TECHNICAL DOCUMENT

Overview of surveillance of influenza 2009/2010 in the EU/EEA

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Stockholm, September 2009

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Abbreviations

ARI	acute respiratory infection
IHR	International Health Regulations
ILI	influenza-like illness
SARI	severe acute respiratory infection
TESSy	The European Surveillance System

Overview

When the current influenza pandemic began in North America in April and the first cases started appearing in Europe soon thereafter, case-based and aggregate reporting systems were rapidly implemented utilising the ECDC Early Warning and Response System in order to fulfil the requirements of the International Health Regulations (IHR). Since then, these data have been used for ECDC's daily situation reports and are considered very useful for presenting an up-to-date overview of the geographic spread and intensity of the pandemic. Additional analyses of the case-based data have provided information on demographic and clinical characteristics of the affected populations [1] (see http://ecdc.europa.eu/en/healthtopics/Pages/Influenza_A(H1N1)_Outbreak_Surveillance_reports.aspx.)

As the pandemic evolves, however, reporting to such a system has become unsustainable in more and more Member States. As of 23 July 2009 [2], several countries have announced that they would concentrate on mitigation measures.

This document gives an overview on how to continue the surveillance of influenza A(H1N1) 2009 at the European level. It is based on the outcomes of the fourth meeting of ECDC's Surveillance and Studies in a Pandemic Working Group, held on 14 and 15 July 2009, and on the WHO guidance on global surveillance of this virus, published on 10 July 2009 (see http://www.who.int/csr/disease/swineflu/WHO_case_definition_swine_flu_2009_04_29.pdf). It is understood that not all Member States will be able to contribute to all planned surveillance systems and that actual participation will depend on individual countries' capacities and priorities.

In the Annex to this document we describe in more detail all relevant components that are new in ECDC's TESSy surveillance system/database.

Figure 1 gives an overview of the components of influenza surveillance in the 2009/2010 season in EU/EEA countries.

Figure 1: Overview influenza surveillance 2009/2010

	In place	In place	New in TESSy	New in TESSy	New in TESSy	External
Component	ILI/ARI sentinel surveillance	Virological surveillance	Case-based reporting of SARI and fatal cases	Aggregate reporting	Qualitative reporting	EuroMOMO
Provides info about	Morbidity in population	Circulating types/ subtypes Antiviral resistance	Severe spectrum of disease	Cases and deaths by age categories	Evolution of pandemic in absence of quantitative data	All-cause mortality
During monitoring phase	To be kept in place as long as possible	To be kept in place as long as possible	To be kept in place as long as possible	For countries monitoring laboratory-confirmed cases	To be used when sentinel system is not working	As soon as it becomes available

Quantitative monitoring

Quantitative monitoring will be based on data from surveillance of influenza-like illness (ILI) or acute respiratory infection (ARI) and severe acute respiratory infection (SARI) sentinel surveillance, as well as from mortality monitoring.

- **ILI/ARI and virologic sentinel surveillance.**
  ILI/ARI and virologic sentinel surveillance are already in place (see http://ecdc.europa.eu/en/activities/surveillance/EISN/). A method for the standard calculation of a common baseline will be explored and communicated in a later proposal.
- **Case-based reporting of severe acute respiratory infection (SARI), including fatal outcomes**.
  In the meeting on Surveillance and Studies in a Pandemic held in Stockholm on 14 and 15 July, it was agreed to focus case-based reporting on severe A(H1N1) 2009 cases and deaths in hospitals in the EU/EEA countries. A set of variables to be collected for these surveillance activities is part of this proposal.
- **Aggregate reporting of cases and deaths due to pandemic (H1N1) 2009 virus.**
  As numbers of pandemic (H1N1) 2009 influenza cases have been increasing in Europe, some of the most heavily affected countries have abandoned generalised laboratory testing and counting of all confirmed cases. The majority of EU/EEA countries, however, are not yet observing any sustained community transmission of the pandemic virus and are thus still in a position to keep track of their aggregate case numbers.

Qualitative monitoring of pandemic (H1N1) 2009 virus

During the pandemic acceleration and peak phase, established surveillance systems that are based on sentinel healthcare providers might break down. In such a situation, qualitative monitoring systems could then be the only means of keeping track of the pandemic dynamics and the impact this has on individual countries. Qualitative monitoring systems will be used when sentinel systems are not functional.

Monitoring of all-cause mortality and excess mortality

Monitoring of all-cause mortality and excess mortality is being set up by the EuroMOMO project. The EuroMOMO project will provide information on the spread and impact of an influenza pandemic. This project is currently in its test implementation phase in Belgium, Denmark, France, Ireland, Israel and Spain. In response to the current A(H1N1)v influenza pandemic, EuroMOMO is accelerating its pilot phase. In the summer of 2009, EuroMOMO has already provided an 'emergency' mortality monitoring system by using a simple algorithm which measures excess deaths and provides standardised indicators for a comparison across Europe (http://www.euromomo.eu/).

The main output of these combined surveillance activities will be a weekly surveillance report that will include not only the information covered by the current weekly bulletin but will provide a more comprehensive picture of the pandemic's epidemiology and impact.

Scope of this document

This document provides an overview of the surveillance activities to be implemented by ECDC and the Member States in early autumn 2009. The list of variables described in the Annexes should not yet be implemented as such, as some technical variables (usually described according to the TESSy standard reporting protocol) have been omitted. A specific reporting protocol will be sent to the participating countries in September 2009, so that Member States will be able to adapt/prepare the data to be collected.

Component 1. Surveillance of influenza-like illness (ILI) or acute respiratory infection (ARI)

1 Objectives

- Collect and provide timely information on influenza activity.
- Estimate the ILI/ARI incidence in the population.

2 Methods

2.1 Case definitions

The case definitions are specified in Decision No 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, as amended by Commission Decision No 2008/426/EC of 28 April 2008). See: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:159:0046:01:EN:HTML.

2.2 Population under surveillance

ILI/ARI surveillance is conducted using a sentinel network model. Clinical data are collected from the population under surveillance. For details see: http://ecdc.europa.eu/en/activities/surveillance/EISN/.

