts to follow up the patient once in care should be pursued. |
| Healthcare providers | <ul style="list-style-type: none"> • Physicians and other healthcare providers will care for patients at any stage of disease, though most are likely to be in more advanced stages • Medical records at the offices of physicians are likely to contain most of the information necessary to complete the case report form • Information that is missing from the medical records can be obtained by the physician when the patient returns for care. |
| ART treatment programme | <ul style="list-style-type: none"> • Patients receiving ART are most likely at clinical stages 3 and 4 and should be reported as having advanced HIV disease • ART monitoring data can identify reportable cases • Follow-up data generally available • May be possible to track deaths. |
| TB clinics/ programmes | <ul style="list-style-type: none"> • HIV-infected persons with pulmonary TB have clinical stage 3 HIV disease and should receive ART (they will often be seen in ART clinics/programmes) • HIV-infected TB patients should be reported as having advanced HIV disease. |
| Hospitals | <ul style="list-style-type: none"> • At hospitals, HIV patients are likely to be in more advanced stages of disease • Information for case report forms should be available. |

Case Reporting Methods

Case-based and aggregate case reporting

In many developing countries, information at individual level is collected at health facilities using a single form for each individual or a line register where each line is dedicated to one individual. Each facility sends the forms/line register to the next level—that is, to the district or province. At the district/province level, the data are aggregated (that is, a single form summarizes all of the patients who were diagnosed with the condition at all the health facilities in the district in a given time period). The data are aggregated by demographic characteristics, risk profile, clinical characteristics, etc. (See Annex 3.1 for example.) Such an approach is called aggregate case reporting and is often simpler than case-based reporting. However, it is not as flexible, as it does not allow data to be analysed in ways that are not pre-determined.

In contrast, in a case-based reporting system, each person diagnosed with the condition is reported using a separate case report form. In this way, information that pertains to that patient specifically is collected and forwarded to the health authorities all the way up to a level where data are computerized. (See Annex 3.2. for example.) 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.

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 as well as newly diagnosed).

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

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

- case report forms
- instructions for completing the forms
- information on who and how to contact the surveillance officer if questions arise.

Laboratory-initiated reporting

Laboratory reporting is a method in which the laboratories notify surveillance programmes of patients who should be reported. Laboratory reporting is an important component of HIV reporting, although it is not currently practiced in SEAR countries. In most SEAR countries, all public-sector laboratories reporting HIV EIA/ Western blot are attached to VCT centers. CD4 testing is done at only a few public-sector laboratories attached to centers where HIV care/ART is provided. Information for surveillance purposes is collected through the VCT or healthcare/ART centers attached to the laboratories.

Laboratory-initiated reporting differs from provider-initiated reporting. Laboratories do not diagnose patients and do not, in general, have enough information to actually report individual cases. However, 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 surveillance programmes of persons who are likely to have HIV infection, care must be taken to include such information that would facilitate surveillance programme officers follow up with the healthcare provider and to report the case.

The following information should be provided by the laboratory to the surveillance programme officers so that the surveillance programme can follow up cases:

- 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), a case should be reported 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 deteriorates to advanced HIV disease
- 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/mm³ (note the need to consider CD4% in children <18 months)
- an HIV-infected person dies.

Countries are not required to report AIDS cases if they are reporting advanced HIV infection cases. If countries wish to continue reporting AIDS cases (feasible only in countries that have a well-functioning AIDS case surveillance system in which completeness of reporting has been at least 80% over the past several years), a case should be reported when:

- an HIV patient is diagnosed with clinical stage 4 or CD4 count <200 cells/mm³ (note the need to consider CD4% in children <5 years)
- a person with AIDS dies.

Surveillance staff should work with healthcare providers and others who will be responsible for completing case report forms to ensure that case reports are submitted at appropriate times. Consider Table 3.2:

Table 3.2

Clinical stages and immunologic criteria to report cases for HIV case surveillance options

| HIV case surveillance 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 surveillance | Submit case report form | Submit case report form | Submit case report form |
| Advanced HIV infection/disease surveillance | | Submit case report form | Submit case report form |
| AIDS case surveillance* | | | Submit case report form |

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

Mandatory variables for counting cases

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

The mandatory variables required on the case report form for the surveillance programme to count a reportable 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
- date of death (or number of deaths if using aggregate reporting).

Updating and un-duplicating cases

Countries that adopt case-based surveillance systems will have *longitudinal computerized databases*.

Longitudinal databases 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 HIV disease deteriorates to advanced HIV disease
- 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 surveillance system, HIV cases may be reported more than once. This is because individuals/patients may get tested at more than one site or may change the place that they receive healthcare. When that happens, both the original and the new healthcare provider will report that patient.

The surveillance system should be able to correctly distinguish newly reported persons 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 for 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.

As individual cases are reported, the surveillance staff should compare the name/code and date of birth (plus 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 probable that it represents 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 standardize the methods used for un-duplicating cases so that all staff responsible for un-duplicating case records do so using the same standardized method.

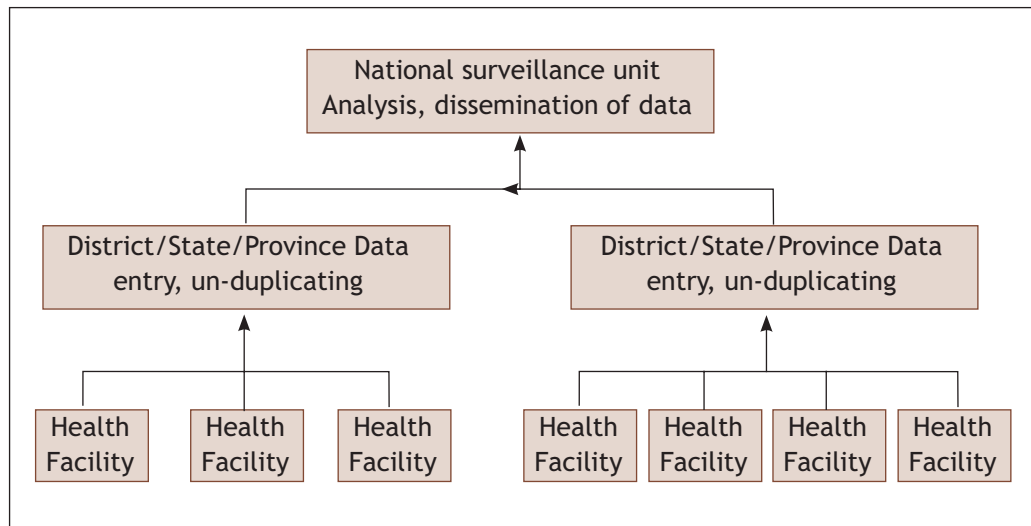
Although un-duplicating cases is important for gathering an accurate case count, there will be situations in which the information necessary to un-duplicate cases is either not available or in which two or more case reports from the same individual are not properly matched. This situation results in 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. This may involve forwarding report forms from healthcare providers to a sub-national level, but ultimately, HIV case reports should be sent to the national surveillance unit where a complete database should be maintained. An example of a three-tier reporting structure is given below:

Figure 3.2

Three-tier reporting structure



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 delineated and communicated to all parties involved in case reporting. Ongoing communication regarding roles and responsibilities should produce a spirit of cooperation and lead to quality surveillance data.

Table 3.3

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 authorized personnel only
- analyse, 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.

Table 3.4

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
- evaluate each case report to determine if 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 authorized 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.

Table 3.5

Responsibilities of healthcare providers

- 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 disease or AIDS, CD4 count <350, etc.)
- complete HIV reporting forms upon death of HIV-infected persons (and include cause of death, if available)
- submit forms to sub-national or national-level surveillance unit, as per reporting chain for the country (under confidential cover, see Unit 5)
- record each instance of case reporting to the surveillance unit on patient's clinical record.

Case Report Form

Purpose of an HIV case report form

The purpose of the case report form is to standardize 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)
- standardize the collection of variables.

