

Human infection with pandemic (H1N1) 2009 virus: updated interim WHO guidance on global surveillance

10 July 2009

Background

This document updates the interim WHO guidance on global surveillance of pandemic (H1N1) 2009 virus infection in humans.¹ The guidance has been revised to make it applicable to current global pandemic phase 6. It will be further reviewed and modified as the pandemic (H1N1) 2009 evolves.

Standardized and coordinated international information sharing is crucial for the management of the pandemic at global and national levels. National authorities need to know how the pandemic is evolving, not only in their own country, but also in neighbouring countries and continents. The continual flow and analysis of information provided by individual countries contributes to the development of a global picture that:

- results in a better understanding of critical clinical, epidemiological and virological features of the (H1N1) 2009 pandemic
- guides global prevention and control activities
- allows health-care providers and public health authorities to modify their own strategies for case management, community mitigation, and health resource allocation
- reduces the impact of inaccurate and unconfirmed rumours.

This updated interim guidance is designed as much as possible, for use by existing or developing systems and infrastructure and takes into account the varying capacities of countries with regard to influenza surveillance. The guidance identifies a minimum set of data that can feasibly be collected in all settings, thereby allowing all Member States to participate in the global surveillance effort while collecting useful information to guide their own national control efforts.

Global surveillance of pandemic (H1N1) 2009 virus infections in humans

The approach and methods for global surveillance vary at different stages of the pandemic. In countries with no or very few cases, the main aims of surveillance remain early detection of the introduction of the virus using laboratory confirmation of cases and initial risk assessment.

In countries where the pandemic (H1N1) 2009 virus is established, the main aims of surveillance are continuous monitoring of the epidemiological, virological and clinical picture of the pandemic and its impact on the health-care infrastructure. Timely sharing of information is needed throughout the pandemic to enable ongoing risk assessment to take place.

¹ WHO guidance for the surveillance of human infection with new influenza A (H1N1) virus posted on WHO web site on 29 April 2009. Based on *Global surveillance during an influenza pandemic* (<http://www.who.int/csr/resources/publications/swineflu/surveillance/en/index.html>). This interim guidance will remain valid until updated, or until 31 December 2009.

A. Early detection, investigation and risk assessment

In countries with no apparent virus circulation the aims of surveillance are to document the first appearance of the pandemic (H1N1) 2009 virus and to collect sufficient information on initial cases for risk assessment. The requirements are to:

- detect and confirm the spread of pandemic (H1N1) 2009 virus into areas, e.g. administrative units, not previously reporting confirmed cases
- investigate changes in the characteristics of the pandemic such as any increase in the severity of the disease.

Triggers/signals for the investigation of suspected cases or clusters of pandemic (H1N1) 2009 virus infection include:

- cluster(s)² of cases of unexplained ILI or acute lower respiratory tract infection
- severe, unexplained respiratory illness
- changes in the epidemiology of mortality associated with the occurrence of ILI or lower respiratory tract illness, an increase in the number of deaths observed from respiratory illness or an increase in the occurrence of severe respiratory disease in previously healthy adults or adolescents and/or among pregnant women
- abnormally high levels of absenteeism in a school or workplace setting.

The initial investigation should include laboratory confirmation of any suspected case of pandemic (H1N1) 2009 virus. Member States without laboratory capacity or with no access to laboratory capacity for confirmation, should contact their WHO regional office, so that an appropriate laboratory can be identified for the submission and testing of samples.

At any stage during the pandemic, unexplained clusters of respiratory disease or deaths, or any change in the epidemiological or clinical presentation of the disease seen to date, requires immediate investigation. The number of samples collected will vary depending on the needs of the investigation.

