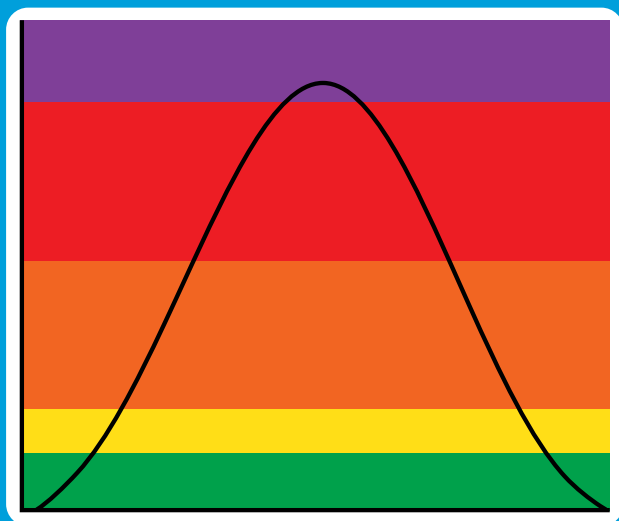


# PANDEMIC INFLUENZA SEVERITY ASSESSMENT ( PISA )

A WHO guide to assess the severity of influenza  
in seasonal epidemics & pandemics



WHO/WHE/IHM/GIP/2017.2

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# 1 SCOPE OF THE DOCUMENT

## 1.1 Background and development history

The events of the 2009 H1N1 pandemic revealed that WHO and national organizations did not have a robust and standardized method for making a timely assessment of the severity of pandemic influenza. They also showed that Member States were not fully prepared to rapidly assess the severity of a pandemic, or to implement the necessary risk management and communications plans.

In 2011, the World Health Assembly adopted a report by the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza (H1N1) 2009<sup>(1)</sup>. The committee recommended that WHO should develop and apply measures that can be used to assess the severity of every influenza epidemic, whether seasonal or pandemic. A severity assessment provides the information needed to determine the timing, scale, emphasis, intensity and urgency of pandemic response actions. The report stated that, “by applying, evaluating and refining tools to measure severity every year, WHO and Member States can be better prepared to assess severity in a timely manner in the next pandemic” <sup>(1)</sup>.

Severity assessments should be conducted in the early phase of a pandemic and regularly thereafter as the pandemic evolves. Since the World Health Assembly highlighted this need, WHO has made great progress on developing a framework on pandemic influenza severity assessment (PISA)<sup>(2)</sup>. The framework was developed through several meetings, expert consultations, collaborative WHO projects and the establishment of a technical working group (TWG) on pandemic influenza severity assessment. The framework defines influenza severity in terms of three indicators: transmission, seriousness of disease and impact.

In April 2014, WHO convened a meeting of the TWG to review the scope of surveillance data currently collected by Member States. The TWG reviewed surveillance data in the selected Member States to identify strengths and gaps, and areas for improvement, all of which varied dramatically among Member States.

Interim guidance describing a structured way of assessing influenza severity was developed, based on the results of previous meetings, work that WHO did with the Robert Koch Institute (Germany), a pilot study performed by Member States in the southern Hemisphere (Australia, Chile, New Zealand and South Africa) in 2014, and ongoing conference calls and expert consultations. Development of this framework formed the basis of discussion for the second and third meetings of the TWG, held in November 2014 and June 2015, respectively.

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From 2014 to 2016, pilot testing of the interim guidance continued in selected Member States: Australia, Bangladesh, Canada, Chile, China, Egypt, France, Germany, India, Iran, Ireland, Japan, Madagascar, New Zealand, Norway, Portugal, Singapore, South Africa, Spain, Thailand, the United Kingdom of Great Britain and Northern Ireland, and the United States of America.

The guidance was further refined based on the findings and experience from the pilot testing. In March 2017, the PISA approach was launched and Member States were encouraged to start implementation. The immediate use of the tool to assess seasonal epidemic severity will highlight the need for strong baseline data; in addition, it will encourage Member States to refine their available data and familiarize themselves with the severity assessment tool, which would also be used during a pandemic.