Elements of a case report form

A comprehensive case report form should include:

- Administrative information:
 - name and address of facility completing report (reporting source)
 - date form completed
 - report status (new or update)
- Demographic information:
 - patient identifier (name or code)
 - date of birth
 - sex
 - race/ethnicity (if applicable)
 - 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*/mother-to-child transmission
 - blood transmission-related variables
 - occupational exposure
- Diagnosis information:
 - date of HIV diagnosis
 - facility of diagnosis
- Clinical stage:
 - date of first clinical stage
 - clinical stage
 - date of first clinical stage 3 diagnosis
 - date of first clinical stage 4 diagnosis
- Immunologic status:
 - date of first CD4 test
 - result of first CD4 test (count and/or percent)
 - date of first CD4 count <350 cells/mm³
 - date of first CD4 count <200 cells/mm³

- Care and treatment:
 - use of ART
 - date first used ART
 - use of prophylaxis against *Pneumocystis carinii* pneumonia
- Vital status:
 - date of death
 - cause of death

Countries should carefully consider which elements to include in the case report form. The form should only include information that is readily available to the person completing the form and information that can be collected from most of the reporting facilities. In addition, the case report form should not be overly burdensome to those who need to complete it.

Surveillance programmes should determine the types of personnel who are responsible for completing the case report form. Issues of patient confidentiality should be carefully considered when making this determination. For example, physicians may report cases, but careful thought should determine whether support staff, such as clerical staff at voluntary counselling and testing sites, should be permitted to report cases. All persons involved in reporting patients with HIV disease should be provided with information on the need for and methods to protect patient privacy.

Modifying and piloting the case report form

A generic HIV case report form is shown in Annex 3.3. This form can be modified to meet country-specific issues and be tailored to ensure that the terminology used is easy to understand. Providing education and instructions on how to complete the reporting form is essential in order to achieve accurate and standardized case reporting. Prior to adopting a new case report form, the form should be pilot-tested at a selected number of reporting sites and modified on the basis of the results from the pilot testing.

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 with HIV disease
- estimating the size of the workforce
- demonstrating the relative impact of HIV-related mortality as 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 that

ART has 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-surveys among women attending antenatal clinics 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 in the country, the results from these activities should be considered as well.

ART monitoring programmes often collect ongoing information on patients. Collecting 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 can also 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

Individual 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 surveillance, matching of the two registries can provide case-level information on HIV cases who 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 surveillance and death registries are complete, then adding the date of death into the HIV case registry provides 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 will soon be in need of care and treatment.

Additional methods of monitoring HIV deaths

In developing countries where vital 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 these systems involve sampling a section of the population and monitoring this sample for vital events including births, deaths and migration 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 provide the causes of deaths in these sampled populations, verbal autopsies can be used. Verbal autopsies are a way of assigning cause of death to persons who have died outside of hospital (where causes of deaths are usually recorded). Once a death has occurred in one of the sampled sites, a health worker conducts an interview with a relative of the deceased.

This interview uses a standardized 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*.

Unit 3 Exercises

Warm-up review

Take a few minutes now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

Small group discussion

Get into small groups to discuss these questions.

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

- | | |
|---|--|
| HIV infection | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| Advanced HIV disease | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| AIDS | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| HIV/AIDS | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| HIV antibody test | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| CD4 counts | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| If yes, what level/count is reportable? | <input type="checkbox"/> all <input type="checkbox"/> <200 <input type="checkbox"/> <350 |
| Viral load | <input type="checkbox"/> Yes / <input type="checkbox"/> No |
| Others, specify: | |

2. If your country conducts case-based reporting, what sort of information is recorded on the form that could be useful for determining the clinical stage of disease?

- Case reporting is not done in my country
- Clinical presentation (HIV/AIDS indicator conditions)
- Clinical staging is recorded by provider

- CD4 counts
- No information is recorded that can be used for clinical staging.

Comment:

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 in the following:

- notifiable diseases list:
 - case definitions:
 - case reporting forms:
 - detailed case investigation forms:
 - reporting sources:
 - data flow
 - others-
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 it is used for reporting all cases of notifiable diseases?
 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 surveillance 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 officer for an urban district in Serosia, a mid-sized country in South-East Asia with a concentrated HIV epidemic. In Serosia, AIDS case reporting has been conducted for many years, but is incomplete. Serosia has opted to conduct reporting of advanced HIV infection (disease) 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 surveillance is used to provide information on the number and characteristics of persons with HIV disease and advanced HIV disease, to determine the current and future need for ART and also prevention programmes; and finally to assess the impact of these programmes.
- HIV case surveillance includes reporting of persons newly diagnosed with HIV, persons previously diagnosed but not reported and persons previously reported with clinical stages 1 and 2 who have now deteriorated to advanced HIV disease (clinical stages 3 and 4).
- Advanced HIV infection (disease) 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 disease.
- 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 surveillance can be conducted using active surveillance methods (in which surveillance officers identify and report cases directly) or through passive surveillance (in which health care providers report cases to the surveillance programme organizers).
- 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 surveillance provides the greatest flexibility for data analysis, but may be too burdensome for healthcare providers and surveillance programmes.
- Monitoring HIV-related deaths can provide useful information. This can, however, 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 identifies vital events in the selected areas. Causes of deaths that are identified in these areas can be determined using verbal autopsy methods.

Notes

Overview

What this unit is about

The periodic evaluation of surveillance systems is needed in order to maintain:

- a responsive and relevant system of monitoring shifting disease trends
- effective disease control and management interventions.

Close monitoring of a newly established surveillance system is needed in order to identify and fix incorrect reporting practices.

This unit discusses how to:

- monitor the establishment of the HIV surveillance system
- conduct an effective evaluation, with emphasis on evaluating the completeness, timeliness and validity (or accuracy) of the data collected in the surveillance system.

Warm-up questions

1. List three aspects of a disease under surveillance that an effective surveillance 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 surveillance system
- describe three elements of a disease under surveillance that a surveillance system should monitor
- describe methods to measure the completeness, timeliness and accuracy of your surveillance system.

Purpose of public health surveillance

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

Why evaluate?

Once you've set up an HIV/AIDS surveillance system, you will want to make sure that it remains effective as the epidemic shifts over time. If your system is not accurately capturing information, surveillance and other public health programmes:

- will not have the right information to control HIV
- cannot appropriately plan 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 surveillance 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 systems⁵. The purpose of evaluating public health surveillance systems is to ensure that problems of public health importance are being monitored effectively. Surveillance systems should be evaluated periodically, and the evaluation should include recommendations for improving quality, efficiency and usefulness. Evaluation of a public health surveillance system focuses on how well the system operates to meet its purpose and objectives. System evaluation provides information to improve services and delivery. Specific objectives of ongoing evaluations of surveillance system may include the following:

- appraising and prioritizing the events to be kept under surveillance
- evaluating the quality of the epidemiologic information produced
- assessing how surveillance results affect disease control and policy
- identifying the elements of the system that can be enhanced in order to improve the quality of information.

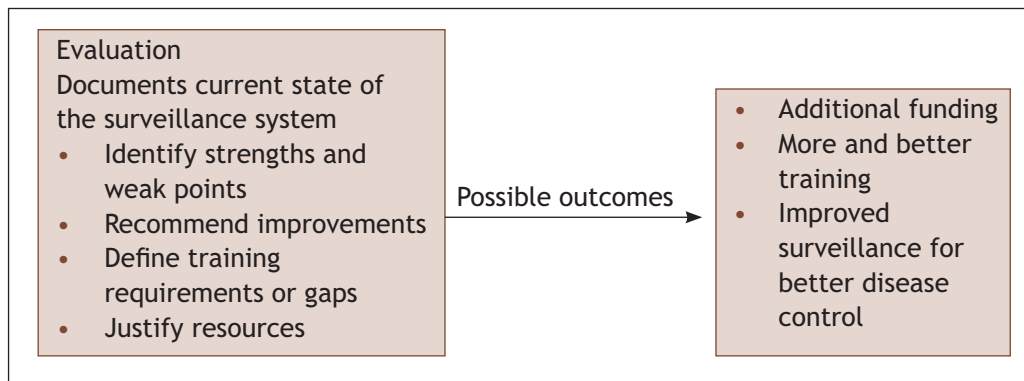
The direction and process of the evaluation must be focused to ensure that time and resources are used as efficiently as possible. Focusing the evaluation design for a public health surveillance system involves:

- 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.

⁵ Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001;50 (No. RR-13):[inclusive page numbers].

Figure 4.1

Elements of a well-focused evaluation



Monitoring and evaluating your HIV surveillance system can help determine:

- if reporting sources are sending 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 surveillance 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. Following are examples:

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

Three attributes of the surveillance system should be reported at least annually. These are:

- completeness of case reporting
- timeliness of case reporting
- 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 of completeness should not be confused with measuring the completeness of information that is collected on a case report form. Surveillance programmes should strive to have reporting as complete 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 are reporting cases. Surveillance units should identify the specific healthcare facilities that should be reporting and determine the number of cases reported from these sites.