2.3 Reporting to ECDC

Clinical and virological data (data on age group are optional) should be uploaded to TESSy once every week by using the online data entry wizard or the file upload option. Ideally, weekly data should be submitted and approved no later than 10:00 a.m. on Thursday of the following week, in order to ensure that the data are included in Friday's weekly influenza report. Influenza contacts in the Member States who have not submitted their weekly data by Wednesday afternoon at 6:00 p.m. will receive automated reminders from the TESSy Helpdesk to kindly upload their data by the next morning.

The definition of the variables to be reported for the related record type can be found in TESSy or in the influenza reporting protocol. Cumulative numbers will be shown in TESSy online reports and in subsequent bulletins based on the weekly data in TESSy.

In addition to submitting weekly data, it is important that Member States take due care in creating and editing a profile for the data source ('data source profile') when submitting influenza data and related matters. The total population of a country (denominator) should be recorded in the data source profile, i.e. the country's surveillance system characteristics. This also applies to the country's age-specific population data if aggregate data are reported by age group.

Support for data upload and other questions can be directed to the TESSy Helpdesk at tessy@ecdc.europa.eu or +46 8 5860 1601, available Monday through Friday from 9:00 a.m. to 4:30 p.m. Stockholm time, excluding ECDC holidays. Additional online training on how to use TESSy, including online video demonstrations of how to report ILI and ARI, can be found at: http://www.world-television.se/projects/ECDC/2009/TESSy_training_03/.

3 Surveillance output

Output includes graphs, maps and tables as currently published weekly in the EISN Bulletin: http://ecdc.europa.eu/en/activities/surveillance/EISN/Pages/EISN_Bulletin.aspx.

Component 2. Virological surveillance

1 Objective

Collect and provide timely information on circulating influenza virus strains.

2 Methods

2.1 Case definitions

The case definitions are published in Decision No 2002/253/EC on case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, as amended by Commission Decision 2008/426/EC of 28 April 2008). See: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:159:0046:01:EN:HTML.

2.2 Population under surveillance

Virological surveillance is conducted using a sentinel network model. Virological data are collected from the population under surveillance. For details see: http://ecdc.europa.eu/en/activities/surveillance/EISN/Pages/Methods_LabNetwork.aspx.

2.3 Reporting to ECDC

Virological data should be uploaded to TESSy once every week using the online data entry wizard or the file upload option. Ideally, weekly data should be submitted and approved no later than 10:00 a.m. on Thursday of the following week, in order to ensure that the data are included in the weekly influenza report. Influenza contacts in the Member States who have not submitted their weekly data by Wednesday afternoon at 6:00 p.m. will receive automated reminders from the TESSy Helpdesk to kindly upload their data by the next morning.

The definition of the variables to be reported for the related record type can be found in TESSy or in the influenza reporting protocol. Cumulative numbers will be shown in TESSy online reports and in subsequent bulletins based on the weekly data in TESSy.

In addition to submitting weekly data, it is important that Member States take due care in creating and editing a profile for the data source ('data source profile') when submitting influenza data and related matters. The total population of a country (denominator) should be recorded in the data source profile, i.e. the country's surveillance system characteristics. This also applies to the country's age-specific population data if aggregate data are reported by age group.

Support for data upload and other questions can be directed to the TESSy Helpdesk at tessy@ecdc.europa.eu or +46 8 5860 1601, available Monday through Friday from 9:00 a.m. to 4:30 p.m. Stockholm time, excluding ECDC holidays. Additional online training on how to use TESSy, including online video demonstrations of how to report ILI and ARI, can be found at: http://www.world-television.se/projects/ECDC/2009/TESSy_training_03/.

3 Surveillance output

Output includes graphs, maps and tables as currently published weekly in the EISN Bulletin: http://ecdc.europa.eu/en/activities/surveillance/EISN/Pages/EISN_Bulletin.aspx.

Component 3. Surveillance of severe acute respiratory infection and fatal cases related to pandemic influenza in the EU/EEA

1 Objectives

1.1 Objectives for severe acute respiratory infection (SARI)

The objectives for the surveillance of severe acute respiratory infection are:

- to contribute to the monitoring of the severity of the pandemic so as to detect indicators of increasing severity at an early stage, which may justify more robust public health measures;
- to monitor and describe SARI and deaths, in order to inform public health stakeholders to better coordinate measures such as:
  - determining the proportion of SARI due to the influenza A(H1N1) 2009 virus;
  - monitoring co-circulating subtypes (if possible);
  - determining the frequency of underlying conditions among individuals with SARI;
  - monitoring the frequency of healthy individuals presenting with SARI; and
- to generate hypotheses on risk factors for severe disease associated with pandemic influenza, to be tested with ad hoc studies as required.

1.2 Objectives for influenza-related fatal cases

The objectives for the surveillance of influenza-related fatal cases are:

- to monitor deaths in persons with SARI;
- to determine the proportion of death due to influenza; and
- to capture information related to post-mortem diagnosis in unexpected deaths that are found to be due to influenza.

2 Methods

2.1 Case definitions

Severe acute respiratory infection (SARI); adapted from [5]

- A patient with SARI is a person with sudden onset of fever of >38 °C and cough or sore throat in the absence of other diagnoses AND shortness of breath or difficulty breathing AND requiring hospital admission.
- This also includes any healthcare-acquired influenza infections (e.g. pneumonia).

SARI-related fatal cases

- Any death recorded in a person with SARI.
- Any unexplained death in hospital.

Case classification

Within the case definition two classifications are distinguished: confirmed and probable cases. The following definitions apply:

- Confirmed = SARI + lab-confirmation of influenza (any type)
- Probable = SARI clinical features

Both confirmed and probable cases should be reported at the EU level (see below).

2.2 Population under surveillance

ECDC proposes that surveillance of SARI by EU/EEA Member States should be carried out by selecting sentinel acute-care hospitals that are willing to participate and have the capacity to do so. (This type of surveillance can also be carried out in all hospitals if a Member States' capacities are sufficient). In these sentinel sites, all SARI

`cases should be reported and the data should be communicated to the national public health organisation in charge of influenza surveillance. The data should be reported to ECDC by the nominated influenza contact point in the Member State, using TESSy.