## 1.2 Purpose of the guidance document

This guidance has been developed by WHO to be used by Member States and WHO as part of the pandemic influenza risk management guidance (PIRM)<sup>(3)</sup> to assess the severity of influenza in seasonal epidemics and pandemics, when sustained human-to-human transmission occurs. The assessments will take place continuously during seasonal epidemics or a pandemic, with a conclusive assessment being undertaken once transmission has subsided.

During a pandemic, time and resources are limited. Therefore, countries need to become familiar with the tool as soon as possible (i.e. during seasonal influenza epidemics), and operationalize the methods and outputs in their routine seasonal influenza situation assessments and reports. This will allow countries to assess severity more easily and efficiently during a pandemic.

This guidance does not apply to the alert phase situation<sup>(3)</sup>; that is, before sustained human-to-human transmission of zoonotic influenza viruses, when the aim is to define the risk of pandemic spread. Other tools are available from WHO for this purpose; for example, the Rapid risk assessment of acute public health events<sup>(4)</sup> or the tool for influenza pandemic risk assessment (TIPRA)<sup>(5)</sup>.

Information to assess severity early and throughout the course of a pandemic will also be provided through special studies and modelling. However, this guidance focuses mainly on the information collected during routine influenza surveillance.

## 1.3 Target audience

This document is intended for use primarily by public health professionals at the national level, who perform or plan to perform national influenza severity assessments, and who can contribute to global influenza severity assessments. It is a living document that will be further updated as needed, and will serve as guidance for seasonal and pandemic influenza severity assessments.

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## 2 AIM OF THE INFLUENZA SEVERITY ASSESSMENT

The aim of the influenza severity assessment at the national level is to<sup>(3)</sup>:

- describe the epidemiological situation and assess the severity of an influenza epidemic or pandemic based on all available information;
- inform national and global risk assessments; and
- inform public health preparedness, response and recovery measures, as well as resource allocation.

The global influenza severity assessment will be used by WHO to monitor and understand the global situation, and to inform and support global decisions and recommendations on public health interventions.

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# 3 INFLUENZA SEVERITY ASSESSMENT CONCEPT & DEFINITIONS

## 3.1 Indicators

Based on consultations between external experts and WHO staff between 2011 and 2015, influenza (pandemic) severity is defined in terms of three indicators: transmissibility of an influenza virus, seriousness of influenza disease and impact. These terms are defined in detail below and in [Table 1](#).

### 3.1.1 Transmissibility

The transmissibility indicator reflects the ease of movement of the influenza virus between individuals and communities. Thus, a virus with high transmissibility will spread rapidly from one person to another. Several factors affect transmissibility: the ability of the virus to spread from person to person, the dynamics of the spread and the susceptibility of the exposed population. Transmissibility will be influenced by social and climatic factors. During seasonal influenza epidemics, transmissibility is usually measured by routine surveillance systems using a proxy (e.g. how many people are seeking health care for influenza-like illness). The actual dynamics of the spread (the reproductive number) and the susceptibility of the exposed population would be measured by ad hoc special studies during a pandemic.

### 3.1.2 Seriousness of disease




The seriousness of disease (also referred to as “severity of infection”) indicator describes the extent to which individual people get sick when infected with the influenza virus. It describes the frequency of clinical symptoms, complications of influenza illness and outcomes following influenza infection. The seriousness of disease depends on the virus; for example, an influenza virus with a high level of clinical severity can result in a disproportionate number of people with serious illnesses, some of whom will be hospitalized and some of whom will die. Seriousness of disease also depends on the host; for example, the presence of underlying medical conditions that predispose individuals to develop severe illness, a history of vaccinations that may be protective (e.g. for influenza and pneumococcal disease), the person’s age and the availability of health care. An infection is likely to be much more severe for some segments of a population than for others, and descriptions of the groups that are at increased risk will be an important part of this indicator. During seasonal influenza, seriousness of disease is measured with routine, hospital-based surveillance; for example, the case fatality ratio among people hospitalized or admitted to intensive care units (ICU) due to influenza.