Methods to measure completeness

You should evaluate completeness of reporting for a specified time period, such as one year. To calculate the completeness of reporting, divide the number of reported cases during a given time period (such as one year) by the total number of expected cases for the same period. The expected number of cases can be obtained as part of the estimation process using the Workbook/Spectrum models. Completeness is usually presented as a percent.

Table 4.1

Calculating completeness of reporting

$$\frac{\text{Number of reported cases during the time period}}{\text{Total number of expected cases during the time period}}$$

Expansion of case finding is likely to result in the identification of cases that were not reported. Once these cases have been identified, they should be reported and the source of report should indicate that cases were identified during the evaluation of the completeness of case reporting.

Measuring Timelines of Reporting

Measuring timeliness

Timeliness refers to how soon after diagnosis the case was reported to the authorities (for example, national surveillance officers or Ministries of Health). Timeliness is to be measured at each level. For example, at the sub-national level, surveillance officers will determine the timeliness of reporting from the health facilities to the sub-national level. In order that surveillance data are useful for implementing effective prevention and control measures and in planning care and treatment for infected persons, health officials must know about diseases in a timely fashion.

Timeliness can be measured as one of the following:

- 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 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 gold standards to strive to achieve:

- 70% 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 demonstrates a four-step process for determining the timeliness of case reporting.

Table 4.2

Determine the timeliness of case reporting

| Step | Action |
|------|--|
| 1 | Calculate completeness of reporting at 12 months after the diagnosis year. If completeness is $\geq 85\%$, 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: $(\text{report date}) - (\text{diagnosis date})$ OR $[(\text{year of report}) * 12] + \text{month}] - [((\text{year of diagnosis}) * 12) + \text{month}]$ For example, the report date is May 2004 and the diagnosis date is November 2003. The time interval (in months) is: $[(2004 * 12) + 5] - [(2003 * 12) + 11] = 6 \text{ months}$ |
| 3 | Determine the number of cases with a time to report ≤ 6 months. |
| 4 | Calculate timeliness of case reporting: $\frac{\text{Number of cases diagnosed within a year and reported within six months of diagnosis}}{\text{Number of cases diagnosed and reported for that diagnosis year}}$ |

Timeliness can also be calculated as the median time between the date of diagnosis and the date of report. In this calculation, completeness of reporting should be at least 85%. The timeliness should be calculated for a specified time period, as described in calculating the proportion of cases reported within six or 12 months.

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 top-level steps for re-abstractation.

Table 4.3

Re-abstraction study steps

| 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 those persons chosen as the sample. |
| 4 | Compare the information (variables) in the record with 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 surveillance 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 record keeping. 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 archive 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 national 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 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%-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 identification number/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 since the time the initial case report form was completed. The new information can (and should) be collected and added to the document-based surveillance data base. In order 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 identification number/code.)

Unit 4 Exercises

Warm-up review

Take a few minutes now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

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 (or AIDS, if only AIDS surveillance has been conducted so far) surveillance system in your country? If so, which parts of the surveillance 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 surveillance 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.

Serosia implemented HIV case surveillance two years ago. Samoy is a large province in the coastal area of Serosia and has the country's major port city. The surveillance

officers of Serosia and Samoy have met to discuss developing an evaluation of HIV case surveillance in Samoy.

- 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 surveillance data depends on the clarity of case report forms, the quality of training and the supervision of those who complete the forms, and the quality of data management.
- Monitoring surveillance 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 using estimation models to compare the number of reported cases with the number of expected cases.
- The timeliness of reporting refers to how soon a diagnosed case is reported to surveillance, 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 surveillance 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.

Notes

UNIT 5

Confidentiality and Ethical Issues

Overview

What this unit is about

Persons with HIV infection, and those at increased risk for HIV, are vulnerable to a number of social, legal and physical harms. Because of this, all programmes involved in HIV case surveillance must address a unique set of issues. This unit discusses those issues and provides guidance on methods to ensure that HIV case surveillance data protect patient confidentiality.

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 surveillance 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 stigmatization. They may even be subject to following criminal charges:

- a. privacy
 - b. informed consent
 - c. confidentiality
 - d. beneficence.
4. List three qualities that are necessary to have in a case identifier.
 - a.
 - b.
 - c.
 5. 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 reported with HIV

- describe issues of confidentiality and how they relate to HIV surveillance
- describe the purpose of including a patient identifier on HIV surveillance case reports.

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 (mark of disgrace or shame) attached to the disease, the surveillance system needs to 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 the ways it may affect them.

Groups at increased risk may include:

- sex workers
- injection drug users
- prisoners
- mobile populations
- men who have sex with men
- 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 marginalized populations depends on assuring the at-risk and infected communities that information about them will be held in strict confidence and used only for designated surveillance purposes.

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, 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 generalized epidemics, public health efforts should focus on both these risk populations and 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 invisible, thus making HIV testing, prevention and care programmes more difficult and encouraging the spread of the virus.

Table 5.1

Potential harms that may occur from HIV surveillance

| Type of harm | Result |
|--------------|--|
| Physical | <ul style="list-style-type: none">• public attack• spousal/partner abuse• domestic violence |
| Legal | <ul style="list-style-type: none">• arrest• prosecution (especially with high-risk populations) |
| Social | <ul style="list-style-type: none">• undesired disclosure to family or peers• workplace discrimination• loss of employment• isolation• loss of healthcare services• exclusion from social environment/network. |

Discussing the table

Examine Table 5.1 and answer the following questions:

- What are two types of social harm that HIV surveillance may accidentally cause?
- Arrest is classified as which type of harm?

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 programme organizers
- 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 a critical consideration in developing security policies and procedures that will be used to meet the requirements and standards described here. The HIV surveillance system was created before the development of technologies such as laptops, portable external storage devices, and the internet, all of which can be potential sources for security breaches. Now, all Ministries of Health should routinely assess the changing world of technology and adjust security policies and procedures to have adequate safeguards against potential new risks.

Case Identifiers

Why case surveillance requires unique case identifiers

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

- an individual can only acquire HIV once
- for surveillance purposes, an HIV-infected person is diagnosed and reported with advanced HIV disease only once.

Note that for clinical purposes, someone may be at clinical stage 3 but, following clinical improvement from treatment, respond to treatment and meet the criteria for clinical stage 2. Patient monitoring systems are used to follow these responses to treatment, but for surveillance purposes, case reports should be submitted only for:

- initial diagnosis of stage 1 or 2 disease
- initial diagnosis of stage 3 or 4 disease.

Surveillance programmes need an accurate count of persons with HIV infection and advanced HIV disease. Since patients may move and receive care at multiple facilities, patients may be reported more than once. To have an accurate count of cases, surveillance programmes need a mechanism that can identify duplicate cases and remove the most recently reported duplicate case(s) from the record. The reason to remove the later report is to maintain the earliest date of diagnosis.

If feasible, surveillance programmes may wish to establish longitudinal surveillance data bases. A longitudinal database can:

- follow reported cases over time
- identify when a patient deteriorates from HIV clinical stages 1 and 2 to advanced HIV disease
- 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 programme organizers 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 characterization 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 for 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 for all of these factors is the use of patient names for HIV case surveillance. 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 develop and maintain methods that ensure that surveillance information is kept confidential and secure.

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

- distinguish and identify duplicate reports for the same person
- distinguish cases with the same code who are different persons
- allow for obtaining 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 performance 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).

Confidentiality and Security Considerations

Why confidentiality is important

Confidentiality protects subjects from adverse consequences that may arise if their personal information is known, such as their:

- HIV infection status
- sexual preference.

If confidentiality about HIV infection is violated, subjects may suffer discrimination, stigma or arrest. Public health officers must maintain the confidentiality of each individual's records to guard against inadvertent disclosure.

Confidentiality and data security guidelines

Case-based (that is, individual patient-level) surveillance data, whether they contain a name or a code, represent confidential information. It is essential that patient confidentiality is protected. As such, surveillance programme organizers should carefully review their surveillance practices to ensure that surveillance data are held securely. Sub-national and national-level surveillance programmes should develop written policies that address security and confidentiality of reportable data. The following areas should be taken into consideration for 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 accessed to by non-authorized staff
 - consider how to store both paper and electronic data
 - restrict access to authorized staff only
 - develop a data-release policy
 - ensure that any off-site storage (such as a backup system of the data) is secure.
- Data must be transferred in a secure manner.
 - This includes submitting reports from healthcare facilities to the sub-national level and from the sub-national level on to the national level.
 - Specific methods of transmitting surveillance data should consider that data might be transmitted by any/each of the following methods:
 - telephone
 - facsimile
 - email
 - postal service
 - computer file transfer
- Computers that hold surveillance data (even temporarily) must be secure.
 - Surveillance programmes must safeguard 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 the time of hire; and periodically thereafter (such as annually).
- A breach in security or confidentiality should be thoroughly investigated to determine the source of the breach. Corrective measures, including additional staff training, should be undertaken to ensure that such a breach does not recur.