Sentinel sites have to be carefully selected, taking into account the balance between urban and rural areas, broad geographical coverage in a country, priorities in the national plan for hospital preparedness, etc. The denominator (hospital catchment population) should be defined and recorded in the related record type (see reporting protocol). Several options may be used to determine the proportion of the population that is covered by the selected sentinel hospitals:

1. In countries where information on the population in the hospitals' catchment areas is available, it should be provided directly.
2. If the information on a hospitals' catchment area is not available, the population covered by the hospitals should be estimated. Two examples of how to calculate denominators are provided below.

Example 1 is based on the number of patient discharges from the previous year: proportion of patient discharges of the selected hospitals, divided by the total number of patient discharges from all hospitals in the Member State.

Example 2 is based on the number of beds. In an urban area, the catchment population can be estimated by taking into account the population of the city, the number of hospitals in the city, and the number of beds in an hospital. Coefficients should be attributed to each hospital in the city depending on their activity estimated by the number of beds. For example, in a city with three hospitals, if hospital A has 50 beds, the coefficient to be applied will be 0.5, if hospital B has 125 beds, the coefficient will be 1.25, and if hospital C has 75 beds, the coefficient will be 0.75, so

catchment population = city population * coefficient (based on the number of beds)/number of hospitals in the city

In this example, the estimation of population coverage of hospitals should first be done for each hospital, and estimates from hospitals should be summed up so that the estimates apply to the full surveillance system.

2.3 Data to be collected

Severe acute respiratory infection (SARI) due to influenza

The information collected is based on a minimum set of variables for surveillance of SARI [5]. A standard list of variables (record type) to be collected is described in Annex 2 which includes:

- Standard demographics (age, gender).
- Dates (date of onset, date of hospital admission, reporting date).
- Clinical presentation: SARI case criteria.
- Treatment, prophylaxis (including vaccination).
- Underlying conditions (including pregnancy) and complications: these outputs will be used for severity assessment. Occurrence of nosocomial infections will be taken into account in the analysis.
- Laboratory variables: virological subtype, antiviral resistance.
- Level of care: hospital unit where the patient was admitted (e.g. ICU, in-patient ward).
- Level and access to respiratory support: this will give an indication of the severity, depending on what technology is available for respiratory support (including ventilation).

This information should be reported according to the TESSy standard transport protocols [5,6]. Additional variables that are part of the TESSy common set are not necessarily listed in Annex 2, but will be included in the reporting protocol.

Influenza-related fatal cases

Death-related information should be collected in the same dataset as the one described above (hospital-based SARI). When a patient dies, the following variables should be reported: outcome (vital status of the patient), date of death, and cause of death.

2.4 Limitations

It is acknowledged that not all severe illnesses or deaths attributable directly or indirectly to influenza will be picked up by this system: the number of reported cases will always be lower than the actual number of cases. Therefore the total number reported should not be seen as an entirely accurate measure of the more severe morbidity or mortality caused by the pandemic, which can only be assessed retrospectively by techniques such as time series analysis [3,4].

2.5 Reporting to ECDC

Data on probable, confirmed and fatal cases of SARI should be uploaded to TESSy once every week by using the file upload option. If in doubt which submission option to use for your data, use the 'Replace' option in the Upload Data menu, or contact the TESSy Helpdesk to clarify.

Ideally, weekly data should be submitted and approved no later than 10:00 a.m. on Thursday of the following week, in order to ensure that the data are included in the weekly influenza report. Influenza contacts in the Member States who have not submitted their weekly data by Wednesday afternoon at 6:00 p.m. will receive automated reminders from the TESSy Helpdesk to kindly upload their data by the next morning.

The definition of the variables to be reported for the related record type can be found in TESSy or in the influenza reporting protocol. Cumulative numbers will be shown in TESSy online reports and in subsequent bulletins based on the weekly data in TESSy.

Before submitting weekly data, it is important that Member States take due care in creating and editing a profile for the data source ('data source profile') when submitting influenza data and related matters. All data are submitted with a new record type, and first-time submissions require the appropriate set-up of a data source profile. This data source profile will be used for all future submissions. The key variables to be collected in the TESSy data source are listed in Annex 1.

Support for data upload and other questions can be directed to the TESSy Helpdesk at tessy@ecdc.europa.eu or +46 8 5860 1601, available Monday through Friday from 9:00 a.m. to 4:30 p.m. Stockholm time, excluding ECDC holidays. Additional online training on how to use TESSy, including online video demonstrations of how to report ILI and ARI, can be found at: http://www.world-television.se/projects/ECDC/2009/TESSy_training_03/.

3 Proposed outputs

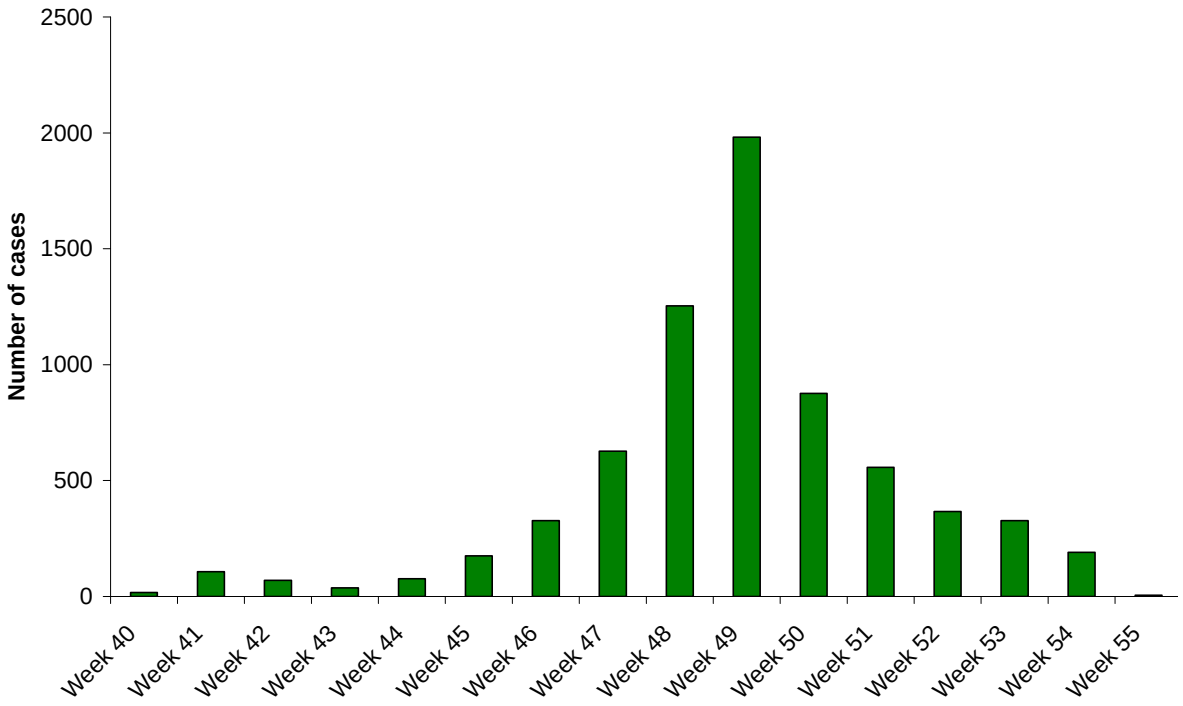
3.1 Cumulative number of reported SARI cases