### 3.1.3 Impact

The impact indicator generally describes how the influenza epidemic or pandemic affects society. It represents the impact on the health-care sector; for example, the impact on health-care use (hospitalization and ICU admissions), on the health-care workforce and on society (including excess mortality). The impact will be affected by the implementation of public health measures, public concern and the behaviour of the affected population. If the health-care sector impact is high, there may be stress on health-care resources. The public health impact may also result in societal and economic consequences, such as absenteeism from workplaces and schools, loss of critical infrastructure, and decreases in trade and tourism.

**Table 1. Summary of the indicators used to describe influenza severity**

INDICATOR	DESCRIBES	INFLUENCED BY	INFORMED BY
<b>Transmissibility</b>  	How many people in a population get sick from influenza on a weekly basis	<ul style="list-style-type: none"> <li>• Ease of movement of virus between individuals (virus shedding, viral replication, and viral binding)</li> <li>• Immunity and vaccination status</li> <li>• Age, contact patterns and health-seeking behaviour</li> <li>• Climatic factors</li> </ul>	Routine surveillance parameters
<b>Seriousness of disease</b>  	How severely sick individual people get when infected with the influenza virus	<ul style="list-style-type: none"> <li>• Virus factors</li> <li>• Host factors</li> <li>• Context (e.g. access to health care and availability of ventilators)</li> </ul>	Hospital-based surveillance parameters
<b>Impact</b>  	How the influenza epidemic or pandemic affects the health-care system (and society)	<ul style="list-style-type: none"> <li>• Public health interventions</li> <li>• Health-care use</li> <li>• Public concern</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital-based surveillance</li> <li>• Vital statistics (e.g. death records)</li> <li>• School and work absenteeism</li> </ul>

## 3.2 Parameters

Each indicator described above is derived from various parameters that come from virological and epidemiological surveillance and clinical sources. These parameters are often collected on a routine basis by a country's public health surveillance systems<sup>(6)</sup>; alternatively, they may be measured in specific investigations (special studies). This guidance document focuses on the information collected through routine surveillance; information from special studies would only be obtained during influenza pandemics or other unusual events.