Unit 5 Exercises

Warm-up review

Take a few minutes now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

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 for determining a case identifier?
3. What do you 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 these reported using a code or name?)
5. What do you think are the existing barriers to implementing HIV case-based surveillance 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 surveillance for Inyo Province in Serosia. 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 with or at risk for HIV may be stigmatized and made vulnerable to social, legal and physical abuse.
- Fears of stigmatization 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 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 among at-risk and infected persons.
- Surveillance programme organizers should be aware of guiding 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

Overview

What this unit is about

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

Warm-up questions

1. List three elements of an HIV surveillance report:
 - a.
 - b.
 - c.
2. True or false? Changes in reporting practices may result in a false increase or decrease in AIDS incidence.

True False

3. When describing the HIV epidemic, why is it preferable to perform analysis based on date of diagnosis versus date of report?
4. True or false? Increases in the number of persons receiving ART can result in a decrease in AIDS incidence (new diagnoses of HIV clinical stage 4 disease) regardless of the number of new HIV infections occurring.

True False

5. Which of the following are potential target audiences for surveillance reports on HIV?
 - a. people who contribute to collecting the surveillance data
 - 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:

- summarize data obtained from HIV surveillance activities
- interpret HIV case surveillance data
- describe the basic elements of an annual HIV surveillance report.

Value of surveillance data

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

- the effective monitoring of trends in HIV infection
- characterization of the populations affected
- identifying the number of persons eligible for ART
- determining the number of persons receiving ART
- the successful development and evaluation of HIV intervention and prevention programmes.

It is also important that surveillance data are presented in a manner that facilitates their use for public health action. Therefore, it is essential that HIV surveillance data meet certain criteria for quality before being analysed and disseminated.

Analysing HIV Case Surveillance Data

Newly established HIV case surveillance

Interpretation of HIV case reporting data should begin only after HIV case reporting 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. For example, as reporting begins, there may be a bias in case reports, particularly if only selected geographic areas or facilities are being reported. Countries should continue to use data from HIV sero-prevalence surveys to estimate the overall prevalence of infection until HIV case surveillance is determined to be sufficiently complete and can provide a reasonably accurate estimate of the HIV prevalence.

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

Many countries have not had complete AIDS case reporting. In those countries, initiating HIV case reporting (all clinical stages) along with reporting of advanced HIV disease/AIDS should not affect the interpretation of data. This is 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. These data sources, rather than HIV case surveillance data, should be used to estimate the level of and trends in HIV incidence.

Analyses using HIV surveillance data

The term “HIV” in the context of surveillance refers to five categories of cases:

1. new diagnosis of HIV infection cases only
2. new diagnosis of HIV infection cases with later diagnosis of advanced HIV disease
3. concurrent diagnosis of HIV infection and advanced HIV disease
4. diagnosis of new HIV infection with later diagnosis of AIDS
5. concurrent diagnosis of HIV infection and AIDS.

HIV, advanced HIV disease and AIDS case data should be examined to answer the following questions.

- Are new diagnoses of HIV, advanced HIV disease and AIDS increasing, decreasing or remaining stable?
- Which geographic areas (for example, urban versus rural areas) have the highest number of new diagnoses HIV, advanced HIV disease and AIDS?
- What are the demographic and risk characteristics of new diagnosis of HIV, advanced HIV disease and AIDS, and have these changed over time?
- What proportion of persons with advanced HIV disease and AIDS are 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 surveillance data to answer the types of questions outlined above will lead to a better understanding of the HIV epidemic. Surveillance 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 already infected, those who are newly infected, and how these populations differ. Knowing the infected populations can help treatment and prevention efforts to be directed 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 facilities can 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 disease is usually not evenly distributed within a country. Often there are particular areas where the disease is concentrated, such as large urban areas or coastal areas. Case surveillance data should be used to locate the areas within a country that are most severely affected. This allows for developing, implementing and evaluating treatment and prevention programmes.

Surveillance data can provide information on how diagnosis of HIV, advanced HIV disease and AIDS change over time. Keep in mind that case surveillance data reflect diagnosis of HIV, and may not provide any information on the number and rate of new HIV infections.

HIV-related mortality

Most South-East Asian countries do not have complete death registries. The hope is that these will be developed over a time. If information on the number and causes of death is available, surveillance programmes should include the number of and trends in HIV-related deaths.

If countries conduct case-based HIV surveillance that can be linked directly to death registries, the number of persons living with HIV can be determined. 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 surveillance reports.

Misinterpreting surveillance data

Increases and decreases in HIV, advanced HIV disease and AIDS cases 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 surveillance data, such as the following:

- 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 sites or changes in HIV testing practices 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.
- The use of ART delays the progression of HIV disease to advanced HIV disease and AIDS, thereby reducing the incidence of these diseases.
- Changes in case reporting practices, such as efforts to increase reporting from private providers, should increase the number of cases reported.
- Increases or decreases in the number of healthcare facilities or other factors that affect the use of healthcare services can impact diagnoses and reporting of HIV. For example, implementing or increasing a user fee may result in fewer people seeking care, which may reduce HIV diagnoses and care reports.
- Duplicate case reports (more than one report provided for one individual) may lead to counting one person twice.

A number of factors may affect the true incidence of advanced HIV disease and AIDS, including the following:

- past HIV incidence (keeping in mind the time it takes to develop advanced HIV disease or AIDS after HIV infection)
- ART impact on delaying the progression of HIV to advanced HIV disease or AIDS
- past HIV prevalence (that is, whether the epidemic is mature or new).

Factors that may affect the true prevalence of advanced HIV disease and AIDS cases are:

- changes in HIV-related mortality
- changes in the incidence of HIV (though this is unlikely to impact trends in advanced HIV disease until many years later)
- changes in advanced HIV disease/AIDS incidence that may occur as persons deteriorate from earlier clinical stages to clinical stages 3 and 4 and reflect HIV infection that may have occurred years earlier.

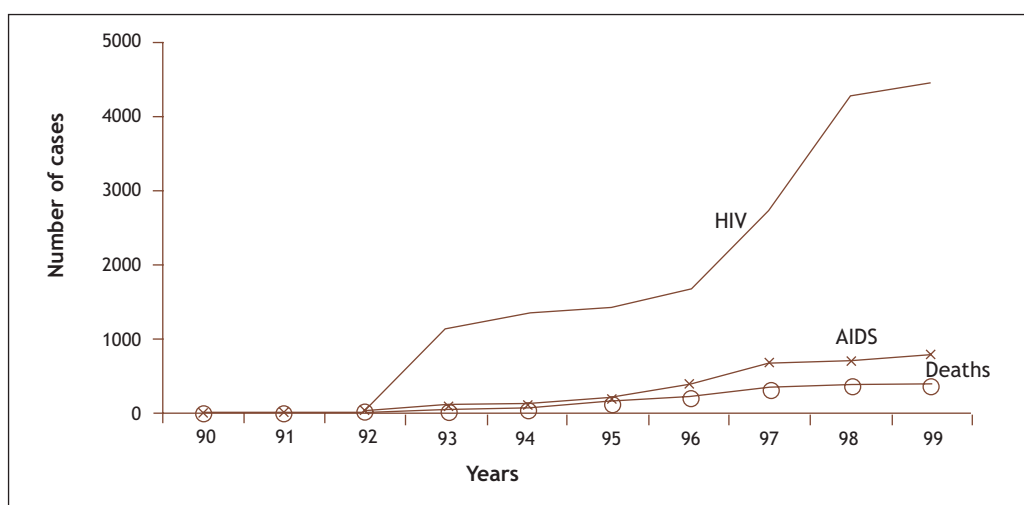
Displaying and Interpreting Surveillance Data

Analysis of the surveillance data should be done with a specific purpose in mind. That is, the surveillance officers/data analysts should know what the data are to be used for. For example, the data may be used by the 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 persons eligible for ART who are receiving it. Trend analysis allows programmes to monitor how well ART is reaching those in need of treatment.

