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WHO-recommended standards for surveillance of selected vaccine-preventable diseases



WHO

Vaccines and Biologicals

World Health Organization

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(for further information please contact epidata@who.int)

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Copies may be requested from:
World Health Organization
Department of Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• Fax: + 41 22 791 4227 • Email: vaccines@who.int •

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Abbreviations

AFRO	World Health Organization Regional Office for Africa
AFP	acute flaccid paralysis
AMRO	World Health Organization Regional Office for the Americas
CIE	counterimmunoelectrophoresis
CSF	cerebrospinal fluid
DTP3	third dose of diphtheria–tetanus–pertussis vaccine
EMRO	World Health Organization Regional Office for the Eastern Mediterranean
EPI	Expanded Programme on Immunization
EURO	World Health Organization Regional Office for Europe
HAV	hepatitis A virus
HBc	hepatitis B core
HBV	hepatitis B virus
HCV	hepatitis C virus
HDV	hepatitis D virus
HEV	hepatitis E virus
HBsAg	hepatitis B surface antigen
HepB3	third dose of hepatitis B vaccine
Hib	<i>Haemophilus influenzae</i> type b
Hib3	third dose of <i>Haemophilus influenzae</i> type b vaccine
IgA	immunoglobulin A
IgG	immunoglobulin G
IgM	immunoglobulin M
ml	millilitre
NT	neonatal tetanus
Nm	<i>Neisseria meningitidis</i>
OPV3	third dose of oral polio vaccine
PAB	protected at birth
PCR	polymerase chain reaction

SEARO	World Health Organization Regional Office for South-East Asia
SIA	supplementary immunization activity
Sp	<i>Streptococcus pneumoniae</i>
TT	tetanus toxoid
TT2+	second and subsequent doses of tetanus toxoid
WHO	World Health Organization
WPRO	World Health Organization Regional Office for the Western Pacific

Introduction

The purpose of this document is to provide WHO recommendations on surveillance standards for selected vaccine-preventable diseases. The recommendations should be carefully adapted to meet national needs in accordance with each country's disease control priorities, objectives and strategies.

Disease surveillance is the routine ongoing collection, analysis and dissemination of health data. An effective surveillance system has the following functions:

- detection and notification of health events;
- collection and consolidation of pertinent data;
- investigation and confirmation (epidemiological, clinical and/or laboratory) of cases or outbreaks;
- routine analysis and creation of reports;
- feedback of information to persons providing data;
- feed-forward (i.e. the forwarding of data to more central levels).

The rationale for the surveillance of a specific health event should be established and based on clear national priorities, disease control objectives and strategies. Otherwise the data collected may be irrelevant. What data to collect depends on the analyses that are needed to guide decision-making on matters of public health. In order not to overburden health staff at the peripheral levels the surveillance system should be as streamlined as possible, i.e. the *minimum necessary* amount of data should be collected. The most efficient and appropriate means of collecting, consolidating and transferring such data should be employed. Staff at all levels should be trained and encouraged to analyse and *use* their data. Data that can be more efficiently collected from other sources (e.g. surveys) should not be included in a surveillance system.

An effective surveillance system is:

- useful;
- efficient;
- flexible;
- representative;
- simple.

These attributes should be assessed when evaluating a surveillance system.

At the national level, clear surveillance standards should be established to achieve maximum efficiency and ensure that data are comparable throughout the country concerned. These standards cover:

- case definitions;
- the type of surveillance to be conducted;
- the data elements to be collected;
- the minimum analyses and routine reports to be produced;
- the use of data in decision-making.

To achieve operational surveillance it is necessary to carefully define:

- the process of surveillance;
- the tasks at each level;
- the data/specimen flow;
- the logistics, including staff issues:
 - designations of staff;
 - staff training;
 - appropriate tool distribution (e.g. means of communication, transportation, specimen kits).

Standard performance indicators should be monitored as a part of supervision to identify weaknesses in the system so that corrective action can be taken.

Acute viral hepatitis

Rationale for surveillance

Several distinct infections are grouped as viral hepatitis. Transmission is mainly through the oral-faecal route for hepatitis A and E, and percutaneous exposure to body fluids, including sexual intercourse, for hepatitis B, C and D. The course of the disease may be fulminating (e.g. hepatitis E in pregnancy); chronic infection and severe sequelae occur mainly in hepatitis B, C and D.

Control measures for blood-related transmission include ensuring transfusion safety, injection safety and (for hepatitis A and hepatitis B at least) immunization. Hepatitis B is targeted by WHO for reduced incidence/prevalence.

Recommended case definition

Clinical description

An acute illness typically including acute jaundice, dark urine, anorexia, malaise, extreme fatigue and right upper quadrant tenderness. Biological signs include increased urine urobilinogen and >2.5 times the upper limit of serum alanine aminotransferase.

Note: Most infections occur during early childhood.
A variable proportion of adult infections are asymptomatic.

Laboratory criteria for diagnosis

Hepatitis A: positive for IgM anti-HAV.
Hepatitis B: positive for IgM anti-HBc **or** (less desirably) hepatitis B surface antigen (HBsAg).
Non-A, non-B: negative for IgM anti-HAV and IgM anti-HBc **or** (less desirably) HbsAg.

Note: The anti-HBc IgM test, specific for acute infection, is not available in most countries. HbsAg is often available but is less desirable since it cannot distinguish acute new infections from exacerbation of chronic hepatitis B. Nevertheless, continued HBsAg seropositivity (> six months) is an indicator of chronic infection. For patients with non-A, non-B, the following testing is used for a diagnosis of acute hepatitis C, D or E.

Hepatitis C: positive for anti-HCV.
Hepatitis D: positive for IgM anti-HBc **or** (less desirably) HBsAg plus anti-HDV- positive (N.B. only occurs as co-infection or superinfection of hepatitis B).
Hepatitis E: positive for IgM anti-HEV.

Case classification

Suspected: A case that is compatible with the clinical description.
Probable: Not applicable.
Confirmed: A suspected case that is laboratory-confirmed **or**, for hepatitis A only, a case compatible with the clinical description in a person who has an epidemiological link (i.e. household or sexual contact with an infected person during the 15-50 days before the onset of symptoms) with a laboratory-confirmed case of hepatitis A.

Acute viral hepatitis (continued)

Recommended types of surveillance

- Routine monthly reporting of aggregated data on suspected cases, and, if available, the number of confirmed cases of each type of hepatitis should be reported from the peripheral level to the intermediate and central levels.
- Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).
- All outbreaks should be investigated immediately and confirmed serologically.

Recommended minimum data elements

Aggregated data:

- Number of third doses of hepatitis B vaccine (HepB3) administered to infants.
- Number of suspect cases.
- If available, number of confirmed cases for each type of hepatitis.

Recommended data analyses, presentations, reports

(from multiple sources of data in addition to surveillance data):

- HepB3 coverage in infants by year and geographical area.
- Number of acute viral hepatitis cases and incidence rate by year, month, geographical area and (if data exist) age group.
- Where data exist on etiological agent, incidence rate of each type of acute viral hepatitis by geographical area, year, month and age group.
- Proportion of all cases of chronic liver disease, cirrhosis and primary liver cancer that are HBsAg-positive or anti-HCV-positive (see special aspects section).

Principal uses of data for decision-making

- Monitor HepB3 coverage by geographical area to measure areas with weak performance and take action.
- Investigate all suspected/reported outbreaks.
- Determine the specific cause of acute viral hepatitis cases (reported routinely or during outbreaks) so that corrective measures can be taken.
- Understand the epidemiology of hepatitis by etiological agent in terms of distribution over time, by age group and geographical area.
- Measure the incidence (including age-specific incidence) and prevalence of HBsAg and anti-HCV.
- Measure the proportion of cases of acute viral hepatitis, chronic liver disease, cirrhosis and primary liver cancer that are hepatitis B virus or hepatitis C virus carriers to:
 - 1) determine the burden of the disease in the population;
 - 2) prioritize it among other diseases of public health importance;
 - 3) choose the proper strategies for its control.

Acute viral hepatitis (continued)

Special aspects

Surveillance data on acute viral hepatitis from developing countries should be interpreted with caution. Differentiation of types of viral hepatitis (A to E) based on clinical diagnosis is unreliable and serological testing is necessary for accurate diagnosis. Unfortunately, many developing countries do not have access to diagnostic reagents. Most infections with hepatitis A, B, C and E virus occur asymptotically (in developing countries usually among children) and are not detected and reported to the surveillance system. Therefore, a low incidence of acute viral hepatitis should not be misinterpreted as a low prevalence of viral hepatitis infection.

Understanding the epidemiology and burden of disease of viral hepatitis requires an understanding of the sequelae of hepatitis B, C and D infection. These include asymptomatic chronic infection, chronic hepatitis, cirrhosis and primary liver cancer. Measuring the burden of these conditions requires data collection from sources not traditionally used by infectious disease epidemiologists, including data on hospital discharge and mortality (for chronic hepatitis, cirrhosis and liver cancer) and cancer registers. Special seroprevalence surveys may be needed to measure the prevalence of hepatitis B and hepatitis C infection in the general population and in special groups such as blood donors, pregnant women, military recruits, health care workers, certain patient groups (e.g. patients with liver disease, people on dialysis, haemophiliacs) and ethnic subpopulations.

The assessment of coverage of hepatitis B vaccine is similar to that of other vaccines used for routine immunization. Vaccine is given to infants (and in some industrialized countries to adolescents) primarily to prevent the development of chronic liver disease and liver cancer. Serological testing for documenting seroconversion in children is usually unnecessary: numerous studies have shown that the vaccine is 85% to 100% effective in preventing chronic infection.

Bacterial meningitis (including *Haemophilus influenzae* type b (Hib), *Neisseria meningitidis*, and *Streptococcus pneumoniae*)

Rationale for surveillance

Bacterial meningitis is one of the most feared infectious diseases of children and epidemic meningitis can have a devastating impact on entire populations. Until recently, antibiotic treatment of cases, and, in some situations, chemoprophylaxis of contacts, was the only means of control. Now, however, vaccines are available for prevention of the major causes of bacterial meningitis – *Streptococcus pneumoniae* (Sp or pneumococcus), *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* (Nm or meningococcus). Hib and the pneumococcus are also the most common causes of severe bacterial pneumonia, a leading cause of death in young children in the developing world.

Surveillance, including the laboratory investigation of suspected cases, is critical for the early detection of epidemics and formulating an appropriate response, clarifying the burden of disease and evaluating the impact of immunization services (see also the section: Principal uses of data for decision-making). Routine bacterial meningitis surveillance focuses on meningitis and other 'invasive' infections such as sepsis, which can be diagnosed with microbiological tests on cerebrospinal fluid (CSF) and blood.

Recommended case definition

Clinical description

Bacterial meningitis is characterized by acute onset of fever (usually > 38.5 °C rectal or 38.0 °C axillary), headache and one of the following signs: neck stiffness, altered consciousness or other meningeal signs. Hib, meningococcal meningitis and pneumococcal meningitis cannot be differentiated on clinical grounds alone.

Laboratory criteria for diagnosis

Bacterial meningitis can be confirmed by three methods. (1) Culture method: isolation of a bacterial pathogen from a normally sterile clinical specimen such as CSF or blood. (2) Antigen detection methods: identification of a bacterial antigen in normally sterile fluids (i.e. CSF or blood) by such methods as latex agglutination or counterimmunoelectrophoresis (CIE). (3) Gram stain results.

Case classification

Suspected: Any person with sudden onset of fever (> 38.5 °C rectal or 38.0 °C axillary) and one of the following signs: neck stiffness, altered consciousness or other meningeal sign.

Probable: A suspected case with CSF examination showing at least one of the following:

- turbid appearance;
- leukocytosis (> 100 cells/mm³);
- leukocytosis (10-100 cells/mm³) AND either an elevated protein (> 100 mg/dl) or decreased glucose (< 40 mg/dl).

Bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitidis and Streptococcus pneumoniae) (continued)

Recommended case definition (continued)

Confirmed: A case that is laboratory-confirmed by growing (i.e. culturing) or identifying (i.e. by Gram stain or antigen detection methods) a bacterial pathogen (Hib, pneumococcus or meningococcus) in the CSF or from the blood in a child with a clinical syndrome consistent with bacterial meningitis.

Note: Any persons with *H. influenzae*, meningococcus or pneumococcus isolated from CSF or blood may be reported as confirmed cases of meningitis if their clinical syndrome was meningitis (i.e. culture from normally sterile fluids is the gold standard). Culture of Hib, pneumococcus or meningococcus from a non-sterile site, such as the throat, does not confirm a case of disease, since the bacteria can grow in these other areas without causing disease.