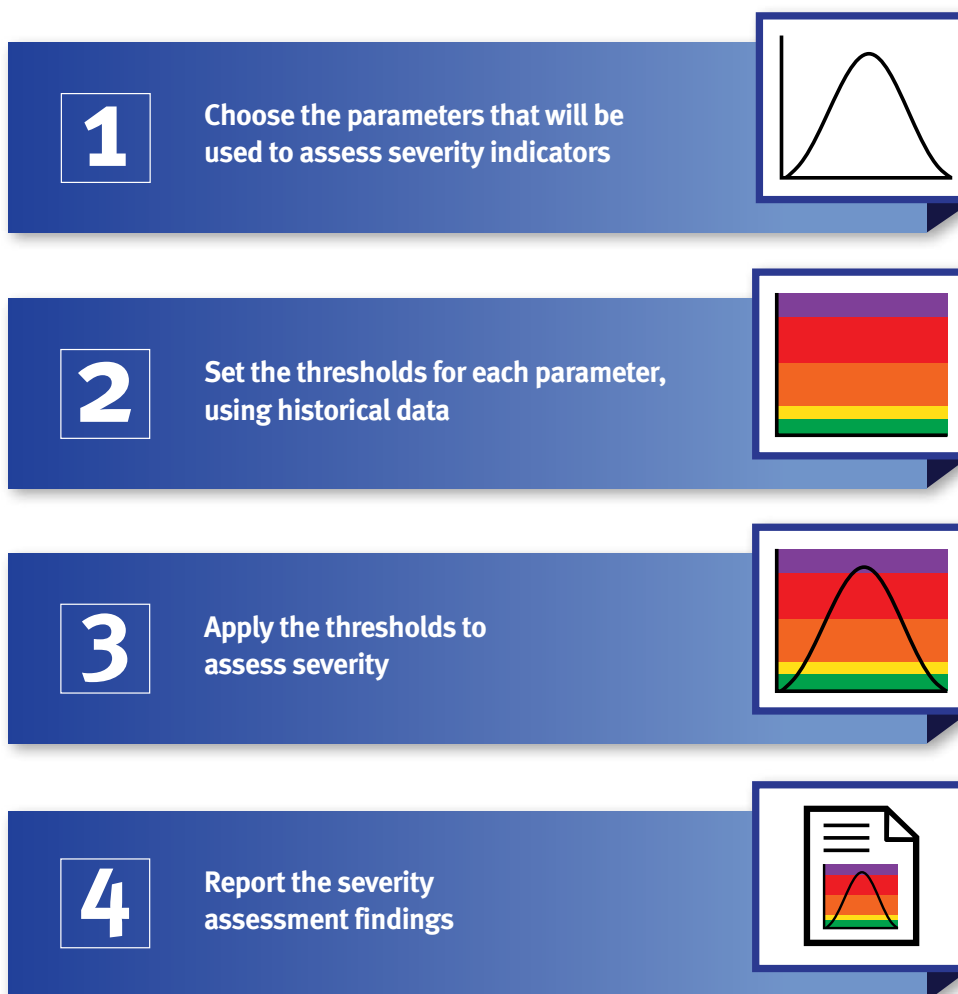
This guidance is intended to be flexible and should be adapted to the country implementing it. Each country has unique surveillance systems and has to choose the parameters (based on their experience) from their surveillance systems that could feed into the three indicators. For assessment of influenza severity, countries are encouraged to identify those parameters that are collected by established routine surveillance systems.

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## 4 STEPS FOR ASSESSING INFLUENZA SEVERITY

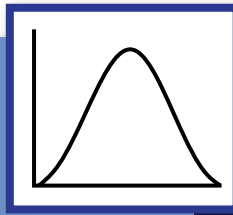
There are four key steps to assessing influenza severity, as shown in [Figure 1](#).

**Figure 1.** Steps for assessing influenza severity



# 1

## Choose the parameters that will be used to assess severity indicators






### Step 1: Choose parameters

Certain criteria should be considered when selecting the parameters that will be used to assess the three severity indicators:

- Parameters must be:
  - indicative of influenza activity; therefore, at least a subset of samples should be laboratory tested for influenza viruses;
  - reliable and come from a surveillance system that is stable over time (or from a system in which changes that occur are well-documented);
  - timely;
- Historical data must be available (on historical seasonal epidemics or pandemics) for the parameters; and
- Where possible, denominators should be available to calculate (representative) proportions or rates.

The parameters considered to be most useful as defined by the WHO TWG are shown in [Table 2](#).

**Table 2. Useful parameters for assessing severity**

INDICATOR	PARAMETERS (examples) <sup>a</sup>
<b>Transmissibility</b> 	<ul style="list-style-type: none"> <li>• Weekly ILI or MAARI cases as a proportion of total visits, or incidence rates</li> <li>• Composite (product) of weekly ILI or MAARI rates and weekly percentage positivity rates for influenza</li> </ul>
<b>Seriousness of disease</b> 	<ul style="list-style-type: none"> <li>• Cumulative death: hospitalization ratio (ideally confirmed influenza cases and cases with outcome or discharge data)</li> <li>• Cumulative ICU: hospitalization ratio (ideally for confirmed influenza)</li> <li>• SARI:ARI or SARI:ILI ratios</li> </ul>
<b>Impact</b> 	<ul style="list-style-type: none"> <li>• Weekly number or proportion of SARI cases, with percentage of SARI cases that are influenza positive</li> <li>• Weekly excess P&amp;I or all-cause mortality (ideally stratified by age)</li> <li>• Weekly number of confirmed influenza cases admitted to ICU, or weekly number of confirmed influenza cases admitted to hospital</li> </ul>