Figure 6.1

Reported HIV infections, AIDS cases, and AIDS deaths, Vietnam, by year of report, 1990 through 1999



Source: Quan VM, Chung A, Long HT, Dondero TH. HIV in Vietnam: the evolving epidemic and the prevention response, 1996 through 1999. *J Acquired Immune Deficiency Syndrome*. 2000;25:311-7.

Listed on the next few pages are examples of some of the ways that data can be displayed.

Discussing the figure

Look at figure 6.1 and answer the following questions:

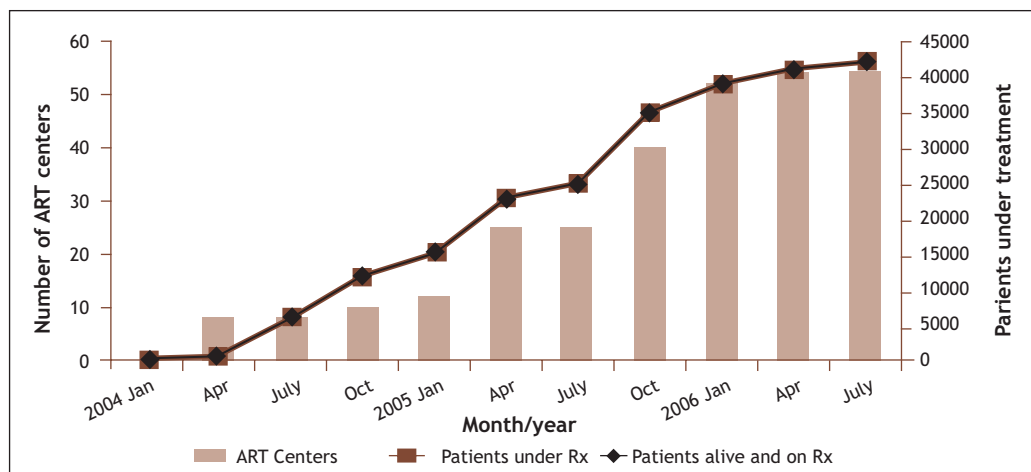
1. What factors may explain the discrepancy in the trends in the number of HIV and AIDS cases between 1992 and 1994 (that is, high numbers of HIV cases, but relatively low number of AIDS cases)?
2. What would you expect to happen to the number of AIDS cases and deaths in the absence of ART in 2004?

Discussing the figure

Look at figure 6.2 and answer the following questions:

Figure 6.2

Trends in the number of ART centers, number of patients on ART, and survival, January 2004 - July 2006



1. Describe the trends in the number of ART centers 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?

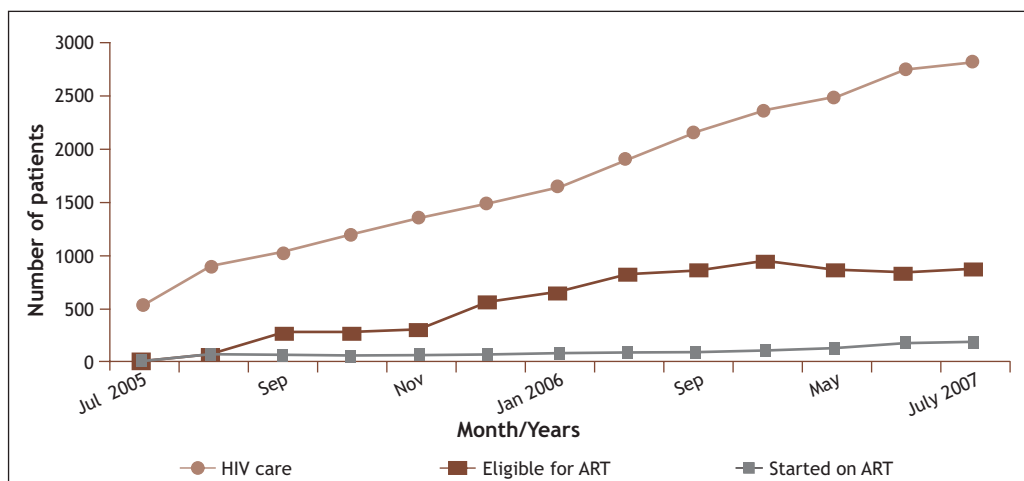
Discussing the figure

Look at figure 6.3 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 are there more patients in HIV care than those receiving ART?

Figure 6.3

Patients in HIV care, July 2005-July 2006



Presenting HIV Surveillance Data

Target audiences for surveillance reports

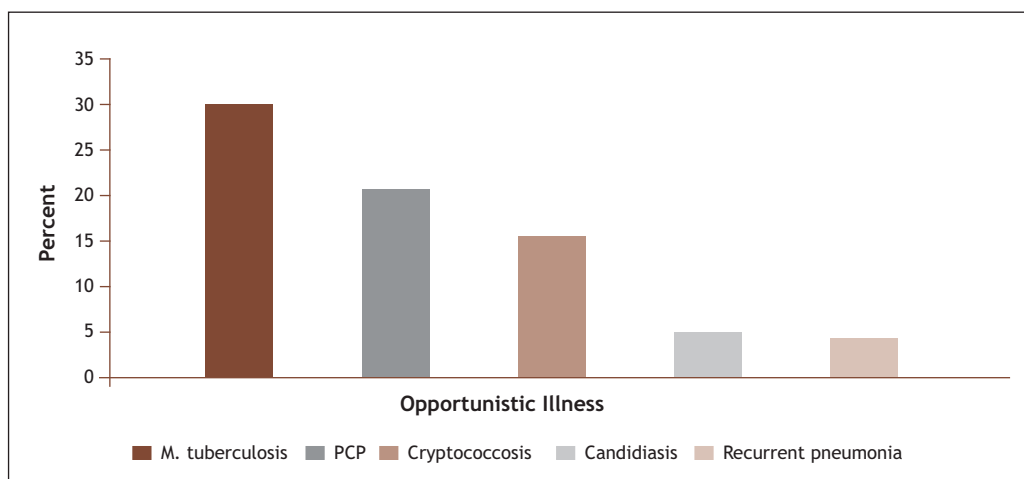
Surveillance reports need to be disseminated to those who are responsible for decision-making. HIV/AIDS surveillance reports are one of the primary means of communication with colleagues, co-workers and other stakeholders in the HIV/AIDS epidemic.

Potential target audiences for surveillance reports on HIV/AIDS include:

- those who contribute to the collection of the surveillance 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.

Figure 6.4

Frequency distribution of AIDS opportunistic illnesses



Meeting minimum performance standards

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

For example, many South-East Asian countries have had AIDS case reporting only from selected healthcare facilities that provide care for HIV disease. Reporting from these facilities may be complete, but this does not mean that reporting for the country is complete. Analysis of surveillance data should always consider the extent to which reporting is incomplete. When using surveillance data, incomplete reporting 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/AIDS database. Countries should establish data-release policies that are described in writing and are available for anyone who has access to case surveillance data. Policies for data release should:

- be guided by knowledge of the overall population characteristics and distribution, and of the HIV-infected population
- maintain confidentiality
- permit use of surveillance data for public health purposes
- specify who can receive case surveillance data and in what format.

The data-release policy should address reports from the surveillance programmes, as well as the release of surveillance 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/AIDS data, you should follow local confidentiality procedures for displaying small cell sizes (5).

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 Surveillance

Communicating surveillance results

A variety of modalities can be used to disseminate the results from analysis of surveillance data. The format used should be tailored to the audience.

Different audiences require different information and presentation styles, based on:

- their familiarity with the terminology and concepts of surveillance
- the action they will take based on the information, perhaps determined by their position in the HIV/AIDS 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 organized the report, the more effective it will be in meeting the objectives.

HIV surveillance report

An HIV surveillance report should be published on a regular basis (annually, at a minimum) The HIV surveillance report will present descriptive statistics to those who report the data, to other units of the Ministry of Health, to national AIDS programmes that use HIV surveillance data to target or prioritize services for HIV prevention and patient care, and to the public. 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 this report is to use the strategic information available in the country to publicize about the HIV epidemic to all concerned. The report provides data from all HIV/STI surveillance activities (HIV case reporting, HIV sentinel site reports, HIV seroprevalence surveys, STI syndromic/aetiology surveillance, etc.) as well as other related programme areas (such as tuberculosis control programmes, prevention of mother-to-child transmission programmes, and care and treatment programmes). Ideally, this report can summarize the state of the HIV epidemic.