Recommended types of surveillance

- Surveillance of suspected and confirmed cases:
 - epidemic season: routine *weekly* reporting of surveillance data is recommended from the peripheral level to the intermediate and central levels.
Note: During the epidemic season, it is important to have a well-functioning system for reporting cases and deaths of suspected meningitis in all provinces and to have laboratory confirmation of initial cases in every epidemic district.
 - inter-epidemic season and throughout the year in countries without epidemic meningitis: routine *monthly* reporting of surveillance data is recommended from the peripheral level to the intermediate and central levels.
Note: The extent of surveillance during the inter-epidemic season and throughout the year in countries without epidemic meningitis varies with the capabilities of individual countries. Hospital-/clinic- or laboratory-based sentinel surveillance may be sufficient to fulfil the goals noted in the Rationale section above (see also Principal uses of data for decision-making at the end of the section). In this context, it is more important to have a well-functioning system in some areas than to have a national system that functions poorly.
 - designated sites at all levels should report even if there are zero cases (referred to as “zero reporting”).
- Probable cases should also be reported if laboratory performance indicators are to be monitored.

Recommended minimum data elements

Aggregated data for reporting

- Number of suspected and confirmed (not confirmed/ Nm/ Sp or Hi/ other) cases.
- Number of deaths among suspected and confirmed (not confirmed/ Nm/ Sp or Hi/ other) cases.
- Number of Nm AC/ACW/ACWY vaccine doses administered and coverage (%).
- Number of third doses of Hib vaccine (Hib3) administered to infants.

Bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitidis and Streptococcus pneumoniae) (continued)

Recommended minimum data elements (continued)

Case-based data for reporting and investigation

- Unique identifier.
- Date of report: dd/mm/yyyy
- Geographical area (e.g. village, district and province names).
- Age or Date of birth: dd/mm/yyyy
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of admission: dd/mm/yyyy
- Admission diagnosis
- Outcome/discharge status: 1 = alive; 2 = discharge with extremely poor prognosis; 2 = dead; 9 = unknown.
- Vaccination status, Nm: Number of Nm AC/ACW/ACWY (indicate vaccine) doses received in the past 3 years: 1, 2, 3, 9 = unknown.
- Vaccination record, Nm vaccine: 1= card confirmed; 2=verbal report, no card; 8 = not applicable.
- Vaccination status, Hib: Number of doses received, ever: 1, 2, 3, 4, 9 = unknown.
- Vaccination record, Hib vaccine: 1= card confirmed; 2=verbal report, no card; 8 = not applicable.
- Specimen type, if specimen collected: 1=CSF; 2=blood; 3=both CSF and blood; 4=other; 6=no specimen collected; 9=unknown.
- Optional: CSF appearance: 1=clear, 2=xanthochromic, 3=cloudy/turbid, 8=unknown.
- Optional: CSF white cell count/ml _____ (enter 88888 if not done; enter 99999 if data are missing).
- Gram stain: 1=negative; 2=*S. pneumoniae* (Gram-positive diplococci); 3=*H. influenzae* (small, pleomorphic Gram-negative rods or coccobacilli); 4=*N. meningitidis* (Gram-negative, diplococci); 5=other/contaminated; 6=not done; 7=pending; 8=missing data.
- Latex agglutination: 1=negative; 2=*S. pneumoniae*; 3=*H. influenzae type b*; 4=*N. meningitidis A*; 5=*N. meningitidis W135*; 5=other/contaminated; 6=not done; 7=pending; 8=missing data.
- Culture, if obtained: 1=no growth; 2=*S. pneumoniae*; 3=*H. influenzae*; 4=*N. meningitidis*; 5=other/contaminated; 6=not done; 7=pending; 8=missing data.
- Anti-sera grouping or typing of culture: 1=negative; 2=*H. influenzae type b*; 3=*N. meningitidis A*; 4=*N. meningitidis W135*; 5=*N. meningitidis C or Y*; 6=indeterminate; 7=not done/pending; 8=missing data.
- Final case classification: 1=suspected; 2=probable; 3=confirmed.
- Final laboratory classification: 1=Sp, 2=Hib, 3=Hi (unknown or other type), 4=Nm A, 5=Nm W135, 6=Nm (unknown or other serogroup), 7=other/contaminated, 8=not done/undetermined.

Note: The efficacy of Hib vaccines for the prevention of meningitis is more than 90% but less than 100%. The occurrence of patients with Hib meningitis who have a history of vaccination can therefore be expected. The efficacy of Nm vaccines is also less than 100%. A history of vaccination should not influence the final case classification or final laboratory classification.

Bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitidis and Streptococcus pneumoniae) (continued)

Recommended data analyses, presentations, reports

Aggregated data

- Hib3 coverage (%) by year and province.
- Dates of Nm campaign, vaccine used (AC/ACW/ACWY), target age group and coverage (%), by province.
- Zero-reporting, completeness of reporting and timeliness of reporting.
- Epidemic season
(see also: www.who.int/csr/disease/meningococcal/epidemiological/en/)
weekly reporting of suspected and confirmed meningitis cases:
 - map: show alert and epidemic provinces (see also: WER; 38: 306-309; <http://www.who.int/wer/pdf/2000/wer7538.pdf>);
 - for every province, graph: total number of suspected cases (axis 1: columns) and case fatality ratio (axis 2: line); include an indication on the graph of when vaccination campaigns begin and end, Nm vaccine used (AC/ACW/ACWY) and coverage (%); include on the graph the serogroup distribution (A, W135) of confirmed *N meningitidis* cases, when available.
- Inter-epidemic season reporting and throughout the year in countries without epidemic meningitis (the following analyses can also be performed for Sp, Hib and Nm, separately, using data from confirmed cases):
 - monthly reporting, nationally and by province: total number of suspected cases (axis 1: columns) and case fatality ratio (axis 2: line).

Case-based data, same as for aggregated data plus:

- Cases by immunization status, separately for Hib and Nm, nationally and by province.
- Epidemic season
 - weekly reporting of suspected and confirmed meningitis cases:
 - for *alert and epidemic* provinces, graph: suspected case incidence rate by age group (0-23m, 2-4y, 5-14y, 15-29y, 30-45y, 45+y).
 - for *alert and epidemic* provinces, graph: case fatality ratio among suspected cases by age group (0-23m, 2-4y, 5-14y, 15-29y, 30-45y, 45+y).
 - for *alert and epidemic* provinces, table: vaccination status (card/ verbal, no card/ no vaccination) of confirmed Nm cases, by serogroup.
 - for *alert and epidemic* provinces, table: vaccination status (card/ verbal, no card/ no vaccination) of deaths among confirmed Nm cases, by serogroup.
- Inter-epidemic season reporting and throughout the year in countries without epidemic meningitis (the following analyses can also be performed for Sp, Hib and Nm, separately, using data from confirmed cases):
 - monthly reporting, nationally and by province, of:
 - suspected cases by age group (0m, 1-5m, 6-11m, 12-23m, 2-4y, 5+y).
 - case fatality ratio among suspected cases by age group (0m, 1-5m, 6-11m, 12-23m, 2-4y, 5+y).
 - vaccination status (card/ verbal, no card/ no vaccination) of confirmed cases, by pathogen (Sp, Hib, Nm).
 - vaccination status (card/ verbal, no card/ no vaccination) of deaths among confirmed cases, by pathogen (Sp, Hib, Nm).

Bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitidis and Streptococcus pneumoniae) (continued)

Recommended data analyses, presentations, reports (continued)

• **Performance indicators of surveillance quality**

- Percentage of all probable cases for which CSF/blood was obtained for evaluation ≥ 90%
- Percentage of probable cases in which a bacterial pathogen was identified from CSF or blood:
 - Among CSF with 10 or more white blood cells/ml³ ≥ 15%
 - Among CSF with 100 or more white blood cells/ml³ ≥ 40%
- Percentage of CSF isolates which are *H. influenzae* ≥ 20%

Note: Although persons with bacterial meningitis have a wide range of CSF white blood cell counts the proportion of probable bacterial meningitis cases with identifiable bacterial causes increases with increasing CSF cell counts. For the evaluation of performance, immunization personnel may wish to determine the proportion of potential bacterial meningitis cases in which bacterial causes have been identified in one or both of the above categories. Results below the target levels suggest that some cases of bacterial meningitis are not being identified from the probable cases and that laboratory and clinical practices should be reviewed.

Principal uses of data for decision-making

- During the epidemic season:
 - 1) the timely detection of epidemics,
 - 2) the timely identification of the causal pathogen,
 - 3) the provision of sufficient antibiotics for case management, and
 - 4) the selection and provision of the appropriate vaccine for epidemic response.
- At any time, to describe the epidemiology of bacterial meningitis by etiological agent in order to:
 - 1) determine the local disease burden (cases, deaths, disability);
 - 2) prioritize bacterial meningitis among other diseases of public health importance;
 - 3) advocate for and implement the proper control strategies such as immunization;
 - 4) evaluate the impact of immunization services, identify areas with weak performance and provide assistance.

Bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitidis and Streptococcus pneumoniae) (continued)

Special aspects

During the epidemic season, it is important to have a well-functioning system for reporting cases and deaths of suspected meningitis in all provinces and to have laboratory confirmation of initial cases in every epidemic district.

The extent of surveillance during the inter-epidemic season and throughout the year in countries without epidemic meningitis varies with the capabilities of individual countries. Hospital-/clinic- or laboratory-based sentinel surveillance may be sufficient to fulfil the goals noted in the Rationale section above (see also Principal uses of data for decision-making above). In this context, it is more important to have a well-functioning system in some areas than to have a national system that functions poorly. For example, hospital-based sentinel surveillance for bacterial meningitis is being implemented in many African countries.

Surveillance in areas with appropriate clinical and laboratory capacity can provide necessary information on epidemic detection and investigation, disease burden and immunization impact. However, coverage data should be obtained nationwide. Evaluating the combination of nationwide coverage data and area-specific disease data can provide necessary information for making decisions about immunization services.

Additional guidance on surveillance methodology may be obtained from:

- Detecting meningococcal meningitis epidemics in highly-endemic African countries. Weekly Epidemiological Record 2000; 38: 306-309; (<http://www.who.int/wer/pdf/2000/wer7538.pdf>);
- A protocol for population-based surveillance (WHO unpublished document WHO/VRD/GEN/95.05);
- The WHO AFRO Hib-Paediatric Bacterial Meningitis (Hib-PBM) Surveillance Network Surveillance Manual, Field Test Version, July 2001 (WHO unpublished document); and
- Laboratory Methods for the Diagnosis of Meningitis Caused by *Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae* (WHO unpublished document WHO/CDS/EDC/99.7).

Diphtheria

Rationale for surveillance

Diphtheria is a widespread severe infectious disease that has the potential for causing epidemics. The control of diphtheria is based on the following three measures.

1) Primary prevention of disease by ensuring high population immunity through immunization. 2) Secondary prevention of spread by the rapid investigation of close contacts to ensure their proper treatment. 3) Tertiary prevention of complications and deaths by early diagnosis and proper management. Surveillance data can be used to monitor levels of coverage (target > 90%) and disease as a measure of the impact of control programmes. Recent epidemics have highlighted the need for adequate surveillance and epidemic preparedness.

Recommended case definition

Clinical description

An illness characterized by laryngitis **or** pharyngitis **or** tonsillitis, **and** an adherent membrane of the tonsils, pharynx and/or nose.

Laboratory criteria for diagnosis

Isolation of *Corynebacterium diphtheriae* from a clinical specimen, **or** a fourfold or greater rise in serum antibody (but only if both serum samples are obtained before the administration of diphtheria toxoid or antitoxin).

Case classification

Suspected: Not applicable.

Probable: A case that meets the clinical description.

Confirmed: A probable case that is laboratory-confirmed or linked epidemiologically to a laboratory-confirmed case.

Note: Persons with positive *C. diphtheriae* cultures who do not meet the clinical description (i.e. asymptomatic carriers) should not be reported as probable or confirmed diphtheria cases.

Recommended types of surveillance

- Routine monthly reporting of aggregated data on probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.
- Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).
- All outbreaks should be investigated immediately and case-based data should be collected.
- In countries achieving low incidence (usually where coverage is > 85-90%), immediate reporting of case-based data of probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

Diphtheria (continued)

Recommended minimum data elements

Aggregated data:

- Number of cases.
- Number of third doses of diphtheria toxoid containing vaccine (e.g. DTP3) administered to infants.