Table 1: Cumulative number of reported SARI cases in sentinel hospitals and fatal cases, as of 'date'

Country	Number of sentinel sites	Estimated population covered by the system	Geographical coverage (national, regional)	Reported number of cases	Estimated notification rate (in the covered geographic area)	Cumulative number (and incidence) of fatal cases reported
Austria						
Belgium						
Bulgaria						
etc.						
Total						

3.2 Epidemic curve of SARI cases reported

Figure 2: Epidemic curve of SARI cases reported in hospital sentinel sites from EU/EEA countries, by date of onset



3.3 Distribution by age and gender of individual case reports of SARI

Table 2: Distribution by age and gender of individual case reports of SARI, in XX sentinel sites of YY EU/EEA countries, from 'date1' to 'date2' (n=)

Age groups*	Female	Male	Unknown	Total	Percentage
Under 2					
2-17					
18-44					
45-59					
≥60					
Unknown					
Total					

* Age groups are examples

3.4 Distribution of the number (percentage) of cases reported by type and subtype of influenza strains.

Table 3: Distribution of individual case reports of SARI, in XX sentinel sites of YY EU/EEA countries, from 'date1' to 'date2' (n=), by influenza type and subtype

Virus type/subtype	Number of cases (and percentage) during current week	Cumulative number of cases (and percentage) since the start of the season
• Influenza A • A (pandemic H1N1) • A (subtyping not performed) • A (not subtypable) • A (H3) • A (H1) • Influenza B		
Total		

3.5 Level of treatment/care of SARI cases

Table 4: Treatment and resistance to treatment of SARI cases reported in XX sentinel sites from YY EU/EEA countries

Antiviral treatment	Number (percentage) of patients who received prophylaxis	Number (percentage) of patients who received anti-viral treatment	Number (percentage) of patients with strains resistant to treatment
• Oseltamivir • Zanamivir • Other • None			
Total			

Table 5: Respiratory support and level of care of SARI cases reported in XX sentinel sites from YY EU/EEA countries

Respiratory support	ICU	In-patient ward	Other	Total
• Oxygen therapy • Ventilator support provided • Ventilator support necessary but not available				
Total				

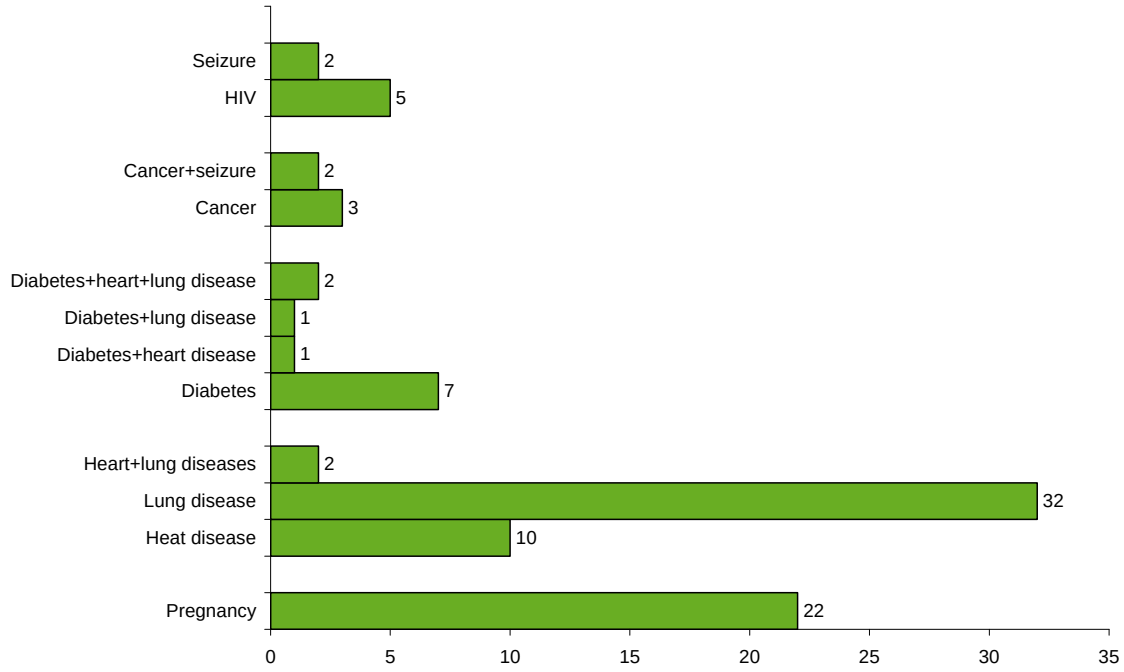
3.6 Vaccination status among reported SARI cases

Table 6: Distribution of individual case reports of SARI, in XX sentinel sites of YY EU/EEA countries, from 'date1' to 'date2' (n=), by vaccination status