Fact sheets

Fact sheets are brief descriptions focused on a specific subject. They are written in simple language and are 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 will often include contact information for follow-up when more in-depth information is desired. They can also be tailored to address local populations of interest. Examples of these populations include:

- gender
- risk category
- age groups (paediatric, adolescents, 50+)
- populations of special interest (sex workers, homeless, migrant populations, etc.).

Recommended analyses include:

- annual number of cases, percentages
- case rates per 1,00,000 population.

Slide sets and presentations

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

- 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 1,00,000 population over time (5-10 years).

HIV Surveillance Report

As mentioned before, an HIV surveillance report should be published on a regular basis (annually, at a minimum) to present descriptive statistics to those who report the data, to other units of the Ministry of Health and National AIDS Programmes that use HIV surveillance data to target or prioritize services for HIV prevention and patient care, and to the public. The report should include observed trends of the HIV epidemic, the risk patterns observed, transmission categories, age and sex distributions and geographic distributions.

In addition to the annual report, medium and high morbidity areas 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-based surveillance for Serosia, the staff who contributed to the report, etc.).

Executive summary

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

Introduction

The introduction includes a statement of objectives/purpose of the report dates and contents of previous reports.

Body of the report

The body of the report includes the methodology of how the data were collected and managed, and the results. This includes the following information:

- definitions of terms used in the surveillance report
- discussion of the quality and limitations of the data (such as timeliness and completeness)
- narrative interpretation of the data presented
- a presentation of the data in a logical sequence (for instance, beginning with the summary or general data and progressing to more specific display of data)
- data presented separately for HIV cases, advanced HIV disease, and AIDS or as combined HIV/advanced HIV/AIDS.

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

- HIV, advanced HIV disease and/or AIDS cases diagnosed in most recent calendar year(s)
- number and percentage of HIV, advanced HIV disease and/or AIDS 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).
- number, percentage and rates of HIV, advanced HIV disease and/or AIDS cases diagnosed by race/ethnicity in most recent calendar year (if applicable)
- information on trends in new diagnoses of HIV, advanced HIV disease and/or AIDS stratified by age and sex and transmission mode.

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 stages and CD4 counts):

- sex
 - age groups and sex
 - mode of exposure/sex.
- the number and percentage of persons living with advanced HIV disease (clinical stage 3 or 4 or CD4 count <350, including AIDS):
 - sex
 - age groups and sex
 - mode of exposure/sex.
- The number of persons living with AIDS (clinical stage 4 or CD4 count <200):
 - sex
 - age groups and sex
 - mode of exposure/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-emphasizes pertinent findings and integrates these findings into a comprehensive statement on the state of the epidemic.

Unit 6 Exercises

Warm-up review

Take a few minutes now to look back at your answers for the warm-up questions at the beginning of the unit. Make any changes you want.

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 surveillance 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 Serosia and are responsible for developing the annual HIV surveillance report. You have data from AIDS case reporting nationwide and from a single cohort of patients who received ART in a large urban clinic. 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 AIDS 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.

Table 6.1

AIDS incidence (per 1 000), 1999-2005, Serosia

| Year | Age group (years) | | |
|------|-------------------|-------|-------|
| | 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. The following table shows information from a clinic that has been providing ART to patients for a few years. Develop a figure that displays the data and provide explanatory text to accompany the figure.

Table: 6.2

Number of persons on ART, 2003-2005

| % on ART | 2003 | | 2004 | | 2005 | |
|----------|------|-------|------|-------|------|-------|
| | Men | Women | Men | Women | Men | Women |
| | 25% | 30% | 35% | 50% | 35% | 60% |

Unit 6 Summary

- Surveillance data should be analysed and disseminated so that they can be used for public health action.
- Surveillance programmes 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 disease) surveillance should wait until the reporting of cases that were diagnosed in the past is complete.
- When interpreting surveillance 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 practices or case definitions.
- Reports that summarize 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, as well as the general public.
- Before analysing and disseminating surveillance data, the surveillance system should be evaluated to make sure that it meets the minimum standards for completeness, timeliness and accuracy.

- Surveillance programmes must take care to ensure that any reports that use surveillance data do so in a way that protects confidentiality.
- Surveillance data 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 practices.
- Surveillance data may be presented as periodic (at least annual) surveillance reports, annual epidemiologic reports (that include surveillance data as well as additional strategic information), fact sheets, and presentations to specific audiences, such as the staff in the Ministry of Health.

Notes

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 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 disease?
 - a. timeline
 - b. key activities
 - c. responsible person
 - d. all of the above.
3. True or false? Case definitions for reporting HIV and AIDS 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 action on the HIV and AIDS 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 operational manual?

An operational manual is a written document that spells out the national policy and procedures on various aspects of HIV infection and AIDS case reporting, including case definitions, sources of data, reporting procedures, data confidentiality and

dissemination. An operational manual should serve the needs of the national AIDS programme and must be consistent with international guidelines on HIV surveillance and case reporting.

Additionally, an operational manual can serve other purposes, like:

- as a reference tool for healthcare workers and surveillance staff
- as a training tool to conduct initial and refresher training on case reporting
- as 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 unit in the national AIDS programme, should be responsible for preparing and distributing the operational manual.

Key sections of an operational manual

Key sections of an operational manual are briefly described below. (Refer to Appendix E and F)

1. Purpose of the HIV case reporting system

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

For 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 characterizing 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 mobilization. Finally, HIV case reporting will add to our understanding of the progression of HIV disease and the impact of ART, and in refining epidemiologic assumptions for estimating and projecting the impact of the HIV epidemic.

2. Reportable events and case definitions

This section lists selected events in the spectrum of HIV disease that should be emphasized 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 emphasized in the national HIV case reporting system. All countries in SEAR have an existing AIDS case reporting system, although the reporting of AIDS cases is highly incomplete (except in Thailand). In countries where AIDS case reporting is more than 80%, an AIDS case reporting system may be continued in order to monitor trends using historical data.

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 (which includes AIDS).

In addition, it is recommended that countries should also consider reporting early HIV infection cases that have not yet progressed to clinical stage 3 or 4. From a perspective of HIV prevention and care, it is undoubtedly of utmost importance to identify HIV infection cases early in order to prevent further spread of infection, as well as to provide the required care, counselling and psychosocial support to the infected individuals. From a surveillance perspective, a comprehensive system that detects HIV infection early is more useful, as it provides a better understanding of the HIV disease and a more complete picture of the HIV epidemic. Ultimately, all countries should aim to move toward the goal of identifying all HIV infections in the surveillance system. 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 in order 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 a few geographical areas. Based on the experience gained, further strategies of implementing a nationwide HIV case reporting system can be considered.

With regard to case definitions, it is recommended that all countries use the 2006 WHO case definitions for surveillance among adults and children.

3. Reporting sources

This section describes the types of facilities that will be included in the HIV case reporting system. The scope of reporting may include the public sector, NGOs and the private-sector facilities. Reporting of advanced HIV infection (including AIDS) requires clinical staging and (or) 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 centers, district hospitals, PMTCT centers, TB clinics, medical colleges, hospitals, etc. A complete list of such facilities should be created in every geographical area.

4. Variables and data collection forms

The central surveillance unit should identify a minimal set of variables that each reporting unit will be required to report on. Standard data collection forms should be developed and provided to all reporting units by the central surveillance unit. In selecting the variables, ensure that every 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 time of health workers at the expense of another programme activity. Therefore, case reporting forms should be carefully designed to avoid collecting non-essential 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.

Refer to Unit 3 for samples set of variables and sample case reporting forms.

5. Data transmission and reporting procedures

This section outlines how to report, who should report, to whom they should report, and when they should report. This section also describes the levels through which the data should flow from the collection source to the central level of analysis and dissemination.

For example, in a large country like India, a four-tier system may be used for data transmission. In this system, data are collected at the first level in a community health center (a health facility for a population of 1,00,000). Data are then forwarded to the second level—that is, the district surveillance unit—and then to the state surveillance unit, where data are entered in a computerized database. After data entry and removal of duplicate records, the electronic files are sent to the fourth level, which is the central surveillance unit.

On the other hand, in a small country such as Maldives, where few HIV cases are reported each year, HIV case reporting forms may be directly faxed to the national AIDS programme. As much as possible, data transmission should follow and build on the existing data transmission systems for HIV and other diseases.

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 units at the district/state/province level to the national level and back (the dissemination feedback loop).