Reporting requirements

Under the IHR (2005) Article 6³, a State Party is required to notify WHO of the first occurrence of pandemic (H1N1) 2009 virus detected in their country. Following this initial notification, the IHR (2005) subsequently requires the country to further communicate to WHO timely, accurate and sufficiently detailed public health information on the notified event. WHO will continue to communicate directly with the IHR National Focal Point (NFP) to request specific information for risk assessment and risk management. Case definitions, laboratory results, source and type of risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed should be included in this information. The guidance below is intended to assist IHR National Focal Points and other national authorities responsible for gathering and providing such information to WHO.

² Cluster: Two or more persons that are detected with onset of illness within a period of 7 days in the same geographical area and/or who are epidemiologically linked.

³ WHO. International Health Regulations (2005) Geneva, Switzerland, 2006. Available at http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf

At first introduction of the virus: early detection and investigation

The first confirmed of pandemic (H1N1) 2009 virus infection detected in a country should be immediately reported by the IHR National Focal Point to the IHR Contact Point at the relevant WHO Regional Office as well as the WHO Country Representative where applicable. WHO will follow established processes for internal communications about such notifications.

Confirmed cases reported to WHO should be attributed to the country, territory or area in which they are identified.

At any stage during the pandemic

IHR National Focal Points or national public health authorities should continue to notify WHO immediately on:

- any changes in the epidemiological, virological or clinical presentation that are likely to be of significance for global risk assessment
- any unusual or unexpected public health events, including clusters of severe unexplained acute respiratory illness or unexplained deaths due to respiratory disease.
- mortality data - the number of deaths due to acute respiratory disease (by age group if available).

B. After detection of the pandemic virus: description of the epidemiology and assessment of the early cases

Once the pandemic (H1N1) virus has been detected it is important to:

- describe the epidemiological and virological features of cases to guide control and prevention activities as required
- assess disease severity.

Following the initial assessment of the early cases, the laboratory testing of a sample of suspected cases of pandemic (H1N1) 2009 virus is sufficient for ongoing virological surveillance. Laboratory sampling should then be directed towards:

- confirming infection in new areas
- testing severe cases
- monitoring the co-circulation of pandemic (H1N1) 2009 virus (and other respiratory viruses in countries with laboratory capacity for more detailed virological investigations).

For countries with limited laboratory capacity, or limited access to laboratory capacity, WHO recommends they aim to test a number of samples per week in order to verify that disease activity is still largely due to pandemic (H1N1) 2009 virus. For countries with laboratory capacity, detailed guidance is given below on virological monitoring during the pandemic.

Reporting requirements

Initial spread of the virus: aggregated case counts and descriptive epidemiology of the early cases

After the first case(s) of pandemic (H1N1) 2009 virus infection have been notified and for as long as is feasible for the country, IHR National Focal Points or national public health authorities should report the following information to WHO on a weekly basis:

- the number of confirmed cases and deaths in confirmed cases
- the age distribution of confirmed cases and deaths (where available).

Case definitions for the purpose of reporting confirmed cases of pandemic (H1N1) 2009 virus infection can be found in Annex 1.

Countries should contact the relevant WHO regional office for reporting arrangements. A summary form has been developed to facilitate the reporting of this information to WHO (Annex 2). WHO will use the information in accordance with Article 11 of the IHR (2005) as required by the circumstances of the pandemic.

In addition to the information asked above, all Member States are strongly encouraged to share with WHO any additional information relevant for ongoing global risk assessment. This includes, in particular, information on the clinical spectrum of the disease, the proportion of cases with severe illness, and risk groups for severe outcome. For detailed case-based information, a form has been developed to facilitate the collection of these data (Annex 3).

C. Continuous epidemiological and virological monitoring of influenza activity

Influenza-related activity should be monitored on a continual basis throughout the pandemic and should start as soon as possible, in all countries. At a minimum, countries should report on influenza activity.

The objectives of on-going monitoring of influenza activity throughout the pandemic are to track:

- global geographical spread
- disease trend
- intensity
- impact of the pandemic on health-care services
- the number of deaths due to acute respiratory disease (by age group if available)
- changes in viral antigenicity and antiviral sensitivity.