ARI: acute respiratory infection; ICU: intensive care unit; ILI: influenza-like illness; MAARI: medically attended acute respiratory illness; P&I: pneumonia and influenza; SARI: severe acute respiratory infection

<sup>a</sup> Other possible parameters that may reflect the impact on the society are school closures, hospital beds occupied, work absenteeism and school absenteeism. These non-health-care-related parameters might not be reported to the disease surveillance units in a country; rather, they might be captured by the ministry of education or social security systems. Such parameters were not tested during the pilot period.

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Where possible, and when enough data are available, the parameters should be looked at by age groups. The minimum age groups are: under 15 years, 15–64 years and 65 years or over. If more age groups are used (e.g. >2 years or <5 years), it is important to ensure that they can aggregate to previously proposed age groups. Data might be insufficient at the beginning of the season to stratify by age groups, but it is important to collect age-specific information from the start.

For the seriousness of disease and impact indicators, the parameters should, where possible, take into account the presence or absence of underlying chronic diseases or conditions known to be linked with severe outcomes for influenza (asthma, HIV/AIDS, pregnancy, heart or lung disease, for example). Refer to appendix 3 of the WHO global epidemiological surveillance standards for influenza for further information on pre-existing conditions.<sup>(6)</sup>

In addition to these proposed parameters, Member States can include other parameters based on their own surveillance system, provided they have confidence in the data.



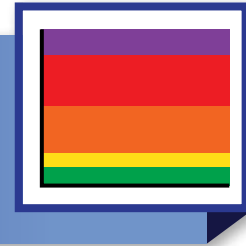
#### INFLUENZA SEVERITY ASSESSMENT:

##### Step 1: Key points

- At the beginning of the assessment, use the criteria included in this guidance to select the parameters you will use.
- Document the following information on the selected parameters:
  - **data source** (e.g. outpatient sentinel or hospital surveillance);
  - **number of years** of data available;
  - **strengths** of this parameter;
  - **limitations** of this parameter; and
  - **proportion of data** that is laboratory confirmed.

## 2

### Set the thresholds for each parameter, using historical data



## Step 2: Set thresholds

Surveillance systems differ widely from one country to another; hence, the absolute values of the parameters cannot be used to make meaningful comparisons between countries. However, within a country, it is possible to see how a parameter compares with previous seasons and, more specifically, how the parameter's value compares with the peak value of previous seasons. Thus, using historical data, each country can describe an epidemic's (or pandemic's) activity compared with previous seasons, using qualitative descriptions such as:

- no activity or below seasonal threshold
- low
- moderate
- high
- extraordinary.

These qualitative assessments can then be compared both within a country over time and between countries.

It is useful to set thresholds or define ranges (using historical data) for the parameters that allow for qualitative categorization by describing the levels of activity. This involves defining the start of the epidemic (or pandemic) and then setting thresholds for each parameter to define the different levels of activity, as outlined below.

## Defining the start of an epidemic

To define the beginning of the influenza epidemic (seasonal or pandemic), the following methods can be used:

- calculating the epidemic threshold using the moving epidemic method (MEM) <sup>(7,8)</sup>; or
- using the weekly positivity rate (ratio of influenza-confirmed samples to all collected samples) to determine the virological threshold.

## Thresholds for transmissibility and impact parameters

To set the thresholds for the transmissibility and impact parameters, the following methods can be used:

- MEM <sup>(7, 8)</sup>;
- WHO method <sup>(6)</sup>; and
- country-specific statistical or empirical approaches, depending on the intrinsic properties of the systems.

The pilot testing indicated that MEM works well in most countries with the transmissibility and impact parameters, but more work is needed in tropical settings.

Country-specific approaches to threshold setting might have to be derived locally using national historical data, and should be comparable to the thresholds derived by MEM and the WHO method. The thresholds have been set in such a way that about 50–60% of the season peaks should be above the moderate threshold,  $\pm 10\%$  above the high threshold and  $\pm 2.5\%$  above the extraordinary threshold.