6. Data management and analyses

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

8. Roles and responsibilities for programmes and personnel involved in HIV surveillance

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), sub-national surveillance staff (district/province/state level) and national surveillance staff. The roles and responsibilities should complement the data flow diagram and data reporting procedures.

Refer to Unit 3 for a sample list of roles and responsibilities.

9. Training of 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, for how many days, and when the training will occur.

To prepare a training plan, list all staff who are likely to be involved in 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 in order to fulfil his/her role in the HIV case reporting system. Using this list, prepare a teaching curriculum and teaching materials, including handouts/training manual. 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 case 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). Pay close attention to ensuring that 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 in accurately collecting this critical information.

The state-level surveillance staff must understand how to enter the data, how to identify duplicate records and how to clean the data. The national staff must be trained in data analysis, interpretation and report-writing. Additionally, all personnel involved in HIV surveillance (MOH and reporting sources/healthcare providers) must attend an annual confidentiality training (See Unit 3).

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 state/province. These trainers will, in turn, train other staff in the state/province, who, in turn, will train healthcare providers at the district level.

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

10. Data dissemination

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. 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 explains how the surveillance 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. Details on these topics are provided in Unit 5.

Apply what you have learned

Work with your country team members to discuss each of the following sections of the HIV case reporting 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.

Implementation plan

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 on surveillance
- determine activities
- determine responsible persons
- establish a deadline for completion of activities.

National Action Plan Worksheet

List of activities

- Identify stakeholders; debrief MoH and NAP.
- Finalize operational procedures manual.
- Finalize and pilot test forms.
- Conduct training of staff at reporting units (go through case report forms, data flow, roles and responsibilities within one month of finalizing forms and operational manual).
- Adapt state/provincial/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
- organizing the training(s) (facility, audiovisual equipment, supplies, etc.)
- evaluating the training
- conducting follow-up activities and site visits after the training in order to reinforce learning.

Timeline

Adding a deadline to an action plan helps you establish a realistic schedule. The sequence of events in planning a deadline 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 deadline?

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 following.

- 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 have learned

Work with your country team members and, using the template provided on the next page, prepare an action plan for implementing HIV case reporting system in your country. You may modify the template as you deem necessary. 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.

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:

NGOs:

International agencies/donors:

Others:
 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, e-mail address and role of each person.
 - Finalize operational procedures manual:
 - Finalize test forms:
 - Co-ordinate training (logistics, materials):
 - Instructors:
 4. List facilities in need of training.
 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).
 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 facilities in each and how many people each 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 funds
 - inadequate staff
- List your possible challenges in the column to the right.
10. List resources that you may be short of.
 11. How can SEARO and partner organizations help you to implement your plan?

**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 one month). | | | | | |
| 2. Finalize operational procedures manual (within two months). | | | | | |
| 3. Finalize test forms (within two months). | | | | | |
| 4. Conduct training of providers and labs (within one month of finalizing forms and operational manual). | | | | | |
| 5. Talk with statistics office to obtain death records (within two months). | | | | | |
| 6. Check national database to make sure it is set up appropriately. | | | | | |
| 7. Train data-entry persons and back-up staff. | | | | | |

Notes

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-surveillance and HIV/AIDS case reporting?

HIV sero-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 disease, advanced HIV disease (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 surveillance.

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 disease/AIDS case reporting?

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

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

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 disease (or AIDS); The prevalence of advanced HIV disease (or AIDS); Deaths from advanced HIV disease (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 Serosia in South-East Asia. Serosia 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 disease/AIDS incidence (clinical stages 3 and 4)*
- *Advanced HIV disease/AIDS prevalence*
- *HIV/AIDS mortality*

Developing methods of measuring each of these points in HIV disease may be very difficult. At the minimum, reporting of advanced HIV disease (clinical stages 3 and 4) should be developed. This would require the development of a standardized 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 HIV/AIDS case reporting. What programmes would you suggest using?
 - *treatment programmes;*
 - *tuberculosis (TB) programmes (especially those that conduct HIV testing among TB patients);*
 - *voluntary HIV counselling 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 AIDS 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 AIDS 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 disease

OR

Where CD4 testing is available, any clinical stage and CD4 count <350 cells/mm³

For infant, the AIDS case definition is:

The presence of HIV infection

AND EITHER

Any clinical stage 3 or stage 4 disease

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/mm³ in children aged 5 years and above*

3. True or false? The clinical criteria included in the revised (2006) WHO AIDS 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.

4. 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.

5. 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 disease (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 Serosia, you are charged with standardizing the country's HIV/AIDS reporting practices. What processes would you implement to insure that HIV/AIDS reporting is standardized?

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 disease 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.
2. Serosia recently began providing free antiretroviral therapy to HIV-infected individuals. Serosia 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 Serosia. 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/mm³
- WHO clinical stage 1 or 2 whose CD4 count is ≤ 200 cells/mm³.

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

If CD4 testing is not available, a total lymphocyte count ≤ 1200 cells/mm³ 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/mm³

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 disease cases
 - b. To provide information on the opportunistic infections associated with advanced HIV disease
 - c. *To measure HIV incidence*
 - d. To determine the burden of disease attributable to advanced HIV disease in the region.
2. Which of the following describes case-based HIV surveillance?
 - a. All HIV cases reported in a given time period are summarized 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 care 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).
4. List three potential sources for HIV case reports.

Any of the following:

- *laboratories*
- *healthcare clinics (health centers)*
- *ART treatment clinics*
- *tuberculosis (TB) clinics*
- *voluntary HIV counselling and testing (VCT) sites*
- *hospice (for advanced HIV disease)*
- *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).*

Case study

Work on this case study independently.

You are the district surveillance officer for an urban district in Serosia, a mid-sized country in South-East Asia with a concentrated HIV epidemic. In Serosia, AIDS case reporting has been conducted for many years, but is incomplete. Serosia has opted to conduct reporting of advanced HIV infection (disease) 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.

Answer.

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

Answer.

Unit 4 Answers

Warm-up questions

1. List three aspects of a disease under surveillance that an effective surveillance 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.

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

- 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, confidentiality does not need to be addressed.

True False

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 surveillance 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 disease. 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 stigmatization. They may even be subject to criminal charges.

- a. privacy
- b. informed consent
- c. confidentiality
- d. beneficence

4. 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.

5. 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 surveillance for Inyo Province in Serosia. 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 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.

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 surveillance 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 surveillance report is an optional element.
False. The conclusion should be included and should re-emphasize 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 practices may result in a false increase or decrease in AIDS incidence.
True. Changes in reporting practices 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 practices 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 practices, such as reporting delays. The date of report should be used to evaluate timeliness of case reporting.

5. *True or false? Increases in the number of persons receiving ART can result in a decrease in AIDS incidence (new diagnoses of HIV clinical stage 4 disease) regardless of the number of new HIV infections occurring.*
True. ART can delay the clinical progression of HIV disease, 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 surveillance reports on HIV/AIDS?
 - a. *people who contribute to collecting the surveillance data*
 - 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 Serosia and are responsible for developing the annual HIV surveillance report. You have data from AIDS case reporting nationwide and from a single cohort of patients who received ART in a large urban clinic. 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 disease, as well as those with advanced HIV disease. 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).

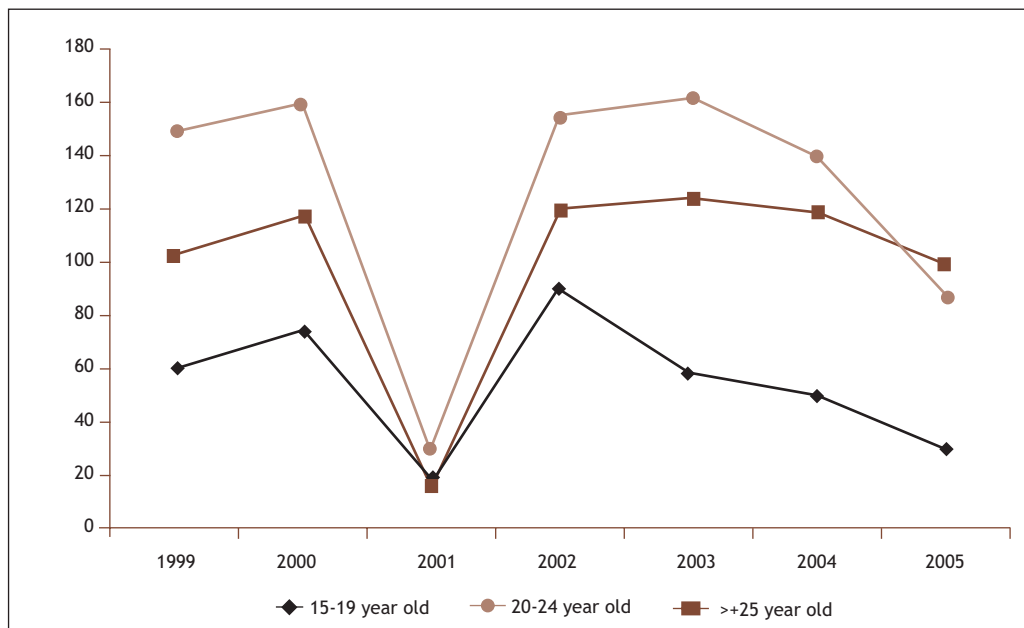
The characteristics of all persons with HIV (that is, after combining all reports of persons with HIV and advanced HIV disease) should be used to show the characteristics of reported cases as well as trends. The data can be stratified by geographic region, age, gender, transmission category (mother-to-child,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

2. The following table shows the AIDS case incidence rates from universal case reporting 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.