Epidemiological monitoring

Epidemiological monitoring will be carried out differently by Member States. Therefore, WHO monitoring activities will accommodate several types of data to allow countries at different stages of the pandemic to participate in this monitoring effort, regardless of their surveillance and laboratory capacities.

- **All Member States** are asked to provide a general interpretation of information derived from a variety of information sources. A set of four qualitative (non-numerical) indicators are defined in Annex 4 and describe the geographical spread, the trend in the number of cases, the intensity of acute respiratory disease, and the impact on the health-care system.

Information sources for the qualitative assessment may include:

- sentinel sites for acute respiratory illness (ARI)⁴ influenza-like illness (ILI)⁵ and severe acute respiratory illness (SARI)⁶
 - absenteeism rates from schools or work places
 - use of pharmaceuticals for symptomatic relief of respiratory disease
 - outpatient or emergency department visits for acute respiratory illness
 - vital statistics indicating respiratory disease as cause of death
 - formal and informal reports from district health authorities or health-care providers.
- **In addition Member States with established epidemiological surveillance systems** will be asked to provide a set of quantitative (numerical) data that can be derived from existing surveillance systems for respiratory disease, influenza or mortality. Case definitions and the type of data to be reported can be found in Annex 5.

Virological monitoring

Global influenza virological monitoring is dependent upon the existing capacity of influenza virus surveillance and national capacity for virus detection and characterization. During Phase 6, the main objective of laboratory surveillance is to monitor the evolution of the virus for the purpose of:

- detecting any genetic drift or re-assortment events that may affect virus pathogenicity
- identifying drug resistance status
- ensuring the specificity and sensitivity of current diagnostic assays
- informing vaccine development.

Virological surveillance activities will vary according to existing laboratory capacities in terms of response, number of samples tested, number of samples selected for full characterization of the virus and many other factors. Accordingly, countries should respond in line with the following criteria:

- **Countries with a WHO designated National Influenza Centre (NIC)**, conducting regular seasonal surveillance are asked to provide WHO Collaborating Centres (WHOCC) with a representative number of isolates for further characterization and for use in vaccine updates or drug resistance monitoring.
- **Countries without a designated NIC but with ongoing existing influenza surveillance activities** that have previously contributed isolates to WHOCCs for vaccine considerations, should continue to do so as category above.
- **Countries without a designated NIC and with no ongoing influenza surveillance activities but with capacity to diagnose the pandemic (H1N1) 2009 virus and/or other influenza A**

⁴ ARI: Acute febrile respiratory illness (fever >38°C) with the spectrum of disease from influenza-like illness to pneumonia.

⁵ ILI: A person with sudden onset of fever of >38 °C and cough or sore throat in the absence of other diagnoses.

⁶ SARI: Meets ILI case definition AND shortness of breath or difficulty breathing AND requiring hospital admission.

subtypes should follow their national guidelines for pandemic preparedness and the global surveillance guidelines in this document and send a representative number of specimens or isolates, depending on their laboratory capacity, to WHOCCs for further characterization.

Countries without a designated NIC, with no ongoing influenza surveillance activities and with no laboratory capacity to diagnose the pandemic (H1N1) 2009 influenza virus should collect representative samples from clinically compatible cases from newly affected areas and among severe cases. Each country should aim to collect clinical samples per week and send to neighboring countries or regional influenza laboratories with laboratory capacity for virus characterization.

Countries should contact the relevant WHO Regional Office or WHO HQ for guidance on the collection, handling, and shipping of specimens.

Reporting requirements

Unless other arrangements are in place between a Member State and the relevant WHO Regional Offices, the following reporting arrangements should be followed by national health authorities in collaboration with their National IHR Focal Point:

- **National health authorities from all countries** should inform WHO on a weekly basis of their qualitative assessment of the geographical spread, trend of cases, intensity of disease, impact on the health-care system, and deaths.
- **National health authorities from countries with established influenza surveillance systems** should report on a weekly basis data on ILI and/or SARI
- **National influenza centres or reporting laboratories** are asked to report weekly via FluNet⁷ on the number of specimens collected and processed for influenza and the number of specimens tested that are positive for influenza by subtype.