Case-based data:

- Unique identifier.
- Geographical area (e.g. district name).
- Date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of onset.
- Date of first treatment.
- Treatment type: 1 = antibiotic and antitoxin; 2 = antibiotic only; 3 = antitoxin only; 4 = no or other treatment; 9 = unknown.
- Laboratory result: 1 = toxigenic *C. diphtheriae* isolated; 2 = non-toxigenic *C. diphtheriae* isolated; 3 = *C. diphtheriae* isolated, toxigenicity unknown; 4 = *C. diphtheriae* not isolated; 5 = no specimen processed; 9 = unknown.
- Total diphtheria vaccine (DTP, DT or Td) doses received.
- Date of last dose.
- Final classification of the case: 1 = confirmed; 2 = probable; 3 = discarded.
- Outcome: 1 = alive; 2 = dead; 9 = unknown.

Recommended data analyses, presentations, reports

Aggregated data:

- Number of cases and incidence rates by month, year and geographical area.
- DTP3 coverage by year and geographical area.
- Completeness/timeliness of monthly reporting.
- Proportional morbidity (compared to other diseases of public health importance).

Case-based data - same as aggregated data plus the following:

- Age-specific, sex-specific and district-specific incidence rates by month and year.
- Cases by immunization status, laboratory results, treatment type.
- Cases treated on time (\leq seven days of onset).
- Case-fatality ratio
- Proportional mortality (compared to other diseases of public health importance).

Diphtheria (continued)

Principal uses of data for decision-making

- Monitor case fatality ratio and, if high, determine cause (e.g. poor case management, lack of antibiotics/antitoxin, patients not seeking treatment in time) so that corrective action can be taken.
- Determine age-specific incidence rate, geographical area and season of diphtheria cases to know risk groups and risk periods.
- Monitor incidence rate to assess impact of control efforts.
- Monitor immunization coverage per geographical area to identify areas of poor programme performance.
- Detect outbreaks and implement control measures.
- Investigate outbreaks to understand epidemiology, determine why outbreaks have occurred (e.g. vaccine failure, failure to immunize, accumulation of susceptibles, waning immunity, new toxigenic strain) and ensure proper case management.

Note: In addition to surveillance, carefully designed serological studies can be used to monitor the immune status of different age groups.

Special aspects

Measles

Rationale for surveillance

The global *Measles Mortality Reduction and Regional Elimination Strategic Plan 2001–2005* (WHO/V&B/01.13) seeks to reduce the number of measles deaths by half by 2005 (compared with 1999 estimates) and to achieve and maintain interruption of indigenous measles transmission in large geographical areas with established elimination goals. Surveillance for measles should evolve with each phase of measles control. Countries in the mortality reduction phase, where the disease is endemic should concentrate on raising routine measles immunization coverage and focusing supplemental immunization efforts in areas with high measles mortality. Countries with more advanced measles control or in the elimination phase are achieving high levels of population immunity against measles and low incidence with or without periodic outbreaks. Surveillance in these countries should be used to identify high-risk populations and to predict and prevent potential outbreaks. Countries in which the objective is to completely interrupt measles transmission (or countries with very low incidence) require intensive case-based surveillance to detect, investigate and confirm every suspected measles case in the community.

Recommended case definition

Clinical case definition

Any person in whom a clinician suspects measles infection, **or**

Any person with fever **and** maculopapular rash (i.e. non-vesicular) **and** cough, coryza (i.e. runny nose) or conjunctivitis (i.e. red eyes).

Laboratory criteria for diagnosis

Presence of measles-specific IgM antibodies.

Case classification

Countries are advised to use the clinical classification scheme until their programmes meet the following two criteria:

- low levels of measles incidence;
- access to a proficient measles laboratory.

The laboratory classification scheme should be used by countries in the low incidence or elimination phase.

Clinical classification scheme

Clinically confirmed: A case that meets the clinical case definition.

Discarded: A suspect case that does not meet the clinical case definition.

Laboratory classification*

Laboratory-confirmed: A case that meets the clinical case definition and is laboratory-confirmed.

Epidemiologically confirmed: A case that meets the clinical case definition and is linked epidemiologically to a laboratory-confirmed case.

* Laboratory classification can also be used for outbreak investigation (see diagram in special aspects section below).

Measles (continued)

Recommended case definition (continued)

Clinically confirmed: A case that meets the clinical case definition and for which no adequate blood specimen was taken.

Discarded: A suspect case that does not meet the clinical or laboratory definition.

Recommended types of surveillance

Mortality reduction phase: When measles is endemic, routine monthly reporting of aggregated data on clinical measles cases is recommended by district, age group and immunization status. Only outbreaks (not each case) should be investigated. During outbreaks it is useful to attempt to document measles mortality.

Laboratory confirmation may be attempted by sampling approximately 10 cases per outbreak. Under special circumstances, the isolation of wild strains from selected cases occurring in outbreaks could be performed to enable genetic characterization of circulating measles virus and determine patterns of importation and exportation for countries in the low-incidence or elimination phase.

Low-incidence or elimination phase: Case-based surveillance should be conducted and every case should be reported and investigated immediately (and also included in the weekly reporting system). Laboratory specimens should be collected from every sporadic suspect case. Suspected measles outbreaks should be confirmed by conducting serology on the first 5–10 cases only. Urine, nasopharyngeal or lymphocyte specimens (for virus detection and genetic characterization) should be collected from sporadic/outbreak cases (approximately 10 cases from each chain of transmission) to characterize viral circulation and importation patterns.

During all phases: Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).

Recommended minimum data elements

Aggregated data:

- Number of cases by age groups and immunization status
- Number of measles vaccine doses administered to infants aged under 12 months and children aged 12–23 months.

Case-based data:

- Unique identifier.*
- Geographical area (e.g. district and province).*
- Date of birth.*
- Sex 1 = male; 2 = female; 9 = unknown.
- Date of onset of rash.*
- Number of prior measles vaccine doses received: 9 = unknown.*

* Essential variable to be collected.

Measles (continued)

Recommended minimum data elements *(continued)*

- Date of receipt of last dose.
- Date of notification.
- Date of case investigation. **
- Date of blood specimen collection.*
- Date blood specimen sent to laboratory.
- Date blood specimen received by laboratory.
- Condition of blood specimen on receipt: 1 = adequate; 2 = inadequate; 9 = unknown.
- Date measles serology results reported.
- Results of measles serology: 1 = positive; 2 = negative; 3 = not tested 4 = indeterminate; 9 = unknown.*
- Results of differential serology (make separate variable for each disease): 1 = positive; 2 = negative; 3 = not tested 4 = indeterminate; ; 9 = unknown.
- Collection of specimen for viral culture/identification: 1 = yes; 2 = no.
- Specimen type: 1 = urine; 2 = respiratory; 3 = lymphocytes.
- Date specimen received for viral culture/identification.
- Results of measles viral culture/identification: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- Final classification: 1 = clinically confirmed; 2 = laboratory-confirmed; 3 = epidemiologically linked to laboratory-confirmed case; 9 = discarded.*
- Source of infection identified: 1 = yes; 2 = no; 9 = unknown.

Note: In every phase, completeness and timeliness of monthly (mortality reduction phase) or weekly (low-incidence or elimination phase) measles reporting should be monitored. To avoid successive changes in forms and other data collection instruments, countries likely to move soon to the elimination phase may wish to move to case-based data while still in the control phase if this is not too burdensome.

* Essential variable to be collected.

** Investigation should include a household visit and search for additional cases in the household.

Recommended data analyses, presentations, reports

Mortality reduction phase

- Number of cases and incidence rate by month and year, and geographical area
- Age-specific, sex-specific and district-specific incidence rates.
- Measles vaccine coverage by year and geographical area.
- DTP1–measles or BCG–measles dropout rate.
- Completeness/timeliness of monthly reporting.
- Proportion of known outbreaks confirmed by the laboratory.

Measles (continued)

Recommended data analyses, presentations, reports (continued)

- Proportion of cases by age group and immunization status. Core age groups suggested: 0–8 months, 9–11 months, 1–4 years, 5–9 years, 10–14 years, 15–19 years, 20–24 years, 25 years and over.

Low-incidence or elimination phase - same as mortality reduction phase plus the following:

Performance indicators	Target
– % of weekly reports received	≥ 80%
– % of cases* notified ≤ 48 hours after rash onset	≥ 80%
– % of cases* investigated with house visit ≤ 48 hours after notification	≥ 80%
– % of cases* with adequate specimen** and laboratory results within 7 days	≥ 80%
– % of confirmed cases with source of infection identified	≥ 80%

* All cases that meet the clinical case definition.

** An adequate specimen is a blood specimen collected within 28 days of the onset of rash.

Principal uses of data for decision-making

Mortality reduction phase: Monitor incidence and coverage to assess progress (i.e. decreasing incidence and increasing coverage) and identify areas at high risk or with poor programme performance. Describe the changing epidemiology of measles in terms of age, immunization status and interepidemic period. Assist in determination of optimal age groups to be targeted by second opportunity for measles vaccination (including mass vaccination campaigns).

Low-incidence or elimination phase: Identify chains of transmission. Monitor the epidemiology (age groups at risk, interepidemic period, immunization status) of measles and accelerate immunization activities accordingly to avert potential outbreaks.

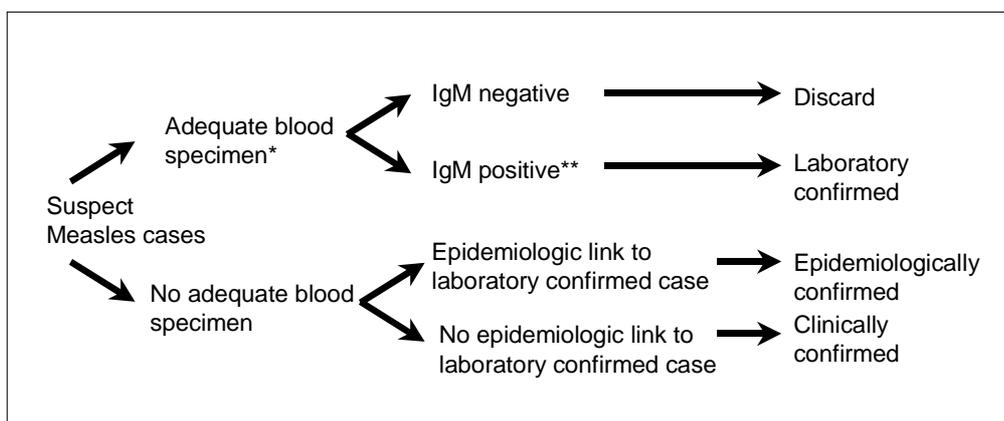
Use epidemiological data to classify cases (see special aspects section). Use performance indicators to assess the quality of surveillance and identify areas that need strengthening.

During all phases: Detect and investigate outbreaks to ensure proper case management, and determine why outbreaks occurred (e.g. failure to vaccinate, vaccine failure or accumulation of susceptibles).

Measles (continued)

Special aspects

Final classification of measles cases.



* While IgM ELISA tests are more sensitive between days 4 and 28 after the onset of rash, a single serum sample obtained at the first contact with the health care system within 28 days after onset is considered adequate for measles surveillance.

** If the case has been vaccinated within six weeks before serum collection, refer to the *Manual for the laboratory diagnosis of measles virus infection, December 1999* (WHO/V&B/00.16). If an active search in the community does not find evidence of measles transmission and there is no history of travelling to areas where measles virus is known to be circulating, the case should be discarded.

Use additional methods such as epidemiological modelling and seroepidemiology studies to monitor the build-up of susceptibles (guidelines on doing this are under development).

Mumps

Rationale for surveillance

Mumps, caused by a paramyxovirus, is generally a mild disease with fever, headache and swelling of the salivary glands, but complications such as meningitis (in up to 15% of cases), encephalitis or orchitis may occur. Although the case-fatality rate of mumps encephalitis is low and overall mortality is 1/10 000 cases, permanent sequelae occur in about 25% of encephalitis cases. Mumps is a leading cause of acquired sensorineural deafness among children, affecting approximately 5/100 000 mumps patients. Mumps infection during the first 12 weeks of pregnancy is associated with a 25% incidence of spontaneous abortion, although malformations following mumps virus infection during pregnancy have not been found.

In the pre-vaccination era mumps was the main cause of viral encephalitis in many countries. By 2002 mumps vaccine was included in the routine immunization schedule of 121 countries/territories. In countries where vaccination was introduced and high coverage was sustained the incidence of the disease has dropped tremendously and circulation has stopped. In countries where vaccination was not introduced the incidence of mumps remains high, mostly affecting children aged 5–9 years.