AIDS Incidence (per 1000), 1999-2005, Serosia

| Year | Age group (years) | | |
|------|-------------------|-------|------|
| | 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

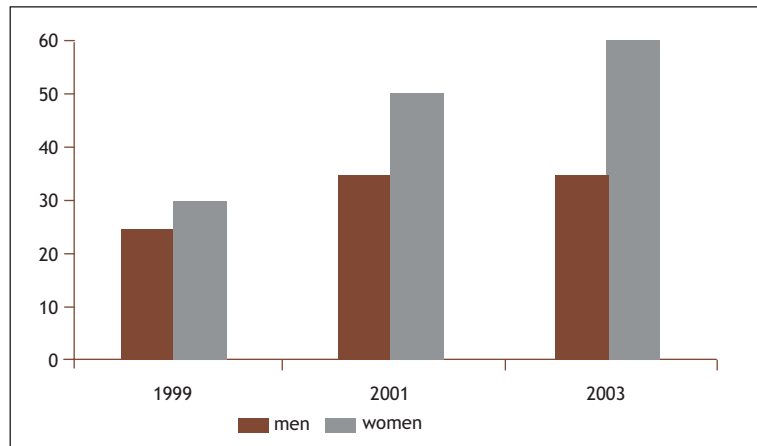


3. What would you write in your report about these data (that is, what is your interpretation of these data)?

AIDS incidence is lowest in the 15-19 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. The following table provides information from a clinic that has been providing ART to patients for a few years. Develop a figure that displays the data and provide explanatory text to accompany the figure.

| | 2003 | | 2004 | | 2005 | |
|----------|------|-------|------|-------|------|-------|
| % on ART | Men | Women | Men | Women | Men | Women |
| | 25% | 30% | 35% | 50% | 35% | 60% |



Proportion of men and women receiving ART, 2003-2005

Between 2003 and 2005, the proportion of both men and women receiving ART increased. Overall, a greater proportion of women received ART than men. The proportion of men on ART increased from 25% in 2003 to 35% in 2005, while for women this proportion increased from 30% in 2003 to 60% in 2005.

Unit 7 Answers

Warm-up questions

1. List the key sections of an operational manual.

The key sections of an operational manual are:

1. Purpose of the HIV case reporting system
2. Reportable events and case definitions
3. Reporting sources
4. Variables and data collection forms
5. Data transmission and reporting procedures
6. Data management and analyses
7. Data security and confidentiality procedures
8. Roles and responsibilities for programmes and personnel involved in HIV surveillance
9. Training of staff in data collection, management and analyses
10. Data dissemination
11. Standards and monitoring

2. Which of the following are elements in an implementation plan to initiate reporting of HIV or advanced HIV disease?
 - a. timeline
 - b. key activities
 - c. responsible person
 - d. *all of the above*

The answer is d. All these are elements in an implementation plan.

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

True.

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 Surveillance'

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 :

Acknowledgments

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

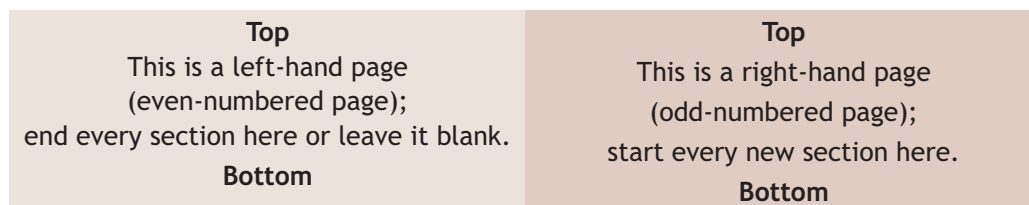
Follow the lead of other documents developed and released by your Ministry.

Table of Contents

Add/generate here. If the Table of Contents is only one page, keep 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...



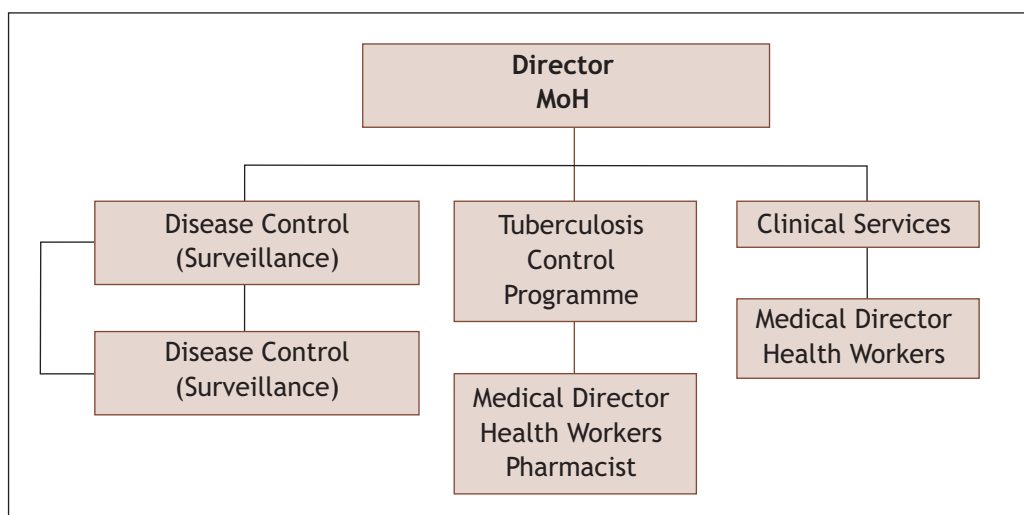
Mission Statement

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

Organizational Chart

This section outlines the organizational structure of the Ministry of Health. It includes the surveillance unit and other programme units. 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 organizational 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 unit 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 organizational 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 surveillance. 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 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 the following functions:

- 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 Serosia | 123-456-6789 (ph) 123-456-7890 (fax) Email: brown-smith@serosia.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 unit should also be apprised of the changes in the surveillance 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 surveillance (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 Surveillance

- a. This section details the roles and responsibilities 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 programme should perform. Identify appropriate staff/positions that will be responsible for each of these functions.

Functions of the HIV/AIDS surveillance programme:

- solicit, receive, review and file HIV/AIDS 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 surveillance database that is secure and has limited access by authorized 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 surveillance data
- critically assess the performance of the surveillance programmes through on-going evaluations of surveillance activity.

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 surveillance 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 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).

COUNTRY: _____

| Manual Section | Section completed in workshop | Source of information | Comment |
|---|-------------------------------|-----------------------|---------|
| Mission statement | To be done in-country | | |
| Organizational 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 (surveillance reports, Epi profile, NAP, indicators, etc.) | | | |
| How to fill out case report form - variables, definitions etc. | | | |
| Standards and monitoring <ul style="list-style-type: none"> • data quality. • timeliness. | | | |

This training module introduces HIV case surveillance with an emphasis on WHO clinical staging and surveillance case definitions, ethical and confidentiality considerations, analysis and presentation of surveillance data and operationalizing an HIV case reporting system. After completing this course, participants will learn how to:

- set up an HIV case reporting system
- analyse reported HIV and AIDS data
- use surveillance data for planning of prevention, care and treatment services
- monitor the HIV case reporting system
- prepare national guidelines on HIV/AIDS case reporting.

This course is meant primarily for district-level surveillance officers. This module can also be used for self-study.



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