

Case definitions for the four diseases requiring notification in all circumstances under the International Health Regulations (2005)

A) Human influenza caused by a new subtype

Case definition for notification of human influenza caused by a new subtype under the IHR (2005)

State Parties to the IHR (2005) are required to immediately notify WHO of any laboratory confirmed case of a recent human infection caused by an influenza A virus with the potential to cause a pandemic. Evidence of illness is not required for this report.

An influenza A virus is considered to have the potential to cause a pandemic if the virus has demonstrated the capacity to infect a human and if the haemagglutinin gene (or protein) is not a variant or mutated form of those, i.e. A/H1 or A/H3, circulating widely in the human population.

An infection is considered recent if it has been confirmed by positive results from polymerase chain reaction (PCR), virus isolation, or paired acute and convalescent serologic tests. An antibody titre in a single serum is often not enough to confirm a recent infection, and should be assessed by reference to valid WHO case definitions for human infections with specific influenza A subtypes.

B) Poliomyelitis due to wild-type poliovirus

Case definition for notification of poliomyelitis due to wild-type poliovirus under the IHR (2005)

Under the IHR (2005), a notifiable case of poliomyelitis due to wild-type poliovirus is defined as a suspected case* with isolation of wild poliovirus in stool specimens¹ collected from the suspected case or from a close contact of the suspected case.

*A suspected case is defined as a child under 15 years of age presenting with acute flaccid paralysis (AFP²), or as any person at any age with paralytic illness if poliomyelitis is suspected.

¹ As a standard procedure, two stool specimens are collected from an AFP case within 14 days of paralysis onset. Since virus excretion in the stool decreases beyond two weeks after paralysis onset, and to increase the sensitivity of virus detection, additional stool specimens from up to five close contacts are taken from AFP cases for whom 2 specimens collected within 14 days of paralysis onset are not available.

² Poliomyelitis cannot be diagnosed reliably on clinical grounds because other conditions presenting with acute paralysis can mimic poliomyelitis. Surveillance for polio eradication therefore requires the reporting of all children < 15 yrs with acute onset flaccid paralysis, with subsequent laboratory testing of stool specimens.

Note concerning notification of wild or vaccine-derived poliovirus from sources other than AFP cases

In addition to notification of laboratory confirmed cases of poliomyelitis due to wild-type poliovirus (a disease which is designated in Annex 2 of the IHR (2005) as "unusual or unexpected and may have serious public health impact"), the isolation of wild or vaccine-derived poliovirus from other human or non-human sources (from persons without paralysis, or from environmental samples) must generally also be notified to WHO under the separate notification requirement for "events which may constitute a public health emergency of international concern" as they fulfil at least two of the four criteria for notification.

C) Severe Acute Respiratory Syndrome (SARS)

Case definition for notification of SARS under the IHR (2005)

In the SARS post-outbreak period, a notifiable case of SARS is defined as an individual with laboratory confirmation of infection with SARS coronavirus (SARS-CoV) who **either** fulfils the clinical case definition of SARS **or** has worked in a laboratory working with live SARS-CoV or storing clinical specimens infected with SARS-CoV.

Clinical case definition of SARS:

1. A history of fever, or documented fever
AND
2. One or more symptoms of lower respiratory tract illness (cough, difficulty breathing, shortness of breath)
AND
3. Radiographic evidence of lung infiltrates consistent with pneumonia or acute respiratory distress syndrome (ARDS) or autopsy findings consistent with the pathology of pneumonia or ARDS without an identifiable cause
AND
4. No alternative diagnosis can fully explain the illness.

Diagnostic tests required for laboratory confirmation of SARS:

A) Conventional reverse transcriptase polymerase chain reaction (RT-PCR) and real-time reverse transcriptase PCR (real-time RT-PCR) assay detecting viral RNA present in:

1. At least two different clinical specimens (e.g. nasopharyngeal and stool)
OR
2. The same clinical specimen collected on two or more occasions during the course of the illness (e.g. sequential nasopharyngeal aspirates)
OR
3. In a new extract from the original clinical sample tested positive by two different assays or repeat RT-PCR/real-time RT-PCR on each occasion of testing
OR
4. In virus culture from any clinical specimen.

B) Enzyme Linked Immunosorbent Assay (ELISA) and immunofluorescent assay (IFA)

1. Negative antibody test on serum collected during the acute phase of illness followed by positive antibody test on convalescent phase serum, tested simultaneously
OR
2. Fourfold or greater rise in antibody titre against SARS-CoV between an acute serum specimen and a convalescent serum specimen (paired sera), tested simultaneously.

Note:

In the absence of known SARS-CoV transmission to humans, the positive predictive value of a SARS-CoV diagnostic test is extremely low; therefore the diagnosis should be independently verified in one or more WHO International SARS Reference and Verification Network laboratories. A single case of SARS must be reported to WHO under the IHR (2005).

A detailed exposure history is an essential part of the diagnostic workup for any person under investigation for SARS. More information on SARS surveillance can be found at: http://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1/en/index.html.

Infections with SARS-CoV that occur as a result of breaches in laboratory biosafety/biosecurity should be fully investigated.

Once an outbreak of SARS has been independently verified by one or more WHO International SARS Reference and Verification Network laboratories, WHO will make the appropriate case definitions for surveillance and reporting available through its usual well-established mechanisms.

D) Smallpox

Case definition for notification of smallpox under the IHR (2005)

States Parties to the IHR (2005) are required to immediately notify to WHO of any confirmed case of smallpox. The case definition for a confirmed smallpox case includes the following:

Confirmed case of smallpox:

An individual of any age presenting with acute onset of fever ($\geq 38.3^{\circ}\text{C}/101^{\circ}\text{F}$), malaise, and severe prostration with headache and backache occurring 2 to 4 days before rash onset

AND

Subsequent development of a maculopapular rash starting on the face and forearms, then spreading to the trunk and legs, and evolving within 48 hours to deep-seated, firm/hard and round well-circumscribed vesicles and later pustules, which may become umbilicated or confluent

AND

Lesions that appear in the same stage of development (i.e. all are vesicles or all are pustules) on any given part of the body (e.g. the face or arm)

AND

No alternative diagnosis explaining the illness

AND

Laboratory confirmation.

Note:

In contrast to the varicella (chickenpox) infection with centripetal and more superficial lesions, the majority of smallpox cases present with a characteristic rash that evolves slowly over days (with each stage lasting 1-2 days) at the same rate and is centrifugal in distribution, i.e. predominantly concentrated on face and extremities with usual involvement of the palms and soles of the feet. More information and illustrative examples to differentiate smallpox from chickenpox can be found at <http://www.who.int/csr/disease/smallpox/preparedness/en/index.html>.

The risk of not identifying atypical presentations of smallpox is weighed against the extreme low risk of reintroduction of the disease and the very high risk of obtaining a false-positive laboratory result. In view of this, laboratory tests to confirm smallpox should be limited to individuals that match the above clinical case definition. Should a single, laboratory confirmed case of smallpox ever occur, it would be then considered an outbreak since smallpox no longer exists as a naturally occurring disease.