	Number of cases	Percentage of cases
Not vaccinated		
Seasonal vaccination		
Pandemic vaccination		
Both, seasonal and pandemic vaccination		
Total		

3.7 Example figure: Number of SARI cases reported with underlying conditions

Figure 3: Number of SARI cases reported with underlying conditions, by XX sentinel sites from YY EU/EEA countries, from 'date' to 'date' (n=)



3.8 Description of underlying conditions by age group

Table 7: Description of underlying conditions by age group, as of 'date', reported in XX sentinel sites from YY countries

Underlying condition/risk factor	Infant below 2 years Numbers and percentage	2-17 years Numbers and percentage	18-44 years Numbers and percentage	45-59 years Numbers and percentage	≥ 60 Numbers and percentage
Asthma					
Pulmonary disease					
Diabetes					
Chronic cardiovascular disease					
Neurocognitive or neuromuscular disorder					
Renal disease					
Immunosuppressive disorder					
Seizure disorder					
Other renal, hepatic, cancer, immunosuppressed, metabolic disorders)					
Morbid obesity (1)					
Obesity (with or without any other underlying condition)					
Pregnancy					
None of above known					

(1) Without any other underlying condition

3.9 Description of complications by age group

Table 8: Description of complications by age group, as of 'date', reported in XX sentinel sites from YY countries

Complications	Infants below 2 years Numbers and percentage	2-17 years Numbers and percentage	18-44 years Numbers and percentage	45-59 years Numbers and percentage	≥ 60 Numbers and percentage
Pneumonia (secondary bacterial infection):					
Acute respiratory distress syndrome					
Bronchiolitis					
Encephalitis					
Myocarditis					
Sepsis/Multi-organ failure					
Other					

3.10 Underlying conditions by ward as of 'date'

Table 9: Underlying conditions by ward as of 'date', reported in XX sentinel sites from YY countries

	Patient wards; numbers and percentage			Respiratory support; numbers and percentage			
	ICU	Inpatient ward	Other	Oxygen therapy	Ventilator support	Ventilator support necessary but not available	No respirator support necessary
Asthma							
Pulmonary disease							
Diabetes							
Chronic cardiovascular disease							
Neuromuscular disorder							
Renal condition							
Immunosuppressive disorder							
Liver condition							
Neurocognitive disorder							
Other (cancer, immunosuppressed, metabolic disorders)							
Obesity							
Pregnancy							
None of above known							

3.11 Description of fatal cases includes:

- number of SARI-related deaths, including post-mortem diagnosis;
- cause of death; and
- underlying conditions/complications.

4 References

[1] Analysis of influenza A(H1N1)v individual case reports in EU and EEA countries. Available from: http://ecdc.europa.eu/en/healthtopics/Documents/090731_Influenza_A(H1N1)_Analysis_of_individual_data_EU_EEA-EFTA.pdf

[2] ECDC daily situation report. Influenza A(H1N1)v infection, Update 23 July 2009, 17:00 hours CEST. [Distributed by e-mail.]

[3] Nogueira PJ,Nunes A, Machado E, Rodrigues E, Gómez V, Sousa L, Falcão JM. Early estimates of the excess mortality associated with the 2008-9 influenza season in Portugal. Available from: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19194

[4] Tillett HE, Smith JWG, Clifford RE. Excess morbidity and mortality associated with influenza in England and Wales. Lancet 1980; i: 793-5**.**

[3] WHO. Human infection with pandemic (H1N1) 2009 virus: updated interim WHO guidance on global surveillance, 10 July 2009. http://www.who.int/csr/disease/swineflu/WHO_case_definition_swine_flu_2009_04_29.pdf

[5] ECDC Technical Document. Transport Protocol Specification CSV — Comma Separated Value. TESSy, Version 2.5. Available from: http://ecdc.europa.eu/en/publications/Publications/0906_TER_TESSy_Transport_Protocol.pdf

[6] ECDC Technical Document. Transport Protocol Specification XML — Extensible Markup Language TESSy, Version 2.6. Available from: http://ecdc.europa.eu/en/publications/Publications/0907_TER_TESSy_transport_protocol_XTML_v2.6.pdf

Component 4. Aggregate reporting of cases and deaths due to pandemic influenza in the EU/EEA

This part of the proposal describes why and how aggregate numbers of cases and deaths due to pandemic (H1N1) 2009 virus should be collected at the national level and reported to TESSy.

- WHO requests the aggregate reporting of new and cumulative confirmed cases of pandemic (H1N1) 2009 virus infections and of deaths in such patients by age group.
- Most European countries are still collecting and reporting aggregate numbers of pandemic (H1N1) 2009 virus infections.
- Aggregate numbers of pandemic (H1N1) 2009 virus infections and deaths remain useful for giving an indication of spread, intensity and severity of the pandemic, as long as this task does not overwhelm a country's public health system.

1 Objectives

- Monitor the geographic spread, intensity and severity of laboratory-confirmed pandemic influenza infections in EU/EEA Member States that are still counting individual cases.
- Publish weekly updates of weekly and cumulative aggregate numbers by country.

2 Methods

2.1 Case definition [5]

A probable case is defined as a person with clinical criteria suggestive of pandemic influenza A(H1N1) 2009. This includes any person with one of the following three conditions:

- Fever > 38 °C AND signs and symptoms of acute respiratory infection.
- Pneumonia (severe respiratory illness).
- Death from an unexplained acute respiratory illness.

A confirmed case is defined as a person with laboratory-confirmed pandemic influenza A(H1N1) 2009 virus infection, confirmed by one or several of the following tests:

- Polymerase chain reaction (PCR).
- Viral culture.
- Fourfold rise in pandemic (H1N1)2009 virus-specific neutralising antibodies.

For the purposes of aggregated reporting, both probable and confirmed cases should be reported.

Any deaths occurring in a person who qualifies as a probable OR a confirmed case should be included in the aggregated reporting of deaths.

2.2 Data to be collected at the national level

Weekly aggregate numbers of:

- laboratory-confirmed cases of pandemic influenza;
- hospitalisations due to pandemic influenza; and
- deaths due to pandemic influenza.