In addition to notifications to the National IHR Focal Point, WHO has developed a surveillance system called FluID that can be used by countries to assist in reporting. The relevant WHO Regional Office should be consulted for further guidance on online access to FluID. WHO HQ should be contacted at GISN@who.int for questions concerning FluNet.

All national health authorities are encouraged to share with WHO any other information relevant to the ongoing risk assessment of this pandemic.

D. Analysis and publication of surveillance data by WHO

Data collected via WHO's global influenza A (H1N1) surveillance systems will be analysed and summary data will be published in graphs, maps and tables on WHO's web site and published in the *Weekly Epidemiological Record*.⁸

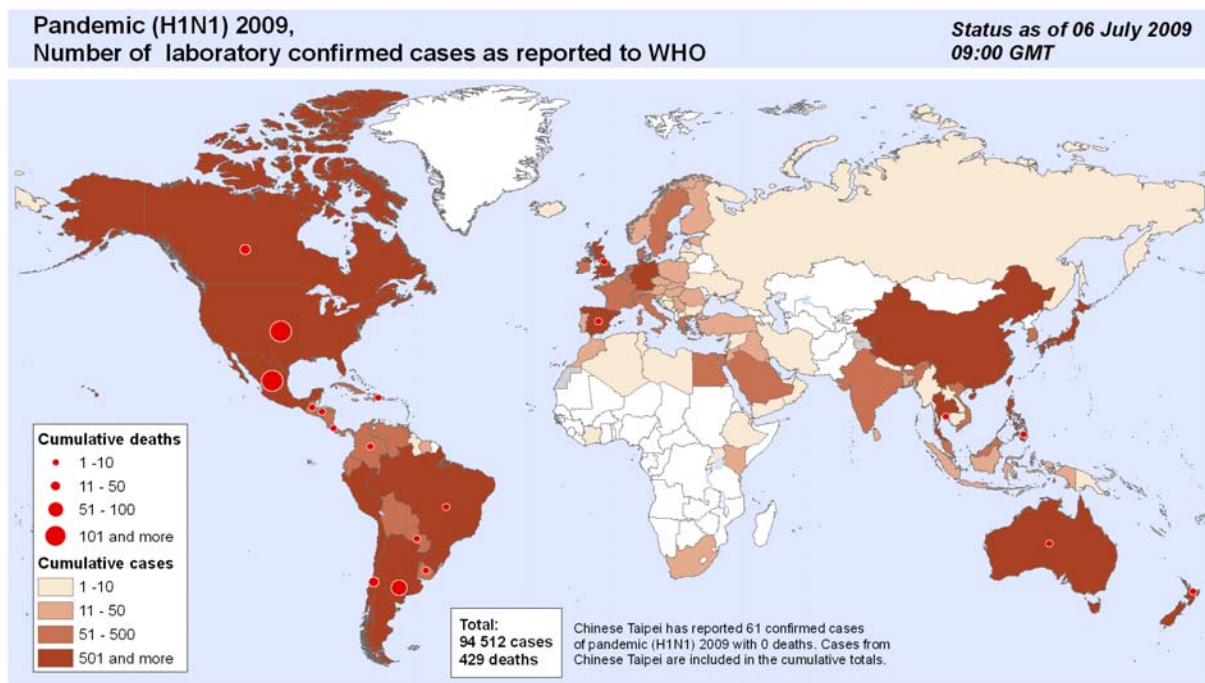
⁷ <http://www.who.int/flunet>

⁸ <http://www.who.int/wer/en/index.html>

WHO will use the information provided to inform global risk assessments, including mathematical modelling of the epidemic, to better understand the spread of the pandemic and the effectiveness of mitigation measures.