Surveillance for mumps should evolve with the level of control and should be adjusted to match country-specific objectives. In countries achieving high routine mumps coverage and with low incidence that includes periodic outbreaks, surveillance should be used to identify high-risk populations and predict and prevent potential outbreaks. Countries having the objective of completely interrupting mumps transmission require intensive case-based surveillance to detect, investigate and confirm every suspect mumps case in the community.

Recommended case definition

Clinical case definition

Acute onset of unilateral or bilateral tender, self-limited swelling of the parotid or other salivary gland, lasting two or more days and without other apparent cause.

Laboratory criteria for diagnosis

Isolation of mumps virus from an appropriate clinical specimen.*

or

Seroconversion or significant (at least fourfold) rise in serum mumps IgG titre as determined by any standard serological assay.**

or

Positive serological test for mumps-specific IgM antibodies.**

* Mumps virus can be isolated from throat swabs, urine and cerebrospinal fluid (CSF). Although mumps viral culture is rarely performed in uncomplicated cases the virus is readily isolated from CSF in cases of mumps meningitis. In research settings, typing methods are available to distinguish wild-type mumps virus from vaccine virus. All commercially available mumps vaccines are based on live attenuated strains of the virus. In general, adverse reactions to mumps vaccination are rare and mild. Vaccine-related mumps meningitis, however, has been known to occur with some vaccine strains.

** In the absence of mumps immunization in the preceding six weeks.

Mumps (continued)

Recommended case definition

Case classification:

Clinical case: A case that meets the clinical case definition.

Laboratory-confirmed: A case that meets the clinical case definition and is laboratory-confirmed.

Epidemiologically confirmed: A case that meets the clinical case definition and is linked epidemiologically to a laboratory-confirmed case.

Recommended types of surveillance

When mumps is endemic, only routine monthly reporting of aggregated data of clinical mumps cases is recommended by district, age group and immunization status. Only outbreaks (not each case) should be investigated.

When a high level of control is achieved (i.e. sustained high vaccine coverage), case-based surveillance should be conducted and every case should be reported and investigated immediately (and also included in the weekly or monthly reporting system). Suspected mumps outbreaks should be confirmed by conducting laboratory investigation on 5–10 cases only. In specific situations, viral isolation can be attempted to differentiate meningitis cases that could be related to the wild virus, the vaccine strain or other factors.

Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).

Recommended minimum data elements

Aggregated data reporting

- Number of cases by age group and immunization status, month and geographical area.

Case-based data

- Unique identifier.
- Geographical area (e.g. district and province).
- Date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of onset.
- Number of mumps vaccine doses received: 99 = unknown.
- Date of receipt of last dose.
- Date of notification.
- Date of case investigation.
- Date of blood specimen collection.
- Date blood specimen sent to laboratory.
- Date mumps serology results reported.

Mumps (continued)

Recommended minimum data elements *(continued)*

- Results of mumps serology: 1 = positive; 2 = negative; 3 = indeterminate; 4 = no specimens processed; 9 = unknown.
- Collection of specimen for viral culture/identification: 1 = yes; 2 = no; 9 = unknown.
- Specimen type: 1 = urine; 2 = throat swab; 3 = CSF; 9 = unknown.
- Date specimen received for viral culture/identification.
- Results of mumps viral culture/identification: 1 = positive; 2 = negative; 9 = unknown.
- Final classification: 1 = clinically confirmed; 2 = laboratory-confirmed; 3 = epidemiologically linked to laboratory-confirmed case.
- Source of infection identified: 1 = yes; 2 = no; 9 = unknown.

Recommended data analyses, presentations, reports

- Number of cases and incidence rate by month, year and geographical area.
- Mumps vaccine coverage by year and geographical area.
- Completeness/timeliness of monthly reporting.
- Proportion of known outbreaks confirmed by the laboratory.
- Age-specific, sex-specific, and district-specific incidence rates by month and year.
- Proportion of cases by age group and immunization status. Core age groups suggested: < 12 months, 1–4 years, 5–9 years, 10–14 years, 15–19 years, 20 years and over.

Principal uses of data for decision-making

Countries where mumps is endemic: Monitor incidence and coverage to assess progress (i.e. decreasing incidence and increasing coverage) and to identify areas at high risk or with poor programme performance. Describe the changing epidemiology of mumps. Monitor vaccine effectiveness. Detect and investigate outbreaks to ensure proper case management and determine why outbreaks occurred (e.g. failure to vaccinate, vaccine failure or accumulation of susceptibles despite high vaccine coverage with effective vaccine).

Countries with high level of control: Monitor the epidemiology (age groups at risk, interepidemic period, immunization status) of mumps and accelerate immunization activities accordingly to avert a potential outbreak.

Mumps (continued)

Special aspects

Where vaccine is used and high coverage is achieved the monitoring of vaccine-associated mumps meningitis and its differentiation from meningitis due to other causes can be an important issue. The monitoring of mumps meningitis, whether related to vaccine or natural disease, can be integrated into overall meningitis surveillance activities.

The vast majority of mumps vaccine is used in combination with measles and rubella vaccines (MMR), and surveillance strategies for mumps should take surveillance for measles, rubella and congenital rubella syndrome into consideration.

Neonatal tetanus

Rationale for surveillance

Neonatal tetanus (NT) is targeted by UNICEF, UNFPA and WHO for **elimination** as a major public health burden along with maternal tetanus. Elimination is defined as less than one NT case per 1000 live births at district level per year. High coverage with tetanus toxoid among pregnant women and in high-risk areas among all childbearing aged women (CBAW), as well as improved access to clean delivery services are primary strategies for achieving this goal. Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions. However, in the absence of reliable surveillance data, actions aimed at reducing the incidence of NT should not be postponed until the establishment or improvement of surveillance systems. In this situation, elimination strategies should be targeted at areas with high neonatal mortality to which NT is likely to be a major contributor.

Recommended case definition

Clinical case definition and case classification

Suspected case:

- Any neonatal death between 3 and 28 days of age in which the cause of death is unknown; **or**
- Any neonate reported as having suffered from neonatal tetanus between 3 and 28 days of age and not investigated.

Confirmed case:

- Any neonate with normal ability to suck and cry during the first 2 days of life **and**
 - who, between 3 and 28 days of age, cannot suck normally **and**
 - becomes stiff or has spasms (i.e. jerking of the muscles)

Note: The basis for case classification is entirely clinical and does not depend on laboratory confirmation. NT cases reported by physicians are considered to be confirmed. However, investigators should examine NT case records during annual hospital record reviews.

Recommended types of surveillance

- **Routine monthly surveillance:** the number of confirmed NT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus.
- **Zero reporting:** Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).
- **Active surveillance:** major health facilities should be visited regularly (at least monthly) to identify any NT case admitted or diagnosed in them. Such visits should preferably be made by staff not attached to the health facilities concerned. During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NT case has been identified in the hospital since the previous visit.

Neonatal tetanus (continued)

Recommended types of surveillance (continued)

- **Retrospective record review:** hospital records should be reviewed for NT cases at least once annually in major hospitals to identify previously unreported NT cases.

For all of the above it is recommended that, at least in the short term, NT surveillance be linked to AFP surveillance. Forms and databases should be adapted and standardized so as to enable easy reporting of NT (and, as appropriate, measles) cases when AFP surveillance is carried out.

- **Community sensitization:** in “silent areas” areas (i.e. where routine reporting is not functional but where other indicators suggest that neonatal tetanus could be a problem) the community should be sensitized about NT and the need to bring suspect cases/deaths to the attention of the health authorities.
- **Case investigation and case response:**
 - To optimize available resources, case investigations should be conducted first in areas considered at low risk, since cases are not expected here and therefore the response should be tailored to the specific cause. Low-risk areas are those with a clean delivery rate $\geq 70\%$ and/or TT2 coverage $\geq 80\%$ (from routine or supplementary immunization activities (SIAs)) or as specified by country-specific criteria.
 - In areas already known to be at high risk the focus should firstly be on implementing SIAs to increase immunity to tetanus, rather than on investigating every case and mounting case-response activities around each one. An NT case often represents a sentinel event indicating a more systematic problem. The findings from the case investigation should therefore help to guide the nature and extent of the immunization response. The latter should attempt to immunize all women in the area who are not adequately protected against tetanus or who are eligible for a TT dose. The NT patient should be treated in accordance with local treatment protocols and the mother of the NT case should be immunized immediately against tetanus.

Recommended minimum data elements

Aggregated data:

- Number of cases.
- Number of doses of TT administered during routine immunization to pregnant women or number of neonates protected at birth (PAB) (see special aspects section).
- Number of doses of TT administered during SIAs (such doses should be recorded by dose rather than by round).
Note: Doses given during routine immunization and during SIAs should be recorded separately on tally sheets and reported separately.
- Completeness/timeliness of monthly zero reports.

Neonatal tetanus (continued)

Recommended minimum data elements

Case-based data (to be obtained through case-investigation):

- Unique identifier.
- Date of case investigation.
- Geographical area, name of place of birth (e.g. village, district and province).
- Date of birth of baby.
- Age (in days) of baby at onset of symptoms (or date of onset).
- Sex: 1 = male; 2 = female; 9 = unknown.
- Number of live births delivered (including this most recent one) by the mother.
- Number of past neonatal deaths with similar symptoms
- Number of contacts the mother had with a midwife or trained health worker during this last pregnancy.
- Protection at birth (PAB) status of the last baby born based on the number of tetanus toxoid doses received, interval between doses, and time since last dose (using card or verbal history):
- Place of birth: 1 = hospital; 2 = health centre; 3 = home; 4 = other; 9 = unknown.
- Assistance during childbirth:* 1 = health staff; 2 = traditional birth attendant; 3 = family member or alone; 4 = other; 9 = unknown.
- Tool(s) used to cut umbilical cord
- Material used as dressing for cord stump.
- Final outcome of child's health: 1 = alive; 2 = dead; 9 = unknown
- Final classification: 1 = confirmed; 2 = suspected; 3 = discarded (i.e. not an NT case); 9 = unknown
- Active case search for additional NT cases done in the locality of birth:*
1 = yes; 2 = no; 9 = unknown.
If yes, number of previously unreported suspected cases detected as having occurred in the previous 12 months.
- *If available at the time of investigation:*
Mother given protective TT dose(s) within three months after the report of an NT case: 1 = yes; 2 = no; 9 = unknown.
- If given a protective dose, date of dose
Note: All mothers whose children are admitted for NT should be immunized immediately on admission to hospital.
- Supplemental immunization conducted within same locality as the case:
1 = yes; 2 = no; 9 = unknown.

* Health workers may have to be interviewed to obtain correct and detailed information on these topics.

Neonatal tetanus (continued)

Recommended data analyses, presentations, reports

Aggregated data (i.e. routine monthly reporting)

- Number of cases and incidence rates by month, year and geographical area
- District-specific, sex-specific, incidence rates per 1000 live births by year
- TT2+ coverage (or PAB) by year and geographical area among pregnant women
- If TT doses are being administered to all women of childbearing age, TT2+ coverage among CBAWs;
- For SIAs, TT1, TT2, and TT3 coverage among child-bearing women targeted.
- Completeness/timeliness of monthly and zero reporting.

Case-based data (i.e. from case investigations only): as for aggregated data plus the following:

- Number, and rate of confirmed NT cases by sex, geographical location of birth, month year.
- Percentage of confirmed NT cases by place of birth (health facility or home delivery), protection status at birth, type of birth assistance, type of cord-cutting tools used, type of umbilical stump dressing used, age group of mother, and parity of mother.
- Percentage of confirmed NT cases whose mother received antenatal care
- Case-fatality ratio among confirmed NT cases.
- Percentage of confirmed NT cases whose mother received a protective TT dose(s) subsequent to the onset of tetanus in the baby.
- Percentage of confirmed NT cases which triggered an active search in the community.
- Percentage of confirmed NT cases which triggered an immunization response.
- Number of unreported cases found through active searches.
- TT2+ coverage (or PAB) by year and geographical area among pregnant women (if TT doses are being administered to all women of childbearing age (CBAW), TT2+ coverage among CBAWs);
- For Supplemental Immunization Activities (SIAs): TT1, TT2, and TT3 coverage among child-bearing women targeted.
- Completeness/timeliness of monthly and zero reporting.