If aggregate data are collected by age group, the European Influenza Surveillance Network (EISN) age groups should be used:

- 0 – 4 years;
- 5 – 14 years;
- 15 – 64 years;
- ≥ 65 years.

Annex 3 gives an overview of the variables and codes to be reported in TESSy format.

2.3 Reporting to ECDC

Aggregate weekly data (optionally broken down by age group) of cases and deaths in probable and confirmed cases should be uploaded to TESSy once every week by using the online data entry wizard or the file upload option. Ideally, weekly data should be submitted and approved no later than 10:00 a.m. on Thursday of the following week, in order to ensure that the data are included in the weekly influenza report. Influenza contacts in the Member States who have not submitted their weekly data by Wednesday afternoon at 6:00 p.m. will receive automated reminders from the TESSy Helpdesk to kindly upload their data by the next morning.

The definition of the variables to be reported for the related record type can be found in TESSy or in the influenza reporting protocol. Cumulative numbers will be shown in TESSy online reports and in subsequent bulletins based on the weekly data in TESSy.

Before submitting weekly data, it is important that Member States take due care in creating and editing a profile for the data source ('data source profile') when submitting influenza data and related matters. All data are submitted with a new record type, and first-time submissions require the appropriate set-up of a data source profile. This data source profile will be used for all future submissions.

Support for data upload and other questions can be directed to the TESSy Helpdesk at tessy@ecdc.europa.eu or +46 8 5860 1601, available Monday through Friday from 9:00 a.m. to 4:30 p.m. Stockholm time, excluding ECDC holidays. Additional online training on how to use TESSy, including online video demonstrations of how to report ILI and ARI, can be found at: http://www.world-television.se/projects/ECDC/2009/TESSy_training_03/.

3 Surveillance output

ECDC will publish weekly updates of country-specific weekly and cumulative aggregate numbers of cases and deaths due to pandemic influenza (Table 10). If a country provides age-specific aggregate data, data will be presented by age group. These numbers will be included in the ECDC weekly influenza online report and will complement ILI/ARI, SARI and virological sentinel surveillance data.

Table 10. Weekly and cumulative aggregate numbers of cases and deaths due to pandemic influenza

Country	Cases		Deaths	
	Weekly	Cumulative	Weekly	Cumulative
Country 1				
Country 2				
...				

Component 5A. Qualitative monitoring of pandemic influenza in the EU/EEA

- Even if hard figures become unavailable, most countries in the EU/EEA will still be able to provide a semi-quantitative assessment of the pandemic situation.
- These assessments would be the only way of knowing how countries are affected and whether the situation is improving or deteriorating.

1 Objectives

- Monitor geographic spread, trend, intensity and impact, if quantitative monitoring systems are no longer functional.
- Publish weekly updates by country.

2 Methods

2.1 Indicator definition

The definitions of the WHO qualitative monitoring indicators are adjusted to the existing indicators collected through EISN.

Table 11. Definitions of adjusted WHO qualitative-monitoring indicators

Indicator	Value	Definition
Geographic spread		
	No activity	Reports indicate no evidence of influenza virus activity. Cases of ILI/ARI may be reported in the country, but the overall level of clinical activity remains at baseline levels and influenza virus infections are not laboratory confirmed. Cases occurring in people recently returned from other countries are excluded.
	Sporadic	Isolated cases of laboratory-confirmed influenza infection in a region, or an outbreak in a single institution (such as a school, nursing home or other institutional setting), with clinical activity remaining at or below baseline levels. Cases occurring in people recently returned from other countries are excluded.
	Local outbreak	Increased ILI/ARI activity in local areas (such as a city, county or district) within a region, or outbreaks in two or more institutions within a region, with laboratory-confirmed cases of influenza infection. Levels of activity in remainder of region, and other regions of the country, remain at or below baseline levels.
	Regional activity	ILI/ARI activity above baseline levels in one or more regions with a population comprising less than 50% of the country's total population, with laboratory-confirmed influenza infections in the affected region(s). Levels of activity in other regions of the country remain at or below baseline levels.
	Widespread activity	ILI/ARI activity above baseline levels in one or more regions with a population comprising 50% or more of the country's population, with laboratory-confirmed influenza infections.
	Unknown	No information available for the previous 1-week period.
Trend		Changes in the level of respiratory disease activity compared with the previous week.
	Increasing	Level of respiratory disease activity is increasing compared with the previous week.
	Unchanged	Level of respiratory disease activity is unchanged compared with the previous week.
	Decreasing	Level of respiratory disease activity is decreasing compared with the previous week.
	Unknown	No information available.
Intensity		Estimate of proportion of the population with acute respiratory disease (from influenza-like illness to pneumonia).
	Low	No influenza activity or influenza activity at baseline level.
	Medium	Level of influenza activity usually seen when influenza virus is circulating in the country, based on historical data.
	High	Higher than usual influenza activity compared with historical data.
	Very high	Influenza activity is particularly severe compared with historical data.
	Unknown	No information available.

Indicator	Value	Definition
Impact		Degree of disruption of healthcare services as a result of acute respiratory disease.
	Low	Demands on healthcare services not above usual levels.
	Moderate	Demands on healthcare services above usual levels, but still below maximum capacity.
	Severe	Demands on healthcare services exceed capacity.
	Unknown	No information available.

During the meeting on 'Surveillance and Studies in a Pandemic (SSiaP)', no consensus was reached on whether to include the suggested indicator for monitoring the pandemic's impact on healthcare systems. To ensure comparability of data with the WHO surveillance guidance and offer the countries the possibility to report on the pandemic's impact on healthcare systems, this indicator was also included in the data to be collected.

2.2 Reporting to ECDC

Qualitative assessments should be uploaded to TESSy once every week by using the online data entry wizard or the file upload option. This record type (basic qualitative indicators) is particularly useful when Member States are no longer able to provide information on ILI/ARI.

Ideally, weekly data should be submitted and approved no later than 10:00 a.m. on Thursday of the following week, in order to ensure that the data are included in the weekly influenza report. Influenza contacts in the Member States who have not submitted their weekly data by Wednesday afternoon at 6:00 p.m. will receive automated reminders from the TESSy Helpdesk to kindly upload their data by the next morning.