Scientists from countries providing data will be invited to participate in the development of, and be co-authors on, publications that draw on their country-specific data. Countries will always be consulted in the development of any articles in which their data has been used.

WHO will report and visualize the surveillance data provided. Reports will include alerts, situational summaries, tables, charts and maps of the evolving pandemic situation. The following graphics are examples of the outputs of WHO's global data collection.



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Map produced: 06 July 2009 09:00 GMT

Data Source: World Health Organization
Map Production: Public Health Information
and Geographic Information Systems (GIS)
World Health Organization



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Country or Region (scroll down): **Northern hemisphere**

Centre(s): All centres (combined data)

After choosing a new country and/or a new centre, please wait for a short while, so that the graphs get refreshed for the new selection. If graphs are blank it indicates data not available.

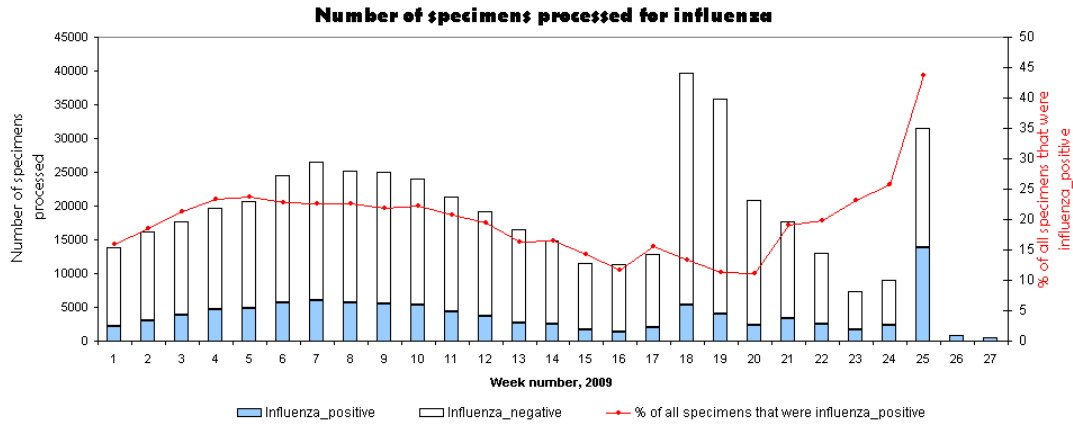
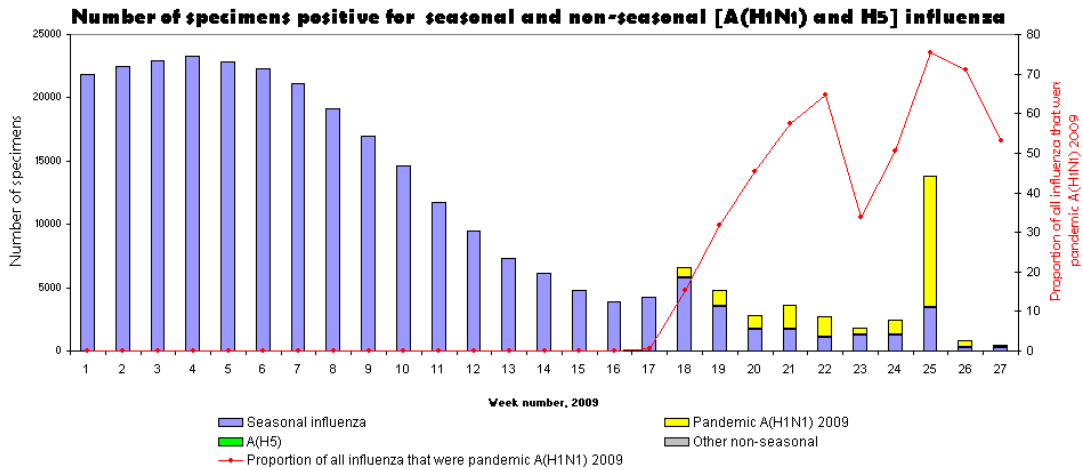
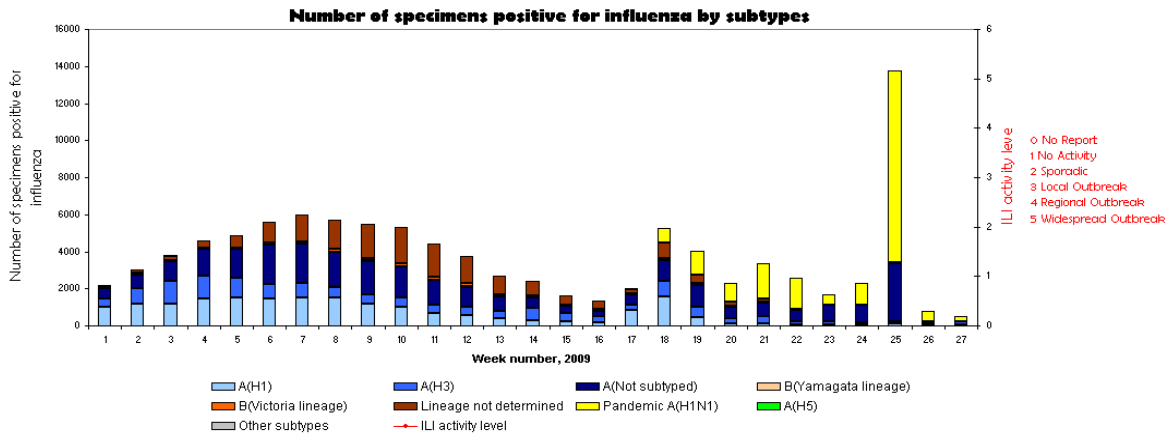