Neonatal tetanus (continued)

Principal uses of data for decision-making

- Monitor progress towards achieving and sustaining high routine TT2+ (or PAB) coverage in all geographical areas.
- Monitor progress towards maternal and neonatal tetanus elimination in every geographical area (progress towards neonatal tetanus elimination is a proxy for maternal tetanus elimination).
- Investigate suspect NT cases in areas not considered at risk for NT to identify risk factors.
- Identify high-risk geographical areas and conduct supplemental immunization activities.
- Identify missed opportunities for tetanus toxoid immunization through antenatal care.
- Monitor whether corrective actions were taken in those areas considered to be at high risk.
- Periodically verify the sensitivity of NT reporting by comparing the number of reported cases with cases identified through active surveillance, hospital record reviews, and active searches.
- Periodically profile risk factors for NT (e.g. place of birth, assistance during delivery, cord care, immunization status, age and parity of mother) to target messages and actions appropriately.
- Monitor risk levels in areas considered at low risk and take corrective action accordingly.
- Monitor specificity of reporting through analysis of age of death, risk factors

Neonatal tetanus (continued)

Special aspects

- Protection at birth

% protected at birth (PAB) is a supplemental method of determining coverage protection (particularly where TT2+ is unreliable and where DTP1 coverage is high). To monitor PAB during DTP1 visits, health workers record whether infants were protected at birth by the mother's TT status. % PAB is then estimated as: number of infants protected divide by the total number of births. If a child was unprotected the mother should receive a dose of TT during the same visit and should be followed up with a subsequent TT dose if needed for protection. The same applies for mothers whose children were protected at birth but who remain eligible for another TT dose.
- Serological investigations

Simple serological test kits for measuring antibody titres in a survey setting have been developed and are being further refined. The role of serological investigations, however, should always be complementary to other surveillance or assessment methods and the expected outcome should be well defined for each setting.
- School-based immunization

Where tetanus toxoid is given in a school setting, coverage of this approach should be monitored.

To monitor the proportion of children receiving school-based TT, the recommended method for monitoring coverage is:

$$\text{TT (grade X)} = \frac{\text{number of children in grade X who received a dose of tetanus toxoid in the school immunization service in a given year}}{\text{total number of children living in the school's catchment area who were born in the same year as the children in grade X}}$$

To monitor school-based TT immunization, the calculation above would be used except that the denominator would be the total number of children enrolled in grade X.

Pertussis (whooping cough)

Rationale for surveillance

Pertussis, caused by *Bordetella pertussis*, is a major cause of childhood morbidity and mortality. There is evidence of a high burden of pertussis in developing countries. It remains one of the world's leading causes of vaccine-preventable deaths. An estimated 50 million cases and 300 000 deaths occur every year; case-fatality rates in developing countries are estimated to be as high as 4% in infants. High immunization coverage with an effective vaccine is the mainstay of prevention. The rationale for pertussis surveillance is to monitor the impact of the immunization system, identify high-risk areas and detect outbreaks (which must then be investigated). In countries where coverage is moderate to low, surveillance should simply monitor improving coverage and decreasing pertussis incidence. Once immunization coverage is high and pertussis incidence is low, surveillance should be enhanced to understand the changing epidemiology of the disease and thus to guide vaccination policy. *Bordetella parapertussis*, which causes milder disease in general and is not responsible for significant mortality, is not a priority for surveillance in most countries at present.

Recommended case definition

Clinical case definition

A case diagnosed as pertussis by a physician **or**

A person with a cough lasting at least two weeks with at least one of the following symptoms:

- Paroxysms (i.e. fits) of coughing.
- Inspiratory whooping.
- Post-tussive vomiting (i.e. vomiting immediately after coughing) without other apparent cause.

Criteria for laboratory confirmation

- Isolation of *Bordetella pertussis* **or**
- Detection of genomic sequences by means of the polymerase chain reaction (PCR) **or**
- Positive paired serology.

Case classification

Clinically confirmed: A case that meets the clinical case definition but is not laboratory-confirmed.

Laboratory confirmed: A case that meets the clinical case definition and is laboratory-confirmed.

Pertussis (whooping cough) (continued)

Recommended types of surveillance

- **Routine surveillance (where DTP3 coverage is < 90%)**
Routine monthly reporting of aggregated data on clinical cases from the peripheral level to the intermediate and central levels is recommended. All levels should be encouraged to report cases stratified by age group (e.g. < 1 year, 1–4 years, ≥ 5 years) and immunization status.
- **Routine surveillance (where DTP3 coverage is ≥ 90%)**
Case-based surveillance is recommended when coverage reaches 90%. Information on age, immunization status and final outcome (i.e. alive or dead) should be collected.
- **Investigation of outbreaks**
Every pertussis outbreak should be reported immediately to the appropriate WHO regional office, investigated to understand why it occurred, and confirmed by laboratory methods. Case-based information should be collected on: date of onset, age, immunization status, geographical location and final outcome.
- **Sentinel surveillance**
Sentinel surveillance is recommended in a few major hospitals to collect more in-depth information than that obtained through routine surveillance. The data collected on each case should include: date of onset, immunization status, age, laboratory confirmation and final outcome (i.e. alive or dead). This provides additional information on the burden and epidemiology of pertussis (e.g. age-specific case-fatality rates). Sentinel surveillance should be linked to developments in laboratory diagnostics and networks.
- Regardless of the type of surveillance, designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).

Recommended minimum data elements

Aggregated data for reporting (when DTP3 coverage is < 90%)

- Number of cases by age group (< 1 year, 1–4 years, ≥ 5 years) and immunization status.
- Number of first and third doses of diphtheria–tetanus–pertussis (DTP) administered to infants.
- Number of DTP booster doses given (if part of the country schedule).

Note: Coverage surveys should collect and analyse data on the timeliness of DTP doses, because doses given on time rather than late can substantially reduce mortality.

Case-based data (when DTP3 coverage is ≥ 90%; also for sentinel surveillance and outbreak investigation)

- Unique identifier.
- Geographical information of case (e.g. district and province).
- Date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of onset.

Pertussis (whooping cough) (continued)

Recommended minimum data elements *(continued)*

- Total number of pertussis vaccine doses; 99 = unknown.
- Date of latest pertussis vaccine dose; 99 = unknown.
- Outcome: 1 = alive; 2 = dead; 9 = unknown.
- Classification: 1 = clinical; 2 = laboratory-confirmed; 3 = discarded.

Recommended data analyses, presentations, reports

Aggregated data:

- Number of cases and incidence rate by month, year and geographical area.
- Proportion of cases immunized, partially immunized and not immunized.
- DTP3 coverage by year and geographical area.
- DTP booster by year and geographical area.
- Dropout rate by year and geographical area from DTP1 to DTP3.
- Completeness/timeliness of monthly reporting by geographical area.

Case-based data: Same as aggregated data plus the following:

- Crude and age-specific case-fatality rate.
- Age-specific, sex-specific and district-specific incidence rates by month and year

Principal uses of data for decision-making

- Monitor incidence rates to assess the impact of the immunization system and policy (e.g. immunization schedule).
- Monitor incidence rates by geographical area to identify high-risk areas or those with poor system performance (so that corrective actions can be taken).
- Monitor age-specific attack rates to identify age groups at risk (which may affect immunization policy).
- Identify outbreaks, conduct investigations to determine causes and understand the epidemiology of pertussis, ensure good case management.
- Understand the changing epidemiology of pertussis (e.g. change in age group at risk, change in periodicity).
- Monitor case-fatality ratios and, if they are high, determine the causes (poor/late diagnosis, poor case management, poor/late access to care).
- On the basis of coverage surveys, analyse whether vaccination doses are given on time; determine the causes of late dosing (since this may affect both morbidity and mortality).

Poliomyelitis

Rationale for surveillance

Poliomyelitis is targeted for **eradication**. Highly sensitive surveillance for acute flaccid paralysis (AFP), including immediate case investigation, and specimen collection are critical for the detection of wild poliovirus circulation with the ultimate objective of polio eradication. AFP surveillance is also critical for documenting the absence of poliovirus circulation for polio-free certification.

Recommended case definition

Clinical case definition

Any child under 15 years of age with AFP* **or** any person of any age with paralytic illness if polio is suspected.

Case classification

Suspected case: A case that meets the clinical case definition.

Confirmed case: See diagram in special aspects section.

* Including Guillain-Barré syndrome.

Recommended types of surveillance

- Aggregated data on AFP cases should be included in routine monthly surveillance reports.
- Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).
- All outbreaks should be investigated immediately.
- All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24–48 hours apart and within 14 days of the onset of paralysis.
- Active surveillance: Regular weekly visits should be made to selected reporting sites that are most likely to admit acute flaccid paralysis patients (e.g. major hospitals, physiotherapy centers) to look for unreported AFP cases.

Recommended minimum data elements

Aggregated data:

- Number of third doses of oral polio vaccine (OPV3) administered to infants.
- Number of AFP cases.

Case-based data (to be linked to specimen-based data for analysis):

- Unique identifier.
- Geographical area (e.g. district and province names).
- Date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of paralysis.
- Date of notification.
- Date of case investigation.

Poliomyelitis (continued)

Recommended minimum data elements (continued)

- Total polio vaccine doses received: 99 = unknown.
- Fever at onset of paralysis: 1 = yes; 2 = no; 9 = unknown.
- Progression of paralysis within four days: 1 = yes; 2 = no; 9 = unknown.
- Asymmetric paralysis: 1 = yes; 2 = no; 9 = unknown.
- Date of 60-day follow-up examination.
- Findings at 60-day follow-up: 1 = residual weakness; 2 = no residual weakness; 3 = lost to follow-up; 4 = death before follow-up; 9 = unknown.
- Final classification: 1 = confirmed; 2 = compatible; 3 = discarded.

Specimen-based data (to be linked to case-based data for analysis):

- Unique identifier.
- Specimen number: 1 = first specimen; 2 = second specimen; 3 = other; 9 = unknown.
- Date of onset of paralysis.
- Date of last OPV dose.
- Date of collection of stool specimen.
- Date stool specimen sent to laboratory.
- Date stool specimen received in laboratory.
- Condition of stool: 1 = good; 2 = poor; 9 = unknown.
- Date final culture results sent from laboratory to EPI.
- Date intratypic differentiation results sent from laboratory to EPI.
- **Results**
 - Polio type 1 isolated? 1 = yes, wild; 2 = yes, Sabin; 3 = yes, pending intratypic differentiation; 4 = yes, mixture of wild and Sabin; 5 = no polio type 1 isolated; 6 = specimen not processed; 9 = unknown.
 - Polio type 2 isolated? 1 = yes, wild; 2 = yes, Sabin; 3 = yes, pending intratypic differentiation; 4 = yes, mixture of wild and Sabin; 5 = no polio type 2 isolated; 6 = specimen not processed; 9 = unknown.
 - Polio type 3 isolated? 1 = yes, wild; 2 = yes, Sabin; 3 = yes, pending intratypic differentiation; 4 = yes, mixture of wild and Sabin; 5 = no polio type 3 isolated; 6 = specimen not processed; 9 = unknown.
 - Non-polio enterovirus (NPEV) isolated? 1 = yes; 2 = no NPEV isolated; 3 = specimen not processed; 9 = unknown

Poliomyelitis (continued)

Recommended data analyses, presentations, reports

Aggregated data:

- Cases and incidence rate by month, year and geographical area.
- OPV3 coverage by year and geographical area.
- Completeness/timeliness of monthly reporting.

Case-based data: same as aggregated data plus the following:

- Confirmed cases by age group, sex, immunization status, geographical area, month and year.
- Confirmed cases from which wild poliovirus was isolated, by geographical area, sex, month and year.
- Compatible cases by geographical area and month.
- All suspect cases by final classification.
- Non-polio enterovirus isolation rate.

Indicators of surveillance performance	Target
– Percentage of all expected monthly reports that were received	≥ 90%
– Annualized non-polio AFP rate per 100 000 children under 15 years of age	≥ 1/100 000
– Percentage of AFP cases investigated within 48 hours	≥ 80%
– Percentage of AFP cases with two adequate stool specimens collected 24–48 hours apart and ≤14 days after onset	≥ 80%
– Percentage of specimens arriving at the laboratory in good condition	≥ 80%
– Percentage of specimens arriving at a WHO-accredited laboratory within three days of being sent	≥ 80%
– Percentage of specimens for which laboratory results sent within 28 days of receipt of specimens	≥ 80%

Principal uses of data for decision-making

- Track wild poliovirus circulation.
- Use data for classifying cases as confirmed, polio-compatible or discarded (see special aspects section).
- Monitor routine coverage, as well as performance of surveillance (by means of the standard indicators listed above) in all geographical areas and focus efforts in low-performing geographical areas.
- Monitor seasonality to determine low season of poliovirus transmission in the interest of planning national immunization days (NIDs).
- Identify high-risk areas with a view to planning mop-up immunization campaigns.
- Provide evidence to certification commissions of the interruption of wild poliovirus circulation.