**Table 3** provides proposed cut-off points for transmissibility and impact parameters used by WHO and in MEM.

**Table 3.** Cut-off points by method for threshold setting for transmissibility and impact

RANGES OF ACTIVITY	MEM	WHO
<b>No activity or below seasonal threshold</b>	Below the seasonal threshold as set by MEM	Below the seasonal threshold as set by the WHO method (annual median value)
<b>Low</b>	Between the seasonal threshold and the upper limit of the 40% one-sided CI of the geometric mean	Between the seasonal threshold and the upper 40% CI of the mean peak value <sup>a</sup> of the average curve
<b>Moderate</b>	Between the upper limit of the 40% and 90% one-sided CIs of the geometric mean	Between the upper limit of the 40% and 90% CIs of the mean peak value <sup>a</sup> of the average curve
<b>High</b>	Between the upper limit of the 90% and 97.5% one-sided CIs of the geometric mean	Between the upper limit of the 90% and 97.5% CIs of the mean peak value <sup>a</sup> of the average curve
<b>Extraordinary</b>	Above the upper limit of the 97.5% one-sided CI of the geometric mean	Above the upper limit of the 97.5% CI of the mean peak value <sup>a</sup> of the average curve

CI: confidence interval; MEM: moving epidemic method; WHO: World Health Organization

<sup>a</sup> When the peak values are very different from one season to another, it is best to use the geometric mean of the peak values instead of the arithmetic mean.

## Thresholds for seriousness of disease parameters

The pilot testing indicated that the parameters for the seriousness of disease indicator (e.g. the cumulative measurements) fluctuate at the beginning of the epidemic and only become stable when the peak of the influenza activity occurs. From season to season, peak values are fairly stable, with differences by age group depending on circulating influenza subtypes. However, the values might be very different during a pandemic. Therefore, country-specific means and standard deviations should be calculated using end-of-season values of previous seasons and thresholds should be refined using historical data including pandemic data, as shown in Table 4. Age-specific thresholds should be set when data are available.

**Table 4.** Example of threshold setting for seriousness of disease

RANGES OF ACTIVITY	
<i>No activity or below seasonal threshold</i>	< Mean outside of the epidemic period
<i>Low</i>	< Mean
<i>Moderate</i>	Mean to mean+1SD
<i>High</i>	Mean+1SD to mean+3SD
<i>Extraordinary</i>	> Mean+3SD

ICU: intensive care unit; SARI: severe acute respiratory infection; SD: standard deviation



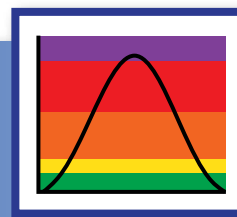
### INFLUENZA SEVERITY ASSESSMENT:

#### Step 2: Key points

- **Define** the beginning of the epidemic or pandemic and document the cut-off values.
- **Set thresholds for qualitative levels** of activity for each parameter, and document the threshold values for each parameter.
- **Describe the methods** and the historical data used.

# 3

## Apply the thresholds to assess severity

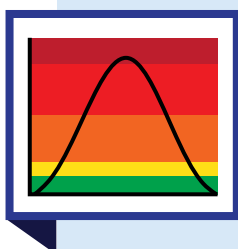


### Step 3: Apply the thresholds

The severity assessment at the national level is mainly driven by quantitative data, expertise and experience. A country will come to a qualitative assessment for each indicator by looking at all parameters for a specific indicator; categorizing the values for the current situation in relation to their own historical data (ideally five seasons), or otherwise available comparable data; and taking into account additional available information. When performing the qualitative assessment, additional information needs to be considered; for example, timeliness, reporting biases and relative reliability of information from different systems.

Ideally, on a weekly basis, after the beginning of the epidemic or pandemic, the thresholds should be applied to the contemporary parameter data for transmissibility and impact indicators. As discussed earlier, assessing the seriousness of disease indicator should be done once influenza activity has peaked.