The definition of the variables to be reported for the related record type can be found in TESSy or in the influenza reporting protocol. Cumulative numbers will be shown in TESSy online reports and in subsequent bulletins based on the weekly data in TESSy.

In addition to submitting weekly data, it is important that Member States take due care in creating and editing a profile for the data source ('data source profile') when submitting influenza data and related matters.

Support for data upload and other questions can be directed to the TESSy Helpdesk at tessy@ecdc.europa.eu or +46 8 5860 1601, available Monday through Friday from 9:00 a.m. to 4:30 p.m. Stockholm time, excluding ECDC holidays. Additional online training on how to use TESSy, including online video demonstrations of how to report ILI and ARI, can be found at: http://www.world-television.se/projects/ECDC/2009/TESSy_training_03/.

A description of the variables to be collected at the national level and submitted to TESSy is available in Annex 4. Descriptions of variables might be adapted for technical reasons; this will be communicated in a reporting protocol at least two weeks before data collection begins.

3 Surveillance output

ECDC will publish weekly updates of country-specific qualitative assessments in its weekly influenza report (Table 12).

Table 12. Country-specific qualitative monitoring of pandemic influenza

Country	Geographic spread	Trend	Intensity	Impact
Country 1				
Country 2				
...				

Component 5B. Mortality monitoring

Monitoring of mortality provides another indicator that can help detailing the impact of the pandemic. The EuroMOMO (www.euromomo.eu) project is currently addressing this issue in a pilot project. The pilot phase includes four European countries, but more countries are scheduled to join in autumn 2009. Outputs depend on the data provided by the participating countries, their agreements, and the results of the pilot project.

Annexes

Annex 1. Key variables to be collected in the TESSy data source (description of a surveillance system in a Member State) for hospital surveillance of SARI and fatal cases

Variable collected	Short description of the surveillance system for the disease
Legal character	**Compulsory**: The surveillance system has a legal basis (at the national administrative level or other) stating that reporting of cases of the disease/s under surveillance is compulsory. **Voluntary**: The surveillance system is based on a voluntary agreement (at the national level or other) stating that reporting of cases of the disease/s under surveillance is on a voluntary basis. **Other**: Any system that does not fall under the above descriptions.
Comprehensiveness	**Comprehensive**: Reporting is based on cases occurring within the whole population of the geographical area where the surveillance system is set up (national, regional, etc). **Sentinel**: Reporting is based on notifications from a selected group of physicians, hospitals, laboratories or other institutions, and/or cases occurring within a selected population group that is defined by age group, gender, exposure, or other selection criteria. **Other**: Reporting is based on an unspecified part of the population or an unspecified group of physicians (or institutions), for example reporting by individual laboratories without existing selection criteria.
Active	**Active**: The surveillance system is based on a public health officials' initiative and actively contacts physicians, laboratory/hospital staff, or other relevant sources in order to solicit surveillance data. **Passive**: The surveillance system relies on physicians, laboratory/hospital staff, or other relevant sources to take the initiative and report data to the health department.
Case-based	**Case-based**: Each individual case of the disease/s under surveillance is reported separately. **Aggregated**: Only the total number of cases of the disease/s under surveillance is reported (possibly broken down by age, sex and/or other criteria).
Number of hospitals	**Number** of hospitals in a Member State participating in the surveillance system.

Annex 2. Variables to be reported weekly for hospital surveillance of SARI and fatal cases

Variable name	Description	Variable coding
RecordId	Unique identifier for each record within and across the national surveillance system. Selected and generated by Member States.	
RecordType	The RecordType defines the structure of the submitted data.	INFLSARI
RecordTypeVersion	Overrides the metadata set, if specified. There may be more than one version of a record type. This element indicates which version the provider used when generating the batch (data files).	1
Subject	The subject of the record, usually the disease the case was reported with.	INFLSARI
Status	If set to 'NEW/UPDATE', the record is added (new) to the database. If a record with the same RecordId exists, the record is replaced by the new information. If set to 'DELETE', the record with the given RecordId is marked as inactive.	NEW/UPDATE DELETE
DataSource	The surveillance system where the data originated.	See list of surveillance systems.
ReportingCountry	Identifies the country that reports the case.	Country, ISO 3166-1 alpha-2 (two-letter code).
DateUsedForStatistics	Date used by the national institute in national reports and other statistics.	Date (YYYY-MM-DD, YYYY-Www)
DateOfOnset	Date of onset of disease.	Date (YYYY-MM-DD) or UNK
DateOfNotification	Date when the case was first reported to the place of notification.	Date (YYYY-MM-DD) or UNK
Classification	Case classification according to EU case definition.	POSS — possible PROB — probable CONF — ponfirmed Unk — unknown
Age	Age of patient as reported in the national system.	Num (0-120), Unk
Gender	Gender of the infected person.	M — male F — female O — other UNK — unknown
AgeMonth	Age of patient in months if less than two years of age.	number between 0-23 NA — not applicable (if age is above 2 years) UNK — unknown
HospitalUnitType	Type of hospital unit the patient was admitted to at the time of reporting.	INPATIENT — in-patient ward ED — emergency department ICU — intensive care unit O — other service UNK — unknown
DateOfHospitalisation	Date of hospitalisation.	Date (YYYY-MM-DD) or UNK