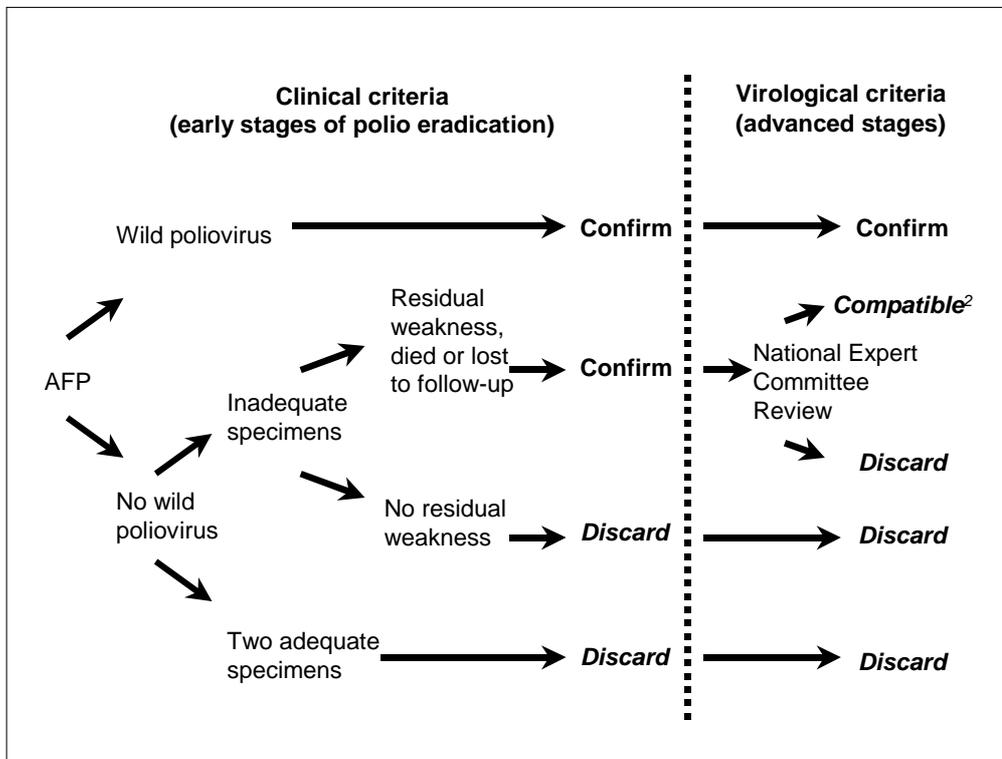
Poliomyelitis (continued)

Special aspects

The scheme in the following illustration should be used to classify AFP cases. Countries should use the clinical classification until their surveillance performance meets the following three criteria:

- 1) a non-polio AFP rate of at least 1/100 000 children under 15 years of age;
- 2) two adequate specimens¹ collected from at least 60% of detected AFP cases;
- 3) all specimens processed in a WHO-accredited laboratory.

Final classification scheme for AFP cases



¹ Collected 24–48 hours apart and within 14 days of the onset of paralysis. Specimens arriving in the laboratory must be of adequate volume (approximately 8–10 g), have appropriate documentation (i.e. laboratory request form) and be in good condition, i.e. with no leakage or desiccation and with evidence that the reverse cold chain has been maintained (presence of ice or temperature indicator).

² Compatible cases indicate surveillance failures and should be monitored for clustering in space and time.

Rubella and congenital rubella syndrome

Rationale for surveillance

Rubella is a mild illness but rubella in a pregnant woman can lead to congenital rubella syndrome (CRS) in the infant. The birth defects associated with CRS include heart disease, blindness, deafness and mental retardation. By 2002 123 countries/territories had introduced rubella vaccine into their routine immunization services. Additional countries, especially those in the elimination phase of measles control, are considering the introduction of rubella vaccine. All countries that include rubella vaccine in their immunization services should conduct surveillance for CRS and rubella. In the CRS prevention stage, disease surveillance should focus on detecting cases of CRS. In the CRS/rubella elimination phase (usually conducted in conjunction with measles elimination), case-based surveillance of febrile rash illness is necessary.

Recommended case definitions

Case definitions for rubella and CRS are provisional, pending field-testing.

Rubella

Suspected rubella case: Any patient of any age in whom a health worker suspects rubella. A health worker should suspect rubella when a patient presents with: fever, maculopapular rash; and cervical, suboccipital or postauricular adenopathy or arthralgia/arthritis.

Clinical confirmation: Rubella cannot be confirmed clinically: laboratory confirmation is required.

Laboratory-confirmed rubella case: Because of the difficulty of clinical diagnosis of rubella, laboratory confirmation is required. A laboratory-confirmed case is a suspected case with a positive blood test for rubella-specific IgM. The blood specimen should be obtained within 28 days after the onset of rash.

Epidemiologically confirmed rubella case: A patient with a febrile rash illness that is linked epidemiologically to a laboratory-confirmed rubella case.

Congenital rubella syndrome (CRS)

Suspected CRS case: Any infant less than one year of age in whom a health worker suspects CRS. A health worker should suspect CRS when an infant aged 0-11 months presents with heart disease and/or suspicion of deafness and/or one or more of the following eye signs: white pupil (cataract), diminished vision, pendular movement of the eyes (nystagmus), squint, smaller eye ball (microphthalmus), or larger eye ball (congenital glaucoma). A health worker should also suspect CRS when an infant's mother has a history of suspected or confirmed rubella during pregnancy, even when the infant shows no signs of CRS.

Clinically confirmed CRS case: An infant in whom a qualified physician detects at least two of the complications listed in (a) below **or** one in (a) and one in (b):

- (a) Cataract(s), congenital glaucoma, congenital heart disease, loss of hearing, pigmentary retinopathy.
- (b) Purpura, splenomegaly, microcephaly, mental retardation, meningocephalitis, radiolucent bone disease, jaundice that begins within 24 hours after birth.

Rubella and congenital rubella syndrome (continued)

Recommended case definitions *(continued)*

Laboratory confirmed CRS case: An infant with clinically-confirmed CRS who has a positive blood test for rubella-specific IgM (100% of such infants are positive at the age of 0-5 months; 60% are positive at 6-11 months). Where special laboratory resources are available the detection of rubella virus in specimens from the pharynx or urine of an infant with suspected CRS provides laboratory confirmation of CRS (60% of such infants shed rubella virus at the age of 1-4 months; 30% at 5-8 months; 10% at 9-11 months).

Congenital rubella infection (CRI): If a mother has suspected or confirmed rubella in pregnancy her infant should have a rubella-specific IgM blood test. An infant who does not have clinical signs of CRS but who has a positive rubella-specific IgM test is classified as having congenital rubella infection (CRI).

Recommended types of surveillance

CRS prevention stage – minimum requirements:

- Routine monthly reporting of the number of suspected CRS cases; zero reporting should be required. All suspected CRS cases in infants aged under 1 year should be investigated. The investigation should include clinical and laboratory analysis.
- Routine monthly reporting of the number of suspected rubella cases
- All febrile rash illnesses in pregnant women should be investigated.
- If a rubella outbreak is detected a limited number of suspected rubella cases should be investigated with rubella-specific IgM tests periodically during the outbreak (5 to 10 cases investigated per outbreak). Active surveillance (defined as regular visits to selected reporting sites to look for unreported cases) should be initiated to improve detection of suspected CRS in infants aged under 1 year and continued for nine months after the last reported case of rubella.

CRS/rubella elimination stage – minimum requirements:

- Same as CRS prevention stage, **plus**
- Routine monthly reporting of the number of *confirmed* rubella cases; zero reporting should be required.
- All febrile rash cases, regardless of age, should be investigated. The investigation should include laboratory analysis of each case for measles and, if the result is negative, for rubella (see section of this document on measles). Priority should be given to the investigation of febrile rash illnesses in pregnant women.
- Regardless of the type of surveillance, designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).

Rubella and congenital rubella syndrome (continued)

Recommended minimum data elements

Routine surveillance data

- The number of suspected CRS cases in each health facility by month.
- For countries with surveillance for febrile rash illnesses, the number of these reported in each health facility by month.
- For other countries, the number of suspected rubella cases in each health facility by month.

Routine immunization coverage data

- Rubella vaccine coverage (%) for each target group (women of childbearing age, schoolgirls, infants, preschool children) in each health facility by month.

CRS case investigation data:

- Patient's date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of notification.
- Date of investigation.
- Date of collection of blood specimen.
- Date blood specimen received by laboratory.
- Date rubella serology results reported.
- Results of rubella-specific IgM test: 1 = positive; 2 = negative; 3 = not tested; 4=indeterminate; 9 = unknown.
- Collection of specimen for viral identification: 1 = yes; 2 = no; 9 = unknown.
- Specimen type: 1 = nasopharyngeal; 2 = other, 9 = unknown.
- Results of rubella virus identification: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- Mother's history of febrile rash illness or exposure to febrile rash illness during this pregnancy 1=had febrile rash illness during pregnancy (but no known exposure to others with febrile rash illness); 2=no history of febrile rash illness during pregnancy but was exposed .; 3=no febrile rash illness during pregnancy and no known exposure; 9=unknown history or exposure to febrile rash illness
- Mother's history of rubella immunization 0 = never immunized against rubella; 1 = 1 dose; 2 = 2 doses; 3 = 3 or more doses; 9 = unknown.
- Mother's rubella immunization history determined by card or history? 1 = card; 2 = verbal history; 3 = some doses by card and some by history; 9 = unknown
- Patient's date of birth or age.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of onset of rash.
- Date of investigation.
- Date of collection of blood specimen.
- Date blood specimen received by laboratory.
- Date rubella serology results reported.
- Results of rubella-specific IgM test: 1 = positive; 2 = negative; 3 = not tested 4 = indeterminate;; 9 = unknown.
- Collection of specimen for virus identification: 1 = yes; 2 = no, 9 = unknown.

Rubella and congenital rubella syndrome (continued)

Recommended minimum data elements (continued)

- Results of rubella virus culture/identification: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- Specimen type: 1 = nasopharyngeal; 2 = other.
- Results of rubella virus identification: 1 = positive; 2 = negative; 9 = unknown.
- History of rubella immunization through routine services or SIAs: 0 = never immunized against rubella; 1 = 1 dose; 2 = 2 doses; 3 = 3 or more doses; 9 = unknown.
- Rubella vaccination history determined by card or history? 1 = card; 2 = verbal history; 3 = some doses by card and some by history; 9 = unknown.
- History of rubella immunizations through routine services or SIAs: 0 = never immunized against rubella; 1 = 1 dose; 2 = 2 doses; 3 = 3 or more doses; 9 = unknown.

Recommended data analyses, presentations, reports

Aggregated data (i.e. from routine reporting)

- Number of CRS cases and incidence rate per 1000 live births by month, year, and geographic area
- CRS cases per 1000 live births per year
- Number of rubella cases and incidence rates by month, year, and geographical area.
- Age-specific, sex-specific, and district-specific rubella incidence rates.
- Rubella vaccine coverage rate by target group and geographical area per year.
- For CRS and rubella cases, completeness/timeliness of monthly reporting.
- Proportion of known outbreaks confirmed by the laboratory.

Case-based data (i.e. from case investigations only)

- Number of CRS cases by sex, month, year, and geographic area.
- Sex-specific, district-specific CRS incidence rates per 1000 live births per year
- Age-specific, sex-specific and district-specific rubella incidence rates
- Final classification of all suspected cases of CRS and rubella.
- Rubella immunization status of mothers of CRS cases.
- Proportion of all cases of febrile rash illness with laboratory investigation which are rubella-specific IgM-positive

Note: This should be linked with investigations described in the measles section of this report

Surveillance quality

- Completeness and timeliness of routine reporting, notification clinical investigation, and laboratory investigation. In the low-incidence or elimination phase, performance indicators for rubella case investigation should be linked to those for measles case investigation.

Rubella and congenital rubella syndrome (continued)

Principal uses of data for decision-making

- Understand the epidemiology of CRS and its burden in the population to guide rubella immunization strategies. Because children with CRS may be blind, deaf, retarded or have major heart disease, CRS creates a long-term burden on health, social and educational systems.
- Use rubella outbreak investigation as a tool for activating CRS surveillance.
- Investigate rash illness in pregnancy and provide culturally appropriate follow-up to women who have rubella, including follow-up of their infants.
- Investigate febrile rash illnesses in the measles/rubella elimination phase to determine the proportion of such illnesses attributable to rubella. This allows the identification of high-risk areas, age groups and/or populations.