Chart Area



Annex 1

Case definition for the reporting of pandemic (H1N1) 2009 virus infections in humans

The following case definition should be used to report **confirmed cases** of pandemic (H1N1) 2009 virus infection to WHO.

- An individual with laboratory-confirmed pandemic (H1N1) 2009 virus infection by one or more of the following tests⁹:
 - polymerase chain reaction (PCR);
 - viral culture;
 - 4-fold rise in pandemic (H1N1) 2009 virus virus-specific neutralizing antibodies.

⁹ Most current information is available at:

http://www.who.int/csr/resources/publications/swineflu/diagnostic_recommendations/en/index.html

Annex 2

Weekly summary reporting form (version 2.0)

Please complete this form on weekly basis at country level (national level).

Fields marked with * are required.

Confirmed cases reported to WHO should be attributed to the country, territory or area in which they are identified.

Week* ending at day (yyyy/MM/dd)

Country*

Human cases of the pandemic (H1N1) 2009 infection

See [WHO case definition](#)

Number of new cases and deaths in reporting week

New laboratory confirmed cases	
New deaths in laboratory confirmed cases	

Cumulative number of cases and deaths since first report

Cumulative laboratory confirmed cases*	
Cumulative deaths in laboratory confirmed cases*	

If available, please indicate cumulative laboratory confirmed cases by age-group

Infants	
Children	
Adults	
Elderly	
Unknown	

See next page...

If available, please indicate cumulative deaths laboratory confirmed by age-group

Infants	
Children	
Adults	
Elderly	
Unknown	

Comments

Please enter any additional comments (indicate once the age ranges used)

Reporter information

Name of reporter

Name of institution

Telephone number

Email

Date of submission (yyyy/MM/dd)

Annex 3

WHO pandemic (H1N1) 2009 case summary form for clinical data collection of laboratory confirmed cases

This form can be used to collect information on a person with laboratory-confirmed cases of pandemic (H1N1) 2009 virus infections to enable disease severity and clinical characteristics to be determined. All data submitted on this form will be treated as confidential in accordance with the International Health Regulations (2005).