At a minimum, the three indicators should be assessed at the middle of the epidemic and at the conclusion of the epidemic. Where data allow, it is important to also check whether there are differences in specific age groups or risk groups. The assessments, including confidence levels, should be used for national risk assessments and to inform public health decisions.



#### INFLUENZA SEVERITY ASSESSMENT:

##### Step 3: Key points

- At a minimum, **assess the contemporary data** for each indicator at the midpoint and end of the epidemic. Transmissibility and impact indicator data can be assessed on a weekly basis.
- **Examine data** for any differences between age groups or risk groups.
- **Use the findings** from the assessments, including confidence levels, to inform national risk assessment.
- **Document the parameters and thresholds used**, the parameters that were most reliable and gave most weight in the overall assessment, how the interpretation was done and how you combined the information of the different parameters to give a judgement on each indicator.



# 4

## Report the severity assessment findings



### Step 4: Report the findings

The qualitative assessment by countries for each indicator, together with a confidence level and any indicator-specific comments, should be reported to WHO ideally on a weekly basis but at a minimum at the midpoint and end of the epidemic (Figure 2).

Where there are differences in the estimates by age groups or groups with underlying conditions, the final assessment should be based on the aggregated data (all age groups). However, if the estimate for a specific age group or risk group is in a higher category, this should be flagged in the comment field.

**Figure 2.** Indicators and categories for severity assessment

<b>Transmissibility</b>	<input type="checkbox"/> No activity or below seasonal threshold <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/> Extraordinary
	Level of confidence: <input type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
	Comments:
<b>Seriousness of disease</b>	<input type="checkbox"/> No activity or below seasonal threshold <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/> Extraordinary
	Level of confidence: <input type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
	Comments:
<b>Impact</b>	<input type="checkbox"/> No activity or below seasonal threshold <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/> Extraordinary
	Level of confidence: <input type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
	Comments:



## INFLUENZA SEVERITY ASSESSMENT:

### Step 4: Key points

- **Report the overall assessment** for each indicator using all available information and the level of confidence in an Excel file that can be uploaded through the PISA SharePoint site ([workspace.who.int/sites/influenza/pisa/default.aspx](https://workspace.who.int/sites/influenza/pisa/default.aspx)).

Include the following:

- **weekly qualitative assessments** for transmissibility and impact indicators;
- **at the peak of the season and at the end of the season**, a qualitative assessment for the seriousness of disease indicator; and
- **any comment you have in the comment box** (e.g. whether certain age groups are more affected or whether a high proportion of cases did not have underlying chronic conditions that put them at risk for severe disease).

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## 5 PRESENTATION OF INFLUENZA SEVERITY ASSESSMENTS AT THE GLOBAL LEVEL