Special aspects

- Outbreaks of rubella and measles have occurred simultaneously.
- CRS cases are likely to be underreported in areas and among populations where a high proportion of births occur at home and where infant deaths may not be reported.
- Infants with CRS are likely to be seen at specialty facilities that do not normally participate in the immunization service or the routine communicable disease surveillance system, e.g. eye hospitals and hospitals specializing in cardiac surgery. For comprehensive CRS surveillance these facilities should be included in CRS detection, investigation and reporting activities.
- Infants with CRS and CRI shed rubella virus for long periods (60% for the first 4 months of life) and appropriate infection control measures should be applied. It is particularly important that pregnant women who are not rubella-immune should not be exposed to infants with CRS or CRI.
- Serological monitoring of rubella susceptibility in women attending selected antenatal clinics can be used to monitor the performance of rubella immunization services. However, serological monitoring requires a different laboratory test, e.g. rubella-specific IgG. If serological screening is conducted, arrangements should be made to provide postpartum rubella vaccination to women found to be seronegative.

Yellow fever

Rationale for surveillance

This mosquito-borne viral disease occurs in tropical regions of Africa and South America and is maintained by sylvatic transmission of virus involving forest-dwelling mosquitos and monkeys. Transmission to humans may occur in forest transition zones and subsequently may enter an urban cycle through the *Aedes aegypti* mosquito. The risk of resurgence of major epidemics of yellow fever, particularly in heavily populated urban settings in both Africa and South America, has greatly increased for many reasons including (1) low immunization coverage, (2) the invasion of urban settings by *Aedes aegypti*, and (3) the change in the demographic balance in most countries, shifting populations from being mostly rural to mostly urban.

The strategies for yellow fever control are: routine infant immunization for children aged 6 months or above, mass vaccination campaigns to prevent epidemics, outbreak detection and rapid response, and control of *Aedes aegypti* in urban centres.

Yellow fever surveillance is therefore critical for monitoring the incidence of the disease and allowing the prediction and early detection of outbreaks and the monitoring of control measures. Case-reporting of yellow fever is universally required by the **International Health Regulations**.

Recommended case definition

Clinical description

The disease is characterized by sudden onset of fever; chills; head, back and muscle pain; nausea and vomiting. These may progress to jaundice and haemorrhagic signs or death within three weeks of onset. The clinical diagnosis of an isolated case of yellow fever is particularly difficult because the symptoms are similar to those of many other diseases, e.g. viral hepatitis, malaria, dengue, typhoid fever, leptospirosis and Ebola disease, and lassa fever. Laboratory confirmation is therefore essential for the differential diagnosis of yellow fever.

Laboratory criteria for diagnosis

Presence of yellow-fever-specific IgM or a fourfold or greater rise in serum IgG levels (acute or convalescent) in the absence of recent yellow fever vaccination.

Or isolation of yellow fever virus.

Or positive postmortem liver histopathology.

Or detection of yellow fever antigen in tissues by immunohistochemistry.

Or detection of yellow fever virus genomic sequences in blood or organs by PCR.

Case classification

Suspected: A case that is characterized by acute onset of fever followed by jaundice within two weeks of the onset of the first symptoms.

Confirmed: A suspected case that is laboratory-confirmed or epidemiologically linked to a laboratory-confirmed case or outbreak.

Yellow fever (continued)

Recommended types of surveillance

- Routine monthly reporting of aggregated data on suspected and confirmed cases from the peripheral level to the intermediate and central levels.
- Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as “zero reporting”).
- Immediate reporting of suspected cases from the peripheral level to the intermediate and central levels.
- All suspected cases and outbreaks should be investigated immediately and blood samples should be collected for laboratory confirmation.
- Case-based surveillance should be implemented in countries identified by WHO as being at risk for yellow fever. Specimens should be collected to confirm epidemics as rapidly as possible. Priority should then be given to collecting specimens from new or neighbouring areas (other than the areas where epidemics are already confirmed).

Note: The International Health Regulations require all yellow fever cases to be reported to WHO within 24 hours of detection.

Recommended minimum data elements

Aggregated data for reporting

- Number of cases.
- Doses of yellow fever vaccine administered to infants by geographical area.
- Completeness/timeliness of monthly reports.

Case-based data for reporting and investigation

- Unique identifier.
- Geographical area (e.g. district and province names).
- Date of birth.
- Sex: 1 = male; 2 = female; 9 = unknown.
- Date of onset of fever.
- Date of notification.
- Date of investigation.
- Travel 10 days prior to fever onset 1 = yes; 2 = no; 9 = unknown
- Ever received a dose of yellow fever vaccine? 1 = yes; 2 = no; 9 = unknown.
- Date yellow fever vaccine last received.
- Date blood sample collected.
- Date blood sample sent to laboratory.
- Date blood specimen received in laboratory.
- Condition of blood sample on receipt: 1 = adequate; 2 = inadequate; 9 = unknown.
- Histopathology specimen collected? 1 = yes, 2 = no, 9 = unknown.
- If yes, record date histopathology specimen collected (if applicable).

Yellow fever (continued)

Recommended minimum data elements *(continued)*

- Depending on which laboratory tests used:
 - IgM results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
 - Virus detection results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
 - IgG (fourfold or greater rise) results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
 - Liver histopathology: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- Date serology results reported.
- Date virus detection results reported.
- Date histopathology results reported.
- Final classification: 1 = confirmed; 2 = suspected; 3 = discarded.
- Final outcome: 1 = alive; 2 = dead; 9 = unknown.
- Date of death.

Recommended data analyses, presentations, reports

Aggregated data

- Among suspected cases, number and incidence rate by month, year and geographical area.
- Among confirmed cases, number and incidence rate by month, year and geographical area.
- Yellow fever vaccine coverage by year and geographical area
- Difference between yellow fever and measles vaccine coverage by geographical area
- Completeness/timeliness of monthly reporting by geographical area.

Case-based data - same as aggregated data plus the following:

- Confirmed cases by age group, immunization status, geographical area, month and year.
- Age-specific, sex-specific, district-specific incidence rate of confirmed yellow fever by month and year
- Case-fatality ratio.
- Final classification of all suspect cases.

Yellow fever (continued)

Recommended data analyses, presentations, reports (continued)

Performance indicators of surveillance quality	Target
– Percentage of districts reporting and collecting blood samples from at least one suspected case of yellow fever per year	> 80%
– Completeness of monthly reporting	≥ 90%
– Timeliness of monthly reporting	≥ 80%
– Percentage of cases investigated within 48 hours of notification	≥ 80%
– Percentage of all suspect cases for which specimens were collected	≥ 50% ¹
– Percentage of samples sent to the laboratory within three days of investigation	≥ 80%
– Percentage of samples reaching laboratory in adequate** condition	≥ 80%
– For IgM test: laboratory results reported < seven days after receipt of blood specimen	≥ 80%
– For virus detection: laboratory results reported < 21 days after receipt of acute blood specimen	≥ 80%
– For IgG test: laboratory results reported < seven days after receipt of convalescent blood specimen	≥ 80%

¹ This is the target during non-outbreak periods. Once an outbreak has been confirmed the priority is to detect outbreaks in neighbouring areas and confirm them in the laboratory.

** Adequate specimen is a blood specimen collected within seven weeks of the onset of symptoms and where reverse cold chain was effectively maintained.

Principal uses of data for decision-making

- Investigate suspect cases and collect laboratory specimens to confirm an outbreak and mobilize emergency immunization activities.
- Develop a better understanding of the epidemiology of yellow fever to guide strategies and assess their impact.
- Identify areas at high risk of a yellow fever outbreak so that preventive measures can be made before the outbreak occurs.
- Monitor yellow fever coverage (both routine infant immunization coverage and population coverage by mass vaccination campaigns) by geographical region to assess progress towards outbreak prevention and to identify areas of poor performance so that corrective actions can be taken.
- Monitor the performance of surveillance
- Monitor the performance of the laboratory

Yellow fever (continued)

Special aspects

Opportunities should be seized to integrate yellow fever surveillance with other surveillance efforts that share similar objectives and strategies (e.g. joint laboratory training on measles and yellow fever diagnosis).

The following 33 countries in Africa are at risk for yellow fever epidemics:

Angola, Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Congo, Côte d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Liberia, Mali, Mauritania, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, Sudan, Tanzania, Togo, Uganda.

The following 11 countries in South America are at risk for yellow fever:

Bolivia, Brazil, Colombia, Ecuador, Guyana, French Guyana, Panama, Peru, Suriname, Trinidad and Tobago, Venezuela.

Japanese Encephalitis

(Updated August 2008)

Rationale for surveillance

Japanese encephalitis (JE) is a mosquito-borne viral encephalitis that occurs in temperate and tropical regions of Asia and is maintained in a cycle of virus transmission between vertebrate amplifying hosts (e.g., pigs, herons, egrets) and several *Culex* mosquito species. The greatest transmission to humans occurs in rural settings, particularly those in which agricultural practices increase the potential for breeding of vectors or infection of vertebrate hosts. In urban settings, the potential for an outbreak of JE is low, although transmission can occur. In recent decades, JE outbreaks have occurred in areas previously non-endemic for the disease. The high case fatality rate (20%-30%) and frequent residual neuropsychiatric damage in survivors (50%-70%) make JE a major public health problem.

JE is the leading form of viral encephalitis in Asia where about 50 000 cases and 10 000 deaths are reported each year, mostly among children. However, officially reported cases of JE greatly under-represent the true impact, due to incomplete surveillance in many affected areas. Among the control strategies, human vaccination has proven to be the single most effective control measure.

Infection with Japanese encephalitis virus (JEV) may be asymptomatic, or may cause febrile illness, meningitis, myelitis or encephalitis. Encephalitis is the most commonly recognized presentation, and is clinically indistinguishable from other causes of an acute encephalitis syndrome (AES). Syndromic surveillance therefore aims to identify patients with AES, and among these confirms JEV infection using standardized laboratory techniques.

In many JE affected countries, the epidemiology and public health burden of JE are poorly understood. The primary goal of disease surveillance in these countries is to characterize the epidemiology and burden of JE so as to advocate for and guide programmatic interventions.

Where JE immunization is already ongoing, the primary purpose of surveillance is to identify high-risk populations or geographical areas in need of improved vaccination coverage and areas with new disease transmission, and to document the impact of control measures.

In summary, JE surveillance is critical to characterize the epidemiology and burden of the disease, identify high risk areas for appropriate public health response and document the impact of control measures.

Japanese encephalitis (continued)

Recommended case definition

Clinical case definition

Clinically, a case of Acute Encephalitis Syndrome (AES) is defined as a person of any age, at any time of year with the acute onset of fever **and at least one of**: a) change in mental status (including symptoms such as confusion, disorientation, coma, or inability to talk); b) new onset of seizures (excluding simple febrile seizures¹). Other early clinical findings may include an increase in irritability, somnolence or abnormal behaviour greater than that seen with usual febrile illness².

Case classification

AES (Suspected JE) Case: A case that meets the clinical case definition for AES. AES cases should be classified in one of the following four ways (see Figure 1):

Laboratory-confirmed JE: An AES case that has been laboratory-confirmed as JE.

Probable JE: An AES case that occurs in close geographical and temporal relationship to a laboratory-confirmed case of JE, in the context of an outbreak.

AES - other agent: An AES case in which diagnostic testing is performed and an etiologic agent other than JE virus is identified.

AES - unknown: An AES case in which no diagnostic testing is performed or in which testing was performed but no etiologic agent was identified or in which the test results were indeterminate.

Laboratory criteria for confirmation

Clinical signs of JE are indistinguishable from other causes of AES. Laboratory confirmation is therefore essential for accurate diagnosis of JE. Detection of IgM antibody by capture ELISA in cerebrospinal fluid (CSF) or serum reaches $\geq 95\%$ sensitivity 10 days after onset of first symptoms (see note below).

The recommended method for laboratory confirmation of a JE virus infection is:

1. Presence of JE virus-specific IgM antibody in a single sample of CSF or serum, as detected by an IgM-capture ELISA specifically for JE virus³.

In addition, any of the following laboratory criteria is confirmatory for JE:

2. Detection of JE virus antigens in brain tissue by immunohistochemistry or immunofluorescence assay; OR

¹ A simple febrile seizure is defined as a seizure that occurs in a child aged 6 months to less than 6 years old, whose only finding is fever and a single generalized convulsion lasting less than 15 minutes, and who recovers consciousness within 60 minutes of the seizure.