This form is an update of the WHO "new" Influenza A (H1N1) Case Summary form version¹⁰.

1. Case Information

Case ID (including country identifier)	_____	
Date of birth (yyyy/mm/dd)	____/____/____	or Age (years) _____
Sex	Male <input type="checkbox"/>	Female <input type="checkbox"/> Unknown <input type="checkbox"/>

2. Symptoms

- Date of onset of symptoms (yyyy/mm/dd) _____/_____/_____
- Symptoms at any time during the course of the infection

	Tick as applicable	Comments (if any)
Fever $\geq 38^{\circ}\text{C}$	<input type="checkbox"/>	_____
History of fever (not measured)	<input type="checkbox"/>	_____
Sore throat	<input type="checkbox"/>	_____
Runny nose	<input type="checkbox"/>	_____
Sneezing	<input type="checkbox"/>	_____
Cough	<input type="checkbox"/>	_____
Shortness of breath	<input type="checkbox"/>	_____
Conjunctivitis	<input type="checkbox"/>	_____
Diarrhoea	<input type="checkbox"/>	_____
Nausea	<input type="checkbox"/>	_____
Vomiting	<input type="checkbox"/>	_____
Headache	<input type="checkbox"/>	_____
Seizures	<input type="checkbox"/>	_____
Altered consciousness	<input type="checkbox"/>	_____
Muscle pain	<input type="checkbox"/>	_____
Joint pain	<input type="checkbox"/>	_____
Nose bleed	<input type="checkbox"/>	_____
Other (specify)	<input type="checkbox"/>	_____

¹⁰ <http://www.who.int/csr/resources/publications/swineflu/caseformadapted20090508.pdf>

3. History and Pre-Existing Conditions

- Did the case have any of the following vaccines or prophylactic medication prior to illness onset?

	<i>Tick as applicable</i>	<i>Comments (if any)</i>
Vaccination with seasonal influenza vaccine within the last year?	<input type="checkbox"/>	_____
Vaccination with pneumococcal vaccine?	<input type="checkbox"/>	_____
Antivirals prophylaxis in the 14 days before onset of illness?	<input type="checkbox"/>	_____
<i>If prophylaxis was used, which</i>		
Oseltamivir	<input type="checkbox"/>	
Zanamivir	<input type="checkbox"/>	
Amantadine	<input type="checkbox"/>	
Rimantadine	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	

- Did the case have any pre-existing conditions?

	<i>Tick as applicable</i>	
Cancer	<input type="checkbox"/>	
Diabetes	<input type="checkbox"/>	
HIV/other immune deficiency	<input type="checkbox"/>	
Heart disease	<input type="checkbox"/>	
Seizure disorder	<input type="checkbox"/>	
Lung disease	<input type="checkbox"/>	
Asthma	<input type="checkbox"/>	
Pregnancy	<input type="checkbox"/>	_____ months
Malnutrition	<input type="checkbox"/>	
Obesity	<input type="checkbox"/>	
Others (<i>specify</i>)	<input type="checkbox"/>	

4. Pneumonia, other complications

- Did the patient show clinical signs of pneumonia? Yes No Unknown
- Was a chest x-ray taken? Yes No Unknown
if no or unknown go to 5.
 - Primary viral/influenza pneumonia diagnosed? Yes No Unknown
 - Secondary bacterial pneumonia diagnosed? Yes No Unknown
- Did other complications (e.g. ARDS¹¹, MOF¹², CNS¹³ involvement) occur? Yes No Unknown
if yes, describe

5. Treatment

- Date (yyyy/mm/dd) of first presentation to health care system? _____/_____/_____
- Case hospitalized during course of infection Yes No Unknown
if yes, date (yyyy/mm/dd) of first hospitalisation _____/_____/_____
 - was case admitted to ICU? Yes No Unknown
 - was case mechanically ventilated? Yes No Unknown
- Did case receive antibiotics? Yes No Unknown
- Did case receive antiviral treatment? Yes No Unknown
if no, go to 6