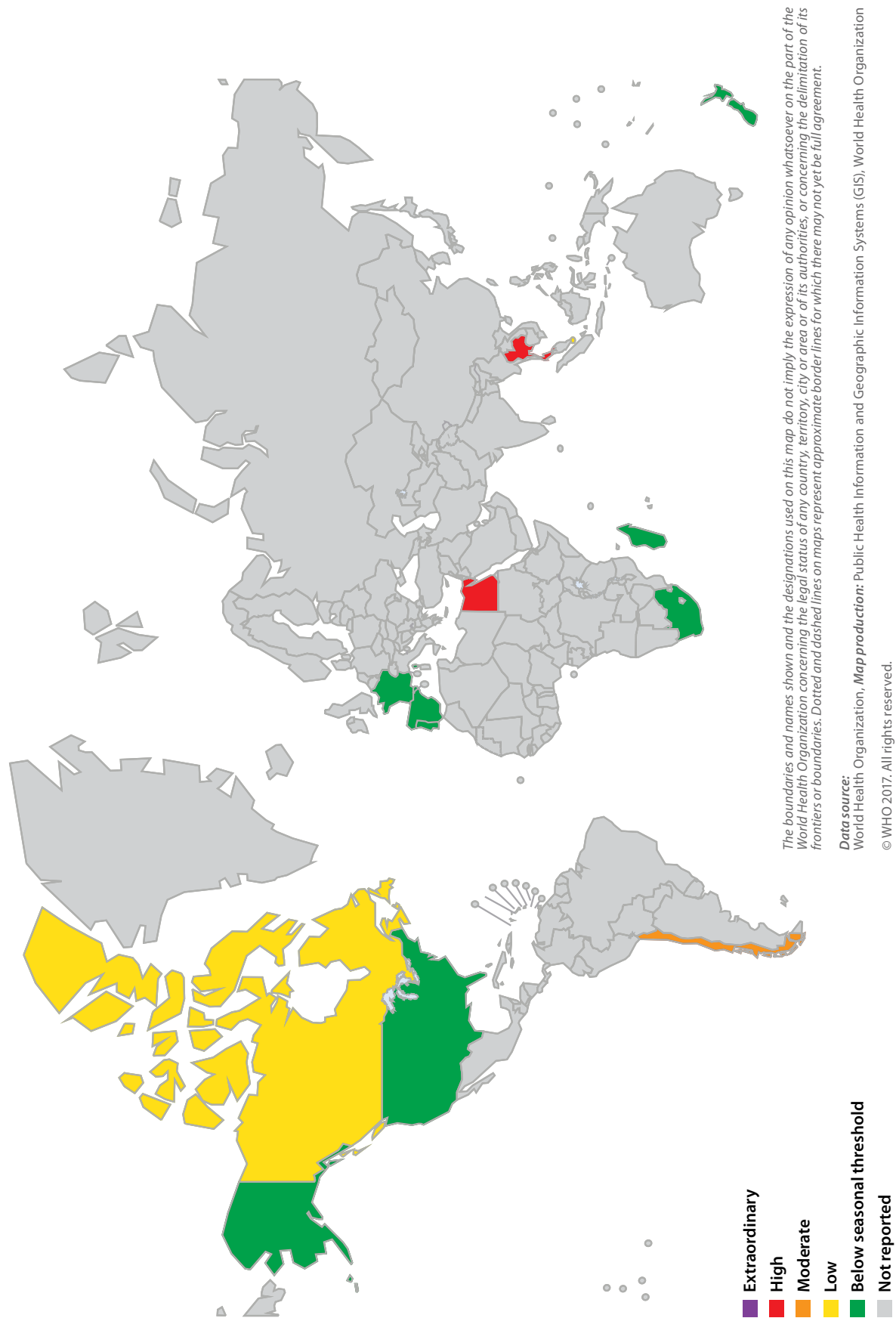
The severity assessment results from countries will be visible to participants reporting data (i.e. there will be user-restricted access). Outputs will include heat charts for each indicator by week and by country, with comments fields visible when the user scrolls over the chart. Maps with results for each indicator will be included, showing assessments per country at a certain time point. WHO will further refine the display of the information received by Member States, but some of the potential outputs are shown in [Figure 3](#) and [Figure 4](#).

WHO will monitor the three indicators on a regular basis and will provide mid-season and end-of-season reports describing the severity in terms of transmission, seriousness of disease and impact, for the temperate northern and southern hemisphere influenza seasons. WHO will also provide situation updates whenever an unusual event is happening or during a pandemic. WHO is encouraging countries to become familiar with these indicators, to apply severity assessments during influenza seasons routinely, and to facilitate communication on national and international influenza events.

**Figure 3:** Heat chart for transmissibility indicator



Figure 4: Transmissibility indicator, week X, year Y



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# PANDEMIC INFLUENZA SEVERITY ASSESSMENT

**World Health Organization**

20 Avenue Appia  
CH-1211 Geneva 27  
Switzerland

WHOinfluenza@who.int

*[www.who.int/influenza/surveillance\\_monitoring/pisa/en/](http://www.who.int/influenza/surveillance_monitoring/pisa/en/)*



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