² JE virus infection can also sometimes present with a meningitis syndrome or an acute limb paralysis syndrome, which are not covered in these clinical case definitions.

³ Further confirmatory tests (e.g., looking for cross-reactivity with other flaviviruses circulating in the geographical area) should be carried out when: a) There is an ongoing dengue or other flavivirus outbreak; b) when vaccination coverage is very high; c) or in cases in areas not having epidemiological and entomological data supportive of JE transmission.

Japanese encephalitis (continued)

Laboratory criteria for confirmation *(continued)*

3. Detection of JE virus genome in CSF, serum, plasma, blood⁴, or brain tissue by reverse transcriptase Polymerase chain reaction (PCR) or an equally sensitive and specific nucleic acid amplification test; OR
4. Isolation of JE virus in CSF, serum, plasma, blood⁴ or brain tissue; OR
5. Detection of a four-fold or greater rise in JE virus-specific antibody as measured by hemagglutination inhibition (HI) or plaque reduction neutralization assay (PRNT) in serum collected during the acute and convalescent-phase of illness. The two specimens for IgG should be collected at least 14 days apart. These should be performed in parallel with other flaviviruses as indicated in footnote 3.

Note:

- CSF is the preferred sample for diagnosis of JE.
- The large majority of JE infections are asymptomatic. Therefore, in areas that are highly endemic for JE, it is possible to have AES due to a cause other than JE virus and have JE virus-specific IgM antibody present in serum. To avoid implicating asymptomatic JE as the cause of other AES illnesses, sterile collection and testing of a CSF sample from all persons with AES is recommended when feasible.
- A serum sample should be obtained at admission. Because it may not yet be positive in a JE-infected person, a second serum sample should be collected at discharge or on the 10th day of illness onset (usually around 7 days after admission) or at the time of death and tested for presence of JE virus specific IgM.
- It is not necessary to test all specimens in a normal seasonal outbreak of JE after the outbreak has been confirmed by laboratory testing. If the outbreak is not an expected seasonal outbreak, or there are unusual epidemiological features (e.g. age distribution of cases not consistent with pattern of JE infection), testing of CSF is especially important, as an encephalitis outbreak could be due to other etiologies.

Recommended types of surveillance

JE surveillance should be conducted year-round. Where feasible, surveillance for and reporting of JE should be performed within the context of integrated disease surveillance, and linked synergistically with similar surveillance activities such as those for acute flaccid paralysis (AFP) or meningitis.

A. In all Asian countries:

Comprehensive syndromic surveillance for acute encephalitis syndrome (AES) with aggregate reporting is recommended. In sentinel hospitals, surveillance should be case-based with specimens collected for laboratory confirmation. The number of sentinel hospitals can be gradually increased if feasible logistically.

⁴ Detection of virus genome or virus isolation in serum, plasma, or blood is very specific for JE diagnosis; however, it is not sensitive as virus levels are usually undetectable in clinically ill JE cases. Therefore a negative result by these methods should not be used to rule out JE in a suspected case. Similarly detection of virus genome or virus isolation in CSF is usually only found in fatal cases and therefore not very sensitive and should not be used for ruling out a diagnosis of JE.

Japanese encephalitis (continued)

Recommended types of surveillance *(continued)*

B. In Asian countries where a high level of JE control has been achieved:

Surveillance should be case-based throughout the country and include laboratory confirmation of all suspect cases.

Regardless of the type of surveillance, reporting should be weekly or monthly and include "zero-reporting" (i.e. no blanks should be left in the reporting forms, a zero should be indicated when there are no cases detected). Outbreak investigations should be initiated if there is a sudden increase in cases or if cases reported are different from historical information, in terms of season, geographical area, age group, or case fatality.

Recommended minimum data elements

Aggregated data

- Number of cases and deaths by week/month
- Number of cases by age group, sex and immunization status
- Number of cases by state/province

Case-based data

- Unique identifier
- Age
- Sex
- Geographical area
- Travel history over the past 2 weeks
- Ever immunized against JE; 1 = yes; 2 = No; 9 = unknown.
- If yes, number of doses administered.
- If yes, type of JE vaccine (most recently received).
- Date of last JE immunization
- Date of onset of first symptoms
- Fever: 1 = yes; 2 = No; 9 = unknown.
- Change in mental status: 1 = yes; 2 = No; 9 = unknown.
- Seizure: 1 = yes; 2 = No; 9 = unknown.
- Date CSF sample taken
- Date serum sample 1 taken
- Date serum sample 2 taken
- Autopsy specimen taken; 1 = yes; 2 = No; 9 = unknown.
- Clinical diagnosis: _____

Japanese encephalitis (continued)

Recommended minimum data elements *(continued)*

Depending on which laboratory tests used for serum or CSF:

- IgM serum 1 results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- IgM serum 2 results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- IgM CSF results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- Virus detection (PCR, virus isolation, immunohistochemistry) results: 1 = positive; 2 = negative; 3 = not tested; 9 = unknown.
- HI or PRNT results on acute and convalescent sera: 1 = positive (4 fold rise or greater); 2 = negative (<4 fold rise); 3 = not tested; 9 = unknown.
- Date serum 1 results reported.
- Date serum 2 results reported.
- Date CSF results reported.
- Date virus detection results reported.
- Final classification: 1= laboratory confirmed JE; 2= probable JE; 3 = AES unknown; 4 = AES other agent
- Status at discharge: 1 = alive; 2 = dead; 9 = unknown.
- Date of death or discharge

Recommended data analyses, presentations, reports

Aggregated data

- Number and incidence of suspected cases by week, month, year, age group, and geographical area
- Number and incidence of confirmed cases by week, month, year, age group, and geographical area
- JE vaccine coverage by year and geographical area.
- Percentage of cases vaccinated and unvaccinated
- Completeness/timeliness of monthly reporting by geographical area.

Case-based data – same as aggregated data plus the following:

- Suspected JE (AES) and confirmed cases age-specific, gender-specific, geographical area-specific, and immunization status-specific incidence
- Percentage of suspected cases with CSF and/or serum specimens
- Percentage of cases with serum ten or more days after onset of illness (when the testing methodology is IgM-capture ELISA)
- Case fatality ratio
- Final classification of all suspect JE (AES) cases.
- Proportion of AES attributed to JE.

Performance indicators of surveillance quality

The following targets are for countries with a well established AES surveillance system (Table 1 and Table 2). Countries commencing with JE surveillance may set intermediate targets.

Japanese encephalitis (continued)

Recommended data analyses, presentations, reports (continued)

Table 1: Targets for countries with established surveillance systems

Indicator	Target
Completeness of monthly reporting	≥ 90%
Timeliness of monthly reporting	≥ 80%
Minimal AES rate per 100,000 population	> 2/100,000
Percentage of serum samples taken a minimum of 10 days after onset (when the testing methodology is IgM-capture ELISA)	≥ 80%

In countries where a high level of JE control has been achieved, the following indicators can be helpful as managerial tools to identify areas where corrective action is needed (Table 2).

Table 2: Indicators to assist corrective action

Indicator	Target
Percentage of all AES cases for which specimens were collected	≥ 80% ^a
Percentage of CSF/serum samples reaching laboratory in adequate ^b condition	≥ 80%
For all tests, laboratory results reported < 1 month after receipt specimen	≥ 80%

^a Only applicable for countries doing nationwide case-based surveillance.
^b "Adequate condition" means the specimen is transported using reverse cold chain and is greater than 100ul volume.

Principal uses of data for decision-making

- Guide policy and strategies on JE control
- Assess the impact of vaccination
- Identify geographical areas or populations at high risk to further guide where immunization coverage should be improved
- Monitor the performance of surveillance
- Monitor the performance of the laboratory

Japanese encephalitis (continued)

Special aspects

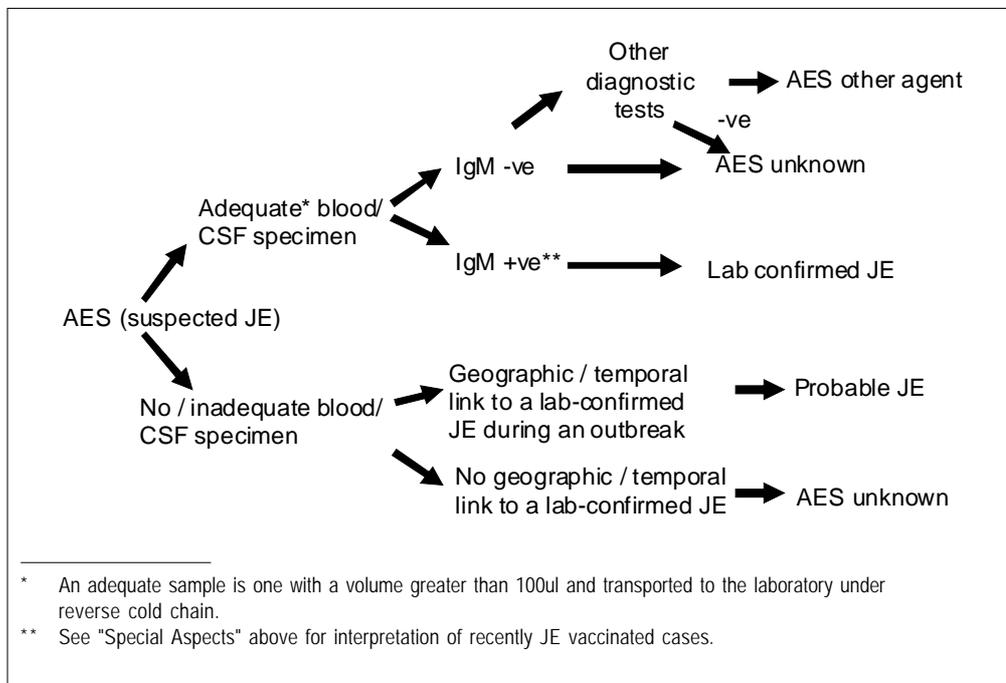
For persons vaccinated with JE vaccine within six months of illness onset, testing a single serum sample for JE IgM may not be diagnostic because any IgM detected may be vaccine-related and not disease-related. In such cases, a diagnosis can only be confirmed by demonstrating JE IgM in the CSF, JE virus isolation, a positive nucleic acid amplification testing, immunohistochemistry, or a four-fold or greater rise in antibody titer in acute- and convalescent-phase serum samples.

Efforts should be made to identify other causes of AES. As a general rule, persons with acute encephalitis should undergo a lumbar puncture to obtain CSF to identify other treatable agents that may result in an illness that manifests as acute encephalitis syndrome. CSF with WBC $\geq 1000/\text{mm}^3$ are unlikely to be due to JE or any other Arbovirus; in these cases, bacterial causes of purulent meningitis such as *Haemophilus influenzae*, *Neisseria meningitidis*, or *Streptococcus pneumoniae* should be considered. In malaria transmission areas, malaria testing should be carried out to rule out cerebral malaria. Health care providers should also rule out Herpes encephalitis, if possible, as it is a treatable cause of AES.

In patients with central nervous system (CNS) disease, there is a clear overlap between those that meet the case definition for "acute encephalitis syndrome" and those that meet the case definition for "bacterial meningitis". It is well recognized that patients with JE can present with signs of meningism. Approaches to encephalitis and meningitis surveillance are also similar, with collection of a CSF specimen for definitive diagnosis. Integration of surveillance for meningitis and encephalitis may be appropriate to help streamline program logistics, ensures case detection is as complete as possible, and to make the best use of available resources. Integrated meningoencephalitis surveillance, for example, could enable data collection for a variety of CNS diseases for which an effective public health control measure - (immunization) is available (e.g. JE, *Haemophilus influenzae* type b, *Streptococcus pneumoniae*, *Neisseria meningitidis*). Public health priorities in country, availability of viral and bacterial diagnostics, and access to testing may all determine the appropriateness of an integrated approach.

Japanese encephalitis (continued)

Figure 1: Final classification scheme for AES cases



A suspected JE (AES) can also be a suspected case of bacterial meningitis (see bacterial meningitis section for definitions). In this event, a CSF/blood sample should be sent to both a bacteriology and a virology laboratory to allow rapid and appropriate case management and classification.

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Department of Vaccines and Biologicals

Health Technology and Pharmaceuticals

World Health Organization

CH-1211 Geneva 27

Switzerland

Fax: +41 22 791 4227

Email: vaccines@who.int

or visit our web site at: <http://www.who.int/vaccines-documents>