Treatment	Tick as applicable	Date started (yyyy/mm/dd)	Duration (days)	Daily Dose
Oseltamivir	<input type="checkbox"/>	____/____/____	_____	_____
Zanamivir	<input type="checkbox"/>	____/____/____	_____	_____
Amantadine	<input type="checkbox"/>	____/____/____	_____	_____
Rimantadine	<input type="checkbox"/>	____/____/____	_____	_____

¹¹ Acute respiratory distress syndrome

¹² Multi organ failure

¹³ Central nervous system

- Were antiviral adverse events noted

Yes No Unknown

if yes, were they

Moderate Severe Life threatening

Specify type of adverse event

6. Outcome

- Patient fully recovered

Yes No Unknown

if yes, Date of resolution of symptoms (yyyy/mm/dd)

____/____/____

- Patient died

Yes No Unknown

if yes, Date of death (yyyy/mm/dd)

____/____/____

Presumed cause of death

7. Other Observations/Comments

Annex 4:

Qualitative indicators, to be reported by all Member States

- **Geographical spread**

Geographical spread refers to the number and distribution of sites reporting influenza activity.

- **No activity:** no laboratory-confirmed case(s) of influenza, or evidence of increased or unusual respiratory disease activity.
- **Localized:** limited to one administrative unit of the country (or reporting site) only.
- **Regional:** appearing in multiple but <50% of the administrative units of the country (or reporting sites).
- **Widespread:** appearing in ≥50% of the administrative units of the country (or reporting sites).
- **No information available:** no information available for the previous 1-week period.

- **Trend**

Trend refers to changes in the level of respiratory disease activity compared with the previous week.

- **Increasing:** evidence that the level of respiratory disease activity is increasing compared with the previous week.
- **Unchanged:** evidence that the level of respiratory disease activity is unchanged compared with the previous week.
- **Decreasing:** evidence that the level of respiratory disease activity is decreasing compared with the previous week.
- **No information available.**

- **Intensity**

The intensity indicator is an estimate of the proportion of the population with acute respiratory disease, covering the spectrum of disease from influenza-like illness to pneumonia.

- **Low or moderate:** a normal or slightly increased proportion of the population is currently affected by respiratory illness.
- **High:** a large proportion of the population is currently affected by respiratory illness.
- **Very high:** a very large proportion of the population is currently affected by respiratory illness.
- **No information available.**

- **Impact**

Impact refers to the degree of disruption of health-care services as a result of acute respiratory disease.

- **Low:** demands on health-care services are not above usual levels.
- **Moderate:** demands on health-care services are above the usual demand levels but still below the maximum capacity of those services.
- **Severe:** demands on health care services exceed the capacity of those services.
- **No information available.**

Annex 5:

Quantitative indicators, to be reported by Member States with established influenza surveillance systems

Case definitions for ILI and SARI surveillance

Influenza-like illness (ILI)

A person with sudden onset of fever of $>38^{\circ}\text{C}$ and cough or sore throat in the absence of other diagnoses.

Severe acute respiratory illness (SARI)

Meets ILI case definition (sudden onset of fever $>38^{\circ}\text{C}$ and cough or sore throat in the absence of other diagnosis) AND shortness of breath or difficulty breathing AND requiring hospital admission.

- **ILI sentinel sites or out-patients visits**

- Number of ILI cases reported in the past 1-week period by age group and sex (if available).
- Number of total outpatient visits for all causes, or population covered.
- Number of reporting sites.

- **SARI sentinel surveillance sites or in-patient facilities**

- Number of new SARI cases admitted in the past 1-week period by age group and sex (if available).
- Number of total admissions (from same facilities as number of SARI cases reported), or population covered.
- Number of SARI-related deaths by age (if available).
- Number of SARI sentinel sites reporting.

- **Mortality data**

- Number of deaths related to acute respiratory disease by age group (if available).
- Population covered.