Variable name	Description	Variable coding
Subtype	Virus type and subtype.	A — A, not sub-typed AH1N1 — A(H1N1) PanAH1N1 — pandemic A(H1N1) 2009 AH5N1 — A(H5N1) AH1 — A(H1), not N sub-typed AH3 — A(H3), not N sub-typed AH3N2 — A(H3N2) AH5 — A(H5), not N sub-typed B — B, lineage not determined BVic — B, Victoria lineage BYam — B, Yamagata lineage UNK — unknown
Resistance	Resistance to antiviral treatment as assessed by virologists. Report if resistance was detected to any antivirals in the coded value list.	NONE — none OSEL — oseltamivir ANA — zanamivir M2 — M2 inhibitors O — other UNK — resistance unknown
ClinicalPresentation (REPEATABLE)	Clinical presentation criteria at disease onset or disease diagnosis.	FEVER — fever above 38 °C or history of fever (temperature not measured) COUGH — dry or productive cough SORETHR — sore throat SBREATH — shortness of breath O — other UNK — unknown
VaccStatus	Indicates the vaccination status of the patient if known. Note: this variable will be developed further.	NOTVACC — not vaccinated VACCSEASON — vaccinated for the current seasonal influenza VACCPAND — vaccinated for A(H1N1)v VACCPANDNOTFULL — not fully vaccinated for A(H1N1)v VACCBOTH — fully vaccinated for both UNK — unknown
DrugUsedProphilaxis	Antivirals used as prophylaxis in the 14 days before onset of illness.	NONE — none OSEL — oseltamivir ZANA — zanamivir OSELZANA — oseltamivir and zanamivir O — other (or combination with other) UNK — unknown
DrugUsedTreatment	Antivirals used in treatment of the case during illness phase.	NONE — none OSEL — oseltamivir ZANA — zanamivir OSELZANA — oseltamivir and Zanamivir M2 — M2 inhibitors O — other (or any other combination) UNK — unknown
DateOfTreatment	Starting date for anti-viral treatment of the case during illness phase.	Date (YYYY-MM-DD) or UNK
RespSupport	Level of respiratory support given to patient.	OXYGEN — oxygen therapy VENT — ventilator NOTNEC — no respiratory support necessary NOTAVAIL — no respiratory support available UNK — unknown respiratory support

Variable name	Description	Variable coding
Precondition (REPEATABLE)	Patient's underlying condition or conditions.	NONE — no underlying condition PREG — pregnancy LUNG — chronic lung disease ASTH — asthma HEART — chronic heart disease CANC — cancer DIAB — diabetes OBESITY — obesity (BMI between 30 and 40) OBESITYMORB — morbid obesity (BMI above 40) NEUROCOG — neurocognitive disorder (including seizures) HIV — HIV/other immune deficiency LIVER — liver-related condition KIDNEY — kidney-related condition NEUROMUS — neuromuscular disorder O — other (please specify separately) UNK — underlying condition unknown
PreconditionOther	If Precondition (see above) is coded as 'other' but known.	TEXT
ComplicationDiagnosis (REPEATABLE)	Complication diagnosis.	NONE — none PNEU — pneumonia (secondary bacterial infection) ARDS — acute respiratory distress syndrome BRONCH — bronchiolitis ENCEPH — encephalitis MYOCARD — myocarditis SEPSIS — sepsis/multi-organ failure O — other (please specify separately) UNK — complication unknown
ComplicationDiagnosisOther	If ComplicationDiagnosis (see above) is coded as 'other' but known.	TEXT
Outcome	Information whether the case is alive or deceased.	A — alive D — dead NA — not applicable UNK — unknown
DateOfDeath	Date of death.	Date (YYYY-MM-DD) or UNK
CauseOfDeath	Cause of death.	INFLMAIN — The main cause of death was influenza. INFLUNDER — The underlying cause of death was influenza. SECBACT — The cause of death was a secondary bacterial infection acquired in hospital. NOTINFL — Cause of death not influenza related. UNK — Cause of death was unknown.

Annex 3. Variables for weekly reporting of aggregate numbers of confirmed pandemic (H1N1) 2009 cases, and deaths

Variable name	Description	Variable coding
RecordType	The RecordType defines the structure of the submitted data.	AH1N1HAGGR
RecordTypeVersion	This element indicates which version the provider used when generating the batch (data files). Overrides the metadata set, if specified.	1
Subject	The subject of the record, usually the disease the case was reported with.	AH1N1
DataSource	The surveillance system where the data originated.	See list of surveillance systems.
ReportingCountry	Identifies the country that reports the case.	See list of country codes (ISO standard).
DateUsedForStatistics	Date used by the national institute in national reports and other statistics.	Date (YYYY-Www)
NumberOfCases	Total number of cases of the disease represented in the dataset.	NUM
Age00-04	Number of cases in age group 0-4 years.	NUM
Age05-14	Number of cases in age group 5-14 years.	NUM
Age15-64	Number of cases in age group 15-64 years.	NUM
Age65+	Number of cases in age group 65+ years.	NUM
AgeUnk	Number of cases with unknown age.	NUM
NumberOfDeaths	Total number of deaths during the reporting period for the specified subject.	NUM
Deaths00-04	Number of deaths in age group 0-4 years.	NUM
Deaths05-14	Number of deaths in age group 5-14 years.	NUM
Deaths15-64	Number of deaths in age group 15-64 years.	NUM
Deaths65+	Number of deaths in age group 65+ years.	NUM
DeathsUnk	Number of deaths with unknown age.	NUM
TestAll	Were all suspected cases tested?	Y — yes N — no

Annex 4. Variables for weekly reporting of qualitative monitoring indicators

Variable name	Description	Variable coding
RecordType	The RecordType defines the structure of the sent data.	INFLQUALIND
RecordTypeVersion	This element indicates which version the provider used when generating the batch (data files). Overrides the metadata set, if specified.	1
Subject	The subject of the record, usually the disease the case was reported with.	INFLCLIN
DataSource	The surveillance system where the data originated.	See list of surveillance systems.
ReportingCountry	Identifies the country that reported the case.	See list of country codes (ISO standard).
DateUsedForStatistics	Date used by the national institute in national reports and other statistics.	Date (YYYY-Www)
GeographicSpread	Number and distribution of sites reporting influenza activity.	NO — no activity L — local R — regional W — widespread S — sporadic UNK — unknown (no information available)
Trend	Trend (weekly clinical morbidity rate versus previous week).	I — increasing D — decreasing S — stable UNK — unknown (no information available)
Intensity	Estimate of proportion of the population with acute respiratory disease (from influenza-like illness to pneumonia).	L — low M — medium H — high V — very high UNK — unknown (no information available)
Impact	Degree of disruption of healthcare services as a result of acute respiratory disease.	L — low M — moderate S — severe UNK — unknown (no